



Penta

Child Health Research

Annual Social Report **2024**





Penta

Child Health Research



Annual Social Report **2024**

Contents

Letter to our stakeholders	2
ABOUT US	7
Why our research matters	16
Our strategy	19
Penta's strategic impact 2020-2024: a Board member's perspective.....	20
HOW WE OPERATE.....	35
Penta Foundation	37
Investing in our people: promoting equality and well-being	48
Building a healthy world for all: our commitment to environmental sustainability.....	54
Penta ID Network	64
Our stakeholders	74
Our key partners.....	76
ACTIVITIES.....	81
Advancing research on pregnancy and child health in 2024.....	82
Current research portfolio	85
Youth engagement & participation.....	105
PentaTr@ining.....	111
THE FUTURE: CHALLENGES AND OPPORTUNITIES	125
FINANCIAL RESULTS	131
Methodological note	136

SDGs

We're committed to doing our part to advance the UN Sustainable Development Goals. Specifically, the highlighted SDGs are the ones Penta supports.



LIST OF ABBREVIATIONS

AMR Antimicrobial Resistance	FDC Fixed Dose Combination	PADO Paediatric Antiretroviral Drug Optimization
ART Antiretroviral therapy	GAP-F Global Accelerator for Paediatric Formulations	PAWG Paediatric Antiretroviral Working Group
ARV Antiretroviral	GARDP Global Antibiotic Research & Development Partnership	PHPT Program for HIV Prevention and Treatment
BFA Brighter Future Award	GDPR General Data Protection Regulation	PPI Patient and Public Involvement
CHAI Clinton Health Access Initiative	GEP Gender Equality Plan	ReAct Action on Antibiotic Resistance
CMV Cytomegalovirus	HBV Hepatitis B virus	RSV Respiratory Syncytial Virus
COST European cooperation in science and technology	HCV Hepatitis C virus	RUNTS (Registro Unico Nazionale del Terzo Settore) National Single Register of Third-Sector organisations in Italy
CRO Clinical Research Organisation	IMI1/IMI2 Innovative Medicines Initiative	RWD Real World Data
CTU Clinical Trial Unit	INSERM Institut National de la Santé et de la Recherche Médicale	SARS-CoV-2 Severe acute respiratory syndrome coronavirus 2
DALY Disability-Adjusted Life Year	JCRC Joint Clinical Research Centre	TAF Tenofovir Alafenamide Fumarate
DEI Diversity, Equity and Inclusion	MENA Middle east and North Africa	TB Tuberculosis
DRV/r Darunavir Ritonavir	MRC CTU Medical Research Council Clinical Trials Unit	UCL University College London
DTG Dolutegravir	MUJHU Makerere University Johns Hopkins	UNAIDS Joint United Nations Programme on HIV/AIDS
ECR Early Career Researcher	NGO Non Governmental Organisation	UNICEF United Nations Children's Fund
EDCTP European and Developing Countries Clinical Trials Partnership	OPBG Ospedale Pediatrico Bambino Gesù	WHO World Health Organization
Enpr-EMA European Network of Paediatric Research at the European Medicines Agency		
ETS (Ente del Terzo Settore) Third Sector Organisation		
FDA Food and Drug Administration		

Letter to our stakeholders

Dear Stakeholders,

As we present the Penta Foundation's Annual Report for 2024, we must confront the stark reality of the global landscape. The international situation, marked by instability and conflict, casts a long shadow over the health and well-being of those we serve: pregnant individuals, infants, children, and adolescents. Compounding this, the recent changes in US funding underscore the fragility of global health initiatives and the **urgent need for sustained support**. These changes are not mere policy adjustments—they represent a critical erosion of essential resources. We cannot afford to stand by. Penta urgently calls upon global leaders and policymakers to recognise the profound impact of these challenges and to prioritise the health and rights of these at-risk, underserved populations. Sustained, robust investment in global health initiatives is essential to safeguard their future.

In the face of these uncertainties, Penta has intensified its focus on **research preparedness**. Throughout 2024, we have dedicated significant efforts to building robust collaborations and funding for studies that address the critical needs of populations traditionally underrepresented in research. The launch of the "PIPELINE" project, a European collaboration established to ensure that pregnant individuals and infants are included in pandemic response efforts through a dedicated clinical trial platform, exemplifies this commitment.

Central to our mission is the unwavering belief in **the power of collaborative research**. Progress in global health is inextricably linked to the collective efforts of researchers, clinicians, communities, policy makers and funders. Penta has long championed collaborative initiatives, fostering partnerships that transcend geographical and institutional boundaries. We understand that by working together, we can accelerate the pace of science and translate research findings into tangible benefits for those who need them most.

Furthermore, we recognise that meaningful research must be grounded in the lived experiences of the communities we serve. Engaging with these communities, listening to their needs, and integrating their perspectives into each stage of our research is paramount. Our experiences with Patient and Public Involvement (PPI) in Penta studies, the Young Reporters project, and the Brighter Future Award are testaments to our dedication to this principle. By **empowering communities to actively participate in the research process**, we ensure that our work is relevant, responsive, and ultimately more impactful.

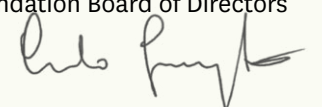
2024 has been a year of reflection and strategic planning for Penta. We have taken the opportunity to analyse the achievements of the past five years and to engage in collective thinking about how to advance our mission in the years ahead. This report includes a strategic overview of **Penta's achievements from 2020 to 2024**, reflecting on the organisation's growth and adaptability. We also provide a detailed account of our research activities and programme highlights for the year 2024. Finally, an overview of the strategic priorities that will guide our work in the coming five years.

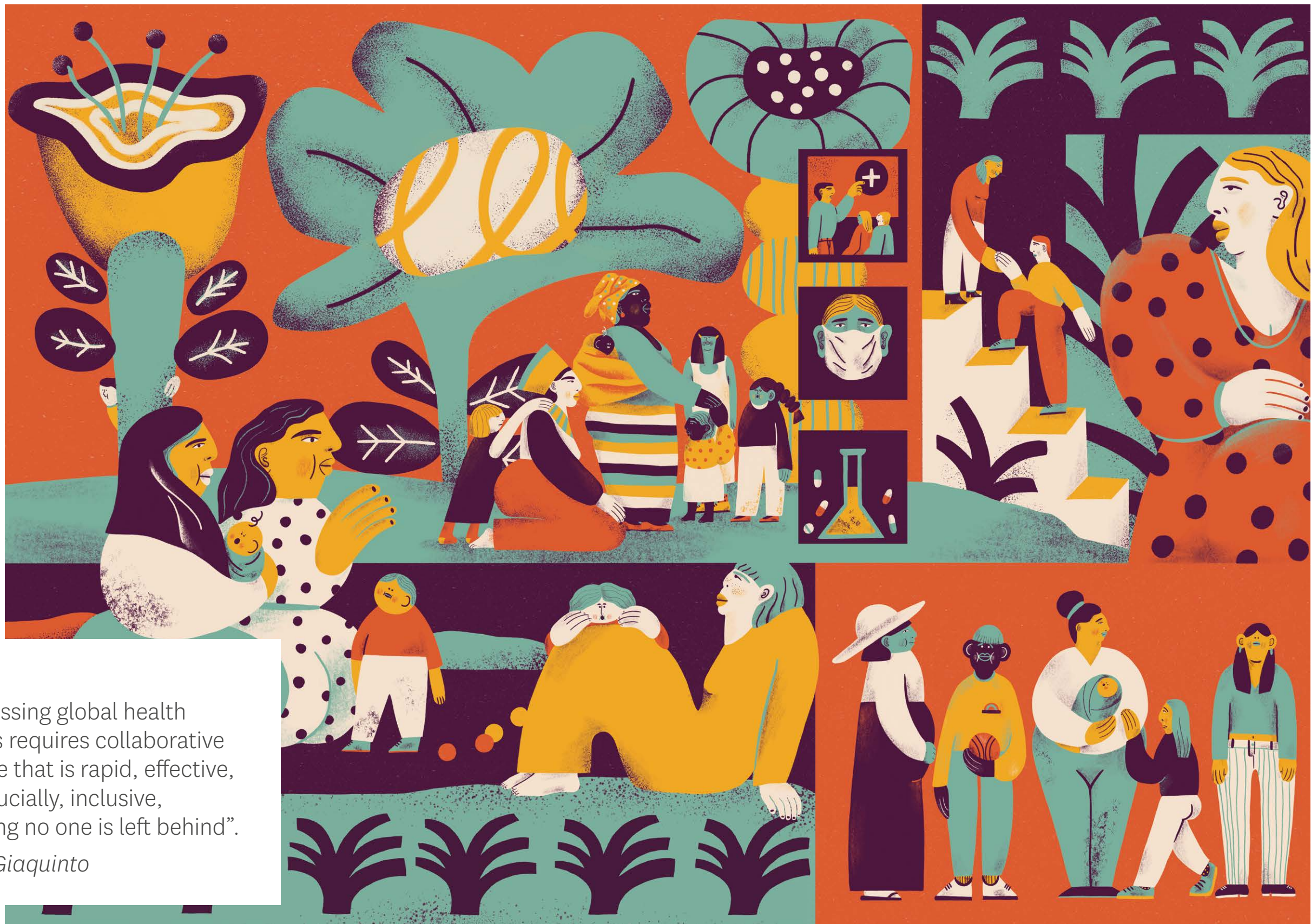
We wish to remember a fantastic friend who is no longer with us - Nigel Klein. The Penta family is grateful for your contributions and unwavering spirit.

We are committed to building on our successes, addressing emerging challenges, and continuing to make a meaningful difference in the lives of children and families affected by infectious diseases.

I extend my heartfelt gratitude to all our stakeholders—**patients and families involved in our studies, our partners, funders, researchers, community members, and staff**—who make Penta's work possible. Your unwavering support and dedication are essential to our continued success.

Carlo Giaquinto,
On behalf of Penta Foundation Board of Directors





“Addressing global health threats requires collaborative science that is rapid, effective, and crucially, inclusive, ensuring no one is left behind”.

Carlo Giaquinto



1. ABOUT US

We are an **international, independent, scientific collaboration** working to advance research that improves the **prevention** and **management** of infections in **pregnancy, infancy, childhood** and **adolescence**

Our vision

A world where the health needs of pregnant people, infants, children and adolescents are always prioritised



Our mission

To be an inclusive network that delivers impactful research to improve the prevention and management of infections in pregnancy, infancy, childhood and adolescence globally



Our approach

Penta's strategic approach involves developing scientific evidence to inform guidelines and practice, while collaborating with partners to accelerate the translation of research into action, prioritising countries with the highest need. Penta promotes equitable healthcare access in every activity and engages directly with communities to achieve the greatest possible impact



What makes us unique

One network

One vision

One voice



Our Network of collaborators and investigators shares our vision. We are all convinced of the power of our partnership and are serious about improving prevention and treatment options for pregnant people, children and adolescents with infections everywhere – for good.

Our values

Sharing, understanding and belonging



We work collaboratively and support the sharing and exchange of ideas, innovations, data and proposals within the Network and with our partners. We value every contribution and respect each other's expertise. We are persistent about finding better ways to prevent, diagnose and treat diseases in pregnancy, infancy, childhood and adolescence.

Our guiding principles

Collaboration, diversity and inclusion, research equity, team spirit, responsibility, transparency



We value and respect the contributions of all investigators within our Network, fostering an inclusive environment that welcomes the passion and expertise of every individual dedicated to our mission. Through collaborative efforts, we empower teams to build a robust body of evidence that contributes to the well-being of the populations we serve.

Our journey continues: from HIV to global impact

We are on an exciting journey to transform the prevention and management of infections in pregnancy, infancy, childhood and adolescence, globally.



Our journey is one of continuous progress, motivated by a common purpose protecting the health of pregnant people, infants, children and adolescents. We began thirty-two years ago, driven by a shared passion among scientists: ensuring no child is left behind in the fight against HIV/AIDS. Today, this passion has ignited a global network, extending beyond HIV to address a wider spectrum of infectious diseases.

In 1991, the Paediatric European Network for Treatment of AIDS (PENTA) emerged as a collaborative effort between European paediatric HIV centres. Its primary focus was conducting **independent clinical trials** specifically tailored for children, complementing existing research efforts.

As the Network's scope grew beyond HIV clinical trials and observational studies, Penta evolved into an ideal platform for fostering and supporting research and training activities. This pivotal moment gave birth to the **Penta Foundation**.

Recognising the urgent need to address other neglected childhood infections, PENTA - the Paediatric European Network for Treatment of AIDS transitioned into **Penta-ID** (Infectious Diseases) in 2010. This broadened its research focus, encompassing both clinical and basic studies, to include a wider range of paediatric infectious diseases. In response to the growing threat of antimicrobial resistance, Penta has developed an ambitious and unique research agenda tackling critical

questions surrounding treatment and prevention for newborns and children.

In 2021, the COVID-19 pandemic demanded urgent action. We rapidly mobilised our Network members and collaborators to investigate the impact of SARS-CoV-2 on perinatal and child health and to inform effective virus control strategies. This reflects our unwavering belief that only through the combined resources and experience of our partners can we effectively advance knowledge and improve virus control.

In 2022, we not only consolidated our collaborative effort to advance the treatment and care of COVID-19, but we also expanded the scope of our research to mpox. This expansion aimed to build **research preparedness for future emerging pathogens** with pandemic potential, harnessing the power of real world data.

To enable all this work, in 2023 we established the **Penta Research Environment**, designed for centralised data coordination and the support of all research activities.

In 2024, Penta continued to prioritise research preparedness by joining key projects like the EU-funded coordination initiative CoMeCT and contributing to proposals such as Be Ready Plus, ensuring the needs of children and pregnant people are championed.

As we solidify our position as the leading experts in maternal and child health research, the values and behaviours that underpin our work will continue to guide us.

Key milestones in Penta's history



1991

First HIV study led by PENTA - Paediatric European Network for the treatment of AIDS



2004

Penta Foundation is set up, an Italian based non-profit organisation



2005

Tr@inforPedHIV is born, Penta's first innovative training programme on paediatric HIV for healthcare professionals



2009

Penta HIV treatment guidelines are launched. The Guidelines offer healthcare workers practical recommendations on managing HIV-1 infection in children in Europe



2010

Penta expands its scope: from HIV to other infections



2011

Enpr-EMA, the European Network of Paediatric Research at the European Medicines Agency, recognises Penta as a Level 1 Paediatric Clinical Trial Network in Europe to conduct clinical trials in paediatric HIV, antimicrobials and vaccinology



2018

The c4c pan-European clinical trial network, led by Penta Foundation and University of Liverpool, sets out to facilitate the development of new drugs and other therapies for children



2019

Penta contributes to the development and launch of Prescribing Medicines for Children, the first international textbook providing guidance on the principles behind optimal neonatal and paediatric prescribing



2020

In response to the COVID-19 pandemic outbreak, Penta starts conceptualising new collaborative research projects to address emerging infectious diseases



2020

Data from the Penta-sponsored trial ODYSSEY contributes to regulators approving a 5mg dispersible tablet for children. Results from ODYSSEY support current WHO Guidelines, which recommend Dolutegravir (DTG)-based treatment as the 1st choice for all children living with HIV over 4 weeks



2021

The PentaTr@ining team is awarded ESPID's Distinguished Award for Education, in recognition of their exceptional contributions to education and training in paediatric infectious disease



2022

Penta contributes to the WHO AWaRe Antibiotic Book, a practical resource for doctors on the best antibiotic choices to treat children and adults with common infections



2023

1st edition of Penta Brighter Future Award, a global initiative to celebrate the grassroots champions who work to improve health outcomes for pregnant people and children living with infectious diseases worldwide

Quantifying success

Research outcomes fuelled by collaboration and expertise.

PENTA-LED AND COLLABORATIVE CLINICAL INVESTIGATIONS

CLINICAL STUDIES

61 ⁵¹ PENTA SPONSORED OR PENTA-COORDINATED EPPICC STUDIES



SITES

124 IN **17** COUNTRIES
CURRENTLY ENGAGED IN OUR STUDIES

COHORTS

26 ENGAGED IN THE EPPICC NETWORK IN

15 COUNTRIES

PARTICIPANTS

50,000+

WOMEN AND CHILDREN ENROLLED IN OUR STUDIES

COLLABORATIVE PROJECTS

47

³⁹ FUNDED BY PUBLIC INSTITUTIONS
(⁸ BY OTHER FUNDING STREAMS)



¹⁵ COORDINATED BY PENTA
(³² IN PARTNERSHIP)



NETWORK

OVER

700

MEMBERS IN OUR NETWORK FROM **94** COUNTRIES

PENTATR@INING

87 TRAINING COURSES IN **40+** COUNTRIES

OVER

9,000+

HEALTHCARE WORKERS TRAINED

SCIENTIFIC OUTPUTS

OVER

380

PEER-REVIEWED SCIENTIFIC ARTICLES

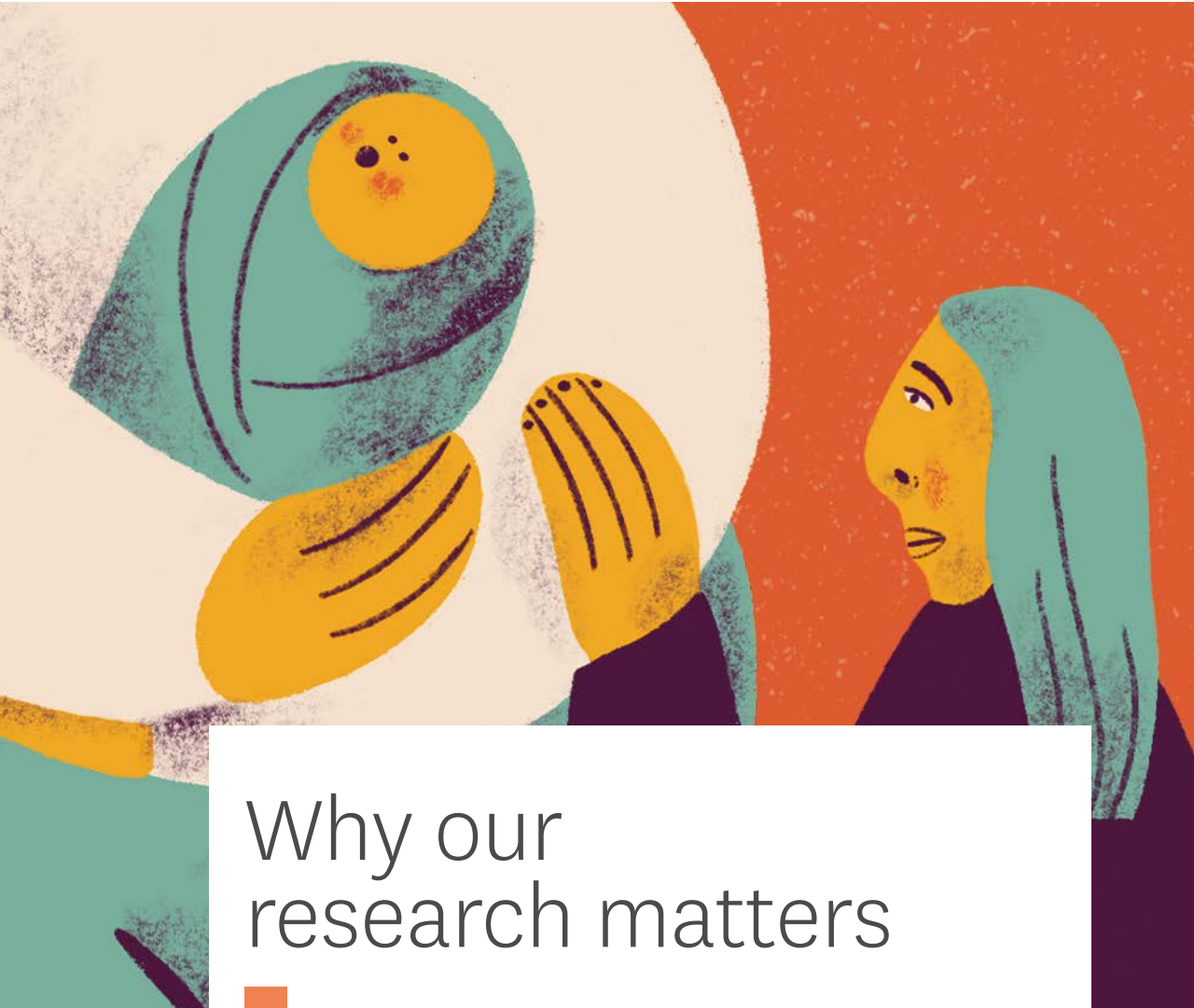
60

PUBLISHED IN TOP 10 HIGH IMPACT FACTOR JOURNALS

- Penta/EACS HIV TREATMENT GUIDELINES GLOBALLY RECOGNISED

- SUBSTANTIAL SCIENTIFIC CONTRIBUTION TO THE WHO AWaRe ANTIBIOTIC BOOK AND PRESCRIBING MEDICINES FOR CHILDREN BOOK

- MAJOR CONTRIBUTION TO ARV DRUG REGISTRATION



Why our research matters

Globally, **INFECTIOUS DISEASES** remain **THE LEADING CAUSE OF DEATH** for children 1 month to 9 years of age.

(Source: WHO 2023 WORLD HEALTH STATISTICS)

CONGENITAL AND PERINATAL INFECTIONS

CONGENITAL AND PERINATAL INFECTIONS, DRIVEN BY PATHOGENS LIKE CMV, HBV, HCV, SYPHILIS, TOXOPLASMOSIS, SARS-COV-2, AND MPOX, REMAIN A MAJOR GLOBAL HEALTH CHALLENGE WITH HEALTH DISPARITIES BETWEEN

COUNTRIES DISPROPORTIONATELY BURDENING RESOURCE-LIMITED SETTINGS, DEMANDING URGENT PUBLIC HEALTH INTERVENTIONS. Congenital CMV, the most prevalent, affects approximately 0.67% of births globally, with rates three times higher in low-resource settings. Vertical transmission of hepatitis B contributes to 254 million chronic infections worldwide. Syphilis rates in European women rose 24% between 2018 and 2022, with untreated maternal cases leading to adverse outcomes in up to 50% of pregnancies.

Despite prevention strategies, gaps in screening, surveillance, and management persist, especially in high-burden areas. Robust research is crucial to inform policy changes that reduce transmission and improve neonatal outcomes. Penta's work focuses on preventing vertical transmission, conducting pharmacovigilance, and optimising treatment for congenital infections.

(WHO, ECDC 2024)

HIV IN CHILDREN

According to the latest data from UNAIDS 2024 Global AIDS Update, an estimated **1.5 MILLION CHILDREN (AGED 0-14) WERE LIVING WITH HIV GLOBALLY IN 2023**. During the same year, approximately 82,000 new HIV infections occurred among children. In sub-Saharan Africa, **ADOLESCENT GIRLS AND YOUNG WOMEN** face a disproportionate burden. UNAIDS reports that in 2023, they accounted for around **63% OF ALL NEW HIV INFECTIONS** among young people aged 15-24 in the region. This disparity highlights a critical gap in access to prevention programmes. Untreated children living with HIV face the highest risk of mortality, particularly in the first five years of life. Furthermore, children continue to have **LOWER ANTIRETROVIRAL THERAPY COVERAGE** compared to adults globally, although progress is being made. Penta's work remains crucial to achieving SDG-3 by researching improved HIV treatment and prevention

for pregnant individuals and children, directly contributing to the goal of ending AIDS by 2030.

HEPATITIS B AND C VIRUSES

In 2022, **OVER 30 MILLION CHILDREN WERE LIVING WITH VIRAL HEPATITIS B AND APPROXIMATELY 3 MILLION WITH HEPATITIS C**. Newborns and children are at risk through **VERTICAL TRANSMISSION OF HEPATITIS**, notably in settings with high hepatitis prevalence (Source: Global Hepatitis Report WHO 2024). Penta is actively contributing to the WHO's goal of eliminating viral hepatitis by 2030 by advancing diagnosis, prevention, and treatment strategies addressing the substantial burden and inequities it causes.

LOWER RESPIRATORY TRACT INFECTIONS IN CHILDREN

Lower respiratory tract infections are **THE LEADING CAUSE OF DEATH AMONG CHILDREN UNDER FIVE, WITH PNEUMONIA ALONE KILLING AROUND 800,000 CHILDREN ANNUALLY**. Despite being preventable and treatable, pneumonia continues to claim a child's life every 39 seconds. **RESPIRATORY SYNCYTIAL VIRUS (RSV)** is a common infection in young children, with nearly all contracting it by age two. While most cases are mild, RSV can lead to severe complications such as bronchiolitis and pneumonia, particularly in infants, making it a leading cause of hospitalisation in children under one. Bacterial infections like **S. PNEUMONIAE** and **M. TUBERCULOSIS** pose additional challenges. While

vaccines have reduced pneumococcal disease, **ANTIBIOTIC RESISTANCE** is an increasing concern. Tuberculosis in children is often difficult to diagnose and requires lengthy, complex treatment regimens, particularly in low-resource settings. To address these critical issues, Penta is establishing a dedicated working group to foster collaboration, advance research, and improve prevention, diagnosis, and treatment strategies, ultimately reducing the burden of respiratory infections in children worldwide.

ANTIMICROBIAL RESISTANCE

Antimicrobial resistance (AMR) **IS A SERIOUS GLOBAL PUBLIC HEALTH THREAT WITH SIGNIFICANT GLOBAL ECONOMIC AND SECURITY IMPLICATIONS**. Excessive or inappropriate use of antimicrobials in humans, animals, and plants is a major driver of AMR development in pathogens, rendering these life-saving treatments ineffective. This overuse allows microbes to develop resistance, rendering these life-saving treatments ineffective.

The most recent data from the World Bank (2022) estimates that **1.27 MILLION DEATHS IN 2019 WERE ATTRIBUTABLE TO BACTERIAL AMR ALONE**. Furthermore, the lack of new antibiotic development since 1987 creates a critical gap in our ability to combat resistant infections. **CHILDREN AND NEONATES ARE PARTICULARLY VULNERABLE** to AMR due to their developing immune systems. Studies indicate that **NEWBORNS**

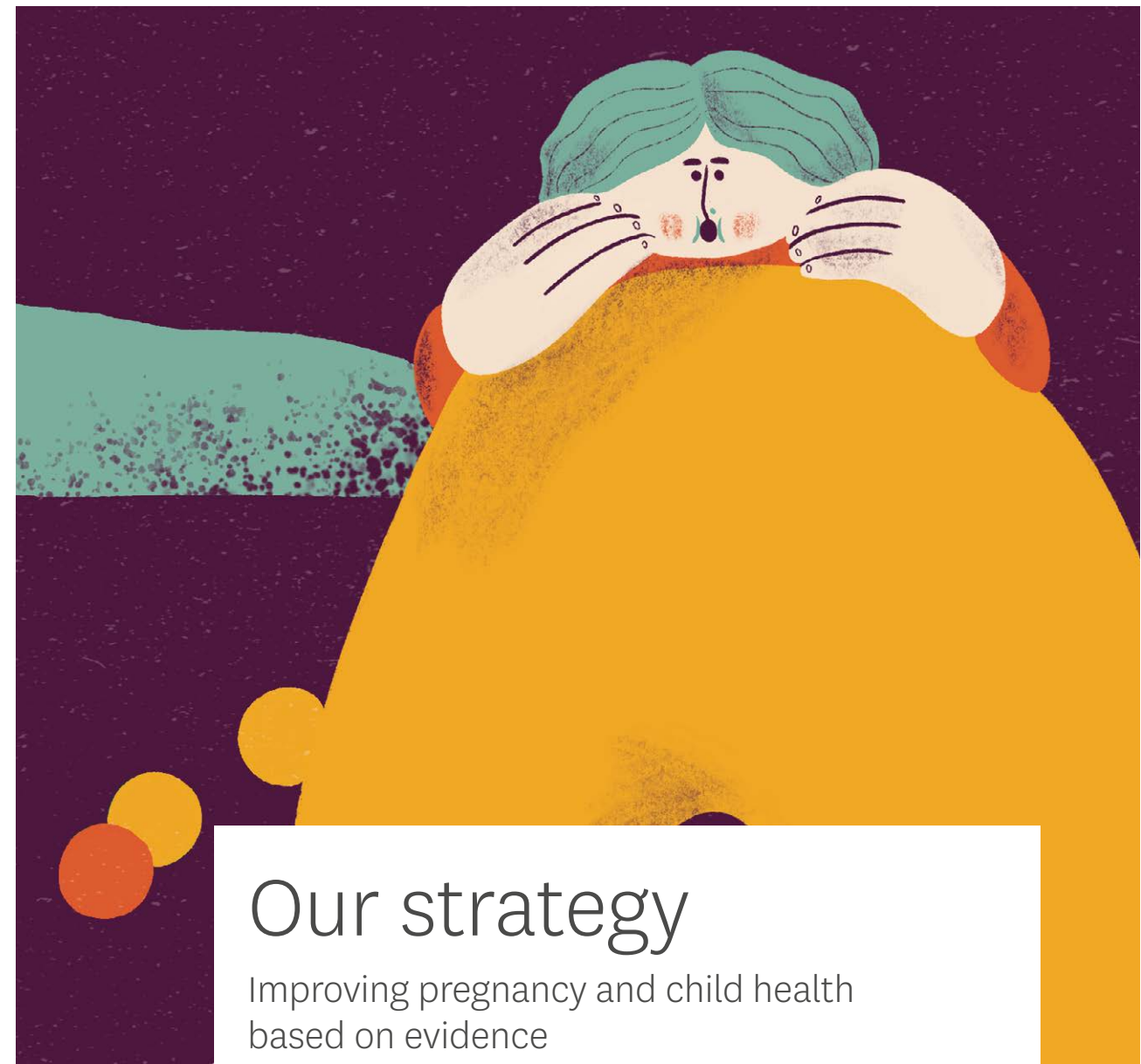
CAN BECOME RAPIDLY COLONISED WITH AMR PATHOGENS, highlighting the need for stricter infection prevention and control practices and appropriate antibiotic use in hospitals. Furthermore, AMR can significantly increase mortality rates for infections like **SEPSIS IN NEONATES**.

Penta is dedicated to defining optimal antibiotic treatment and infection prevention strategies for severe bacterial infections in hospitalised children, including pneumonia and sepsis. We achieve this through observational and interventional studies aimed at maximising efficacy while minimising resistance and toxicity.

FUNGAL INFECTIONS

Invasive fungal infections threaten the most vulnerable: newborns and children, including those born prematurely and children with cancer or HIV. **MORTALITY RATES RANGE FROM 40% TO 100%**. Effective treatment is lacking for several fungal diseases, and the usefulness of the few classes of antifungals are challenged by emerging **ANTIFUNGAL RESISTANCE**. Lack of availability and access to treatment and diagnostics in many parts of the world contributes further to poor outcomes. (SOURCE: WHO REPORT ON FUNGAL DISEASES 2023).

Penta is committed to improving the evidence base for the management and prevention of severe fungal infections in neonates and children across the world.



Our strategy

Improving pregnancy and child health based on evidence

Penta has a rich, 30+ year history of investing in top-tier research on pregnancy and child health. We translate this evidence into real-world impact by informing policy and practice. Building on this legacy, our 2020-2024 strategy prioritised the translation of evidence into tangible improvements for preventing and

managing infectious diseases in children and in pregnancy. This unwavering commitment ensures all children, regardless of where they live, have access to the best possible care. Fuelling this mission is our ever-growing network of passionate researchers, who are relentless champions for child health.

Penta's strategic impact 2020-2024: a Board member's perspective



By
Claire Thorne
Penta Foundation's
Vice President,
Professor of
Infectious Disease
Epidemiology at
the UCL Great
Ormond Street
Institute of Child
Health, University
College London

As we conclude the 2020-2024 strategic period, it's a moment for reflection on Penta's remarkable journey. This period, unexpectedly marked by a global pandemic, tested our agility and reinforced our commitment to improving the health of children and in pregnancy. This review offers a strategic overview of our achievements and lessons learnt, providing insight into our organisational evolution.

When we developed the 2020-2024 Penta strategy, we had no inkling that a global pandemic with a novel coronavirus was just around the corner. Whilst our scientific priorities included emerging childhood infections, our main research focus was on our key scientific priority areas of HIV and blood-borne viruses, severe bacterial infections and antimicrobial resistance and infection in pregnancy and vertical transmission.

Over the last five years, Penta has maintained its strong HIV research theme, reflecting our origins as a paediatric HIV trials network. Our HIV research in 2020-2024 spanned clinical trials, observational studies and fundamental research. This included the impactful ODYSSEY trial, which helped to make **dolutegravir accessible for children globally**, and our cohort collaboration, EPPICC, which provides real world

data on safety and effectiveness of new antiretrovirals in pregnancy and childhood. Meanwhile the EPIICAL platform has not only provided critical evidence for the HIV cure agenda but also established paediatric cohorts around the world as **a resource for future research**. Our AMR research has similarly gone from strength to strength, with expanded activities in Africa such as the PediCAP trial and SNIP-AFRICA, both of which have applied innovative methodologies.

Recognising the need for specific research on SARS-CoV-2 infection in children and pregnant people, Penta's research took a new direction when the COVID-19 pandemic hit. We coordinated pregnancy and paediatrics studies in the ORCHESTRA project, and have subsequently led the VERDI project, focusing on the impact of SARS-CoV-2 variants on pregnant people and children, which expanded in 2022 to address mpox and research preparedness more generally. This work has paved the way for further partnerships, such as in CoMeCT (Coordination Mechanism for Cohorts and Trials), in which Penta continues to highlight the specific needs of children and pregnant people.

Our expanding research and training portfolios have strengthened collaborations with clinicians, researchers and institutions across the world, and stimulated substantial growth of the Penta ID Network over the past five years. The Network Engagement Committee has played a key role in supporting this growth and "nurturing our network", a key strategic objective, together with the Penta Foundation team. Meanwhile our virtual Penta Aperitivo webinars provide valuable opportunities for **scientific exchange and connection** across the network.

These **strategic adaptations and collaborations** have significantly impacted our research, empowering our researchers and improving outcomes for the communities we serve.

The lessons learnt from the 2020-2024 period are informing Penta's 2025-2029 strategy, particularly in expanding our global network to underrepresented regions and enhancing our preparedness for emerging infectious diseases, ensuring rapid and equitable responses for our target populations.

Our objectives 2020-2024

- **To nurture** a vibrant network of experts and investigators generating solutions for children's health, notably infections
- **To develop** impactful research on prevention, diagnosis and treatment of infections in children
- **To deliver** training and education programmes for clinical providers and researchers that ensures high quality patient care and research
- **To collaborate** with international partners to drive research agendas and deliver impact
- **To inspire** a new generation of leading researchers in paediatric infectious diseases

Penta's strategic impact

2020-2024

INPUT

€15,7M

AVERAGE FUNDS OVER THE PERIOD FROM PRIVATE AND PUBLIC FUNDERS

122%
INCREASE OVER THE PERIOD

43 42 IN 2024
AVERAGE NUMBER OF EMPLOYEES

100 80 IN 2024
PENTATR@INING FACULTY MEMBERS FROM LATIN AMERICA, AFRICA, EUROPE, MIDDLE EAST, ASIA AND NORTH AMERICA

720 127 NEW MEMBERS IN 2024 FROM 94 COUNTRIES
PENTA ID NETWORK MEMBERS

124
STUDY SITES IN 17 COUNTRIES COLLABORATING IN OUR STUDIES

ACTIVITIES

PROJECT COORDINATION

BASIC AND CLINICAL RESEARCH

NETWORK MANAGEMENT AND ECRs

TRAINING

YOUTH ENGAGEMENT AND PARTICIPATION IN RESEARCH

STUDY SPONSORSHIP

HORIZON SCANNING FOR GRANTS/PROJECTS

OUTPUT

43 ON AVERAGE PENTA PROJECTS AND STUDIES EVERY YEAR (20 STUDIES ONGOING + 23 PROJECTS)
IN 2024 25 PROJECTS AND 24 STUDIES ONGOING 5 NEW STARTED

14 64% AVERAGE NUMBER OF APPLICATIONS SUBMITTED APPROVED PROJECTS
IN 2024 19 PROJECTS SUBMITTED 10 APPROVED (1 PENDING)

233 PEER-REVIEWED PUBLICATIONS FROM STUDIES AND PROJECTS WHERE PENTA PARTICIPATES
28.95% PUBLICATIONS IN THE 10 HIGHEST IMPACT FACTOR JOURNALS

COLLABORATIVE PENTA/EACS HIV TREATMENT GUIDELINES (ENDORSED 2021) BENEFIT FROM JOINT EXPERTISE AND A ROBUST REVIEW PROCESS, ENSURING SCIENTIFIC RIGOR AND RELEVANCE. ADDITIONAL OUTPUTS INCLUDE A PERINATAL VIRTUAL CLINIC (WITH IMPERIAL COLLEGE) AND AN HIV CALCULATOR TOOL

22 PENTATR@INING COURSES
6,000+ HEALTHCARE WORKERS TRAINED

475 HOURS OF LEARNING DELIVERED
5 DISEASE AREAS COVERED

3 NEW FUNDING PARTNERS
3 NEW GLOBAL REGIONS FOR TRAINING ACROSS AFRICA, MENA, AND LATIN AMERICA

6 INITIATIVES INTEGRATING YOUTH PERSPECTIVES IN RESEARCH
90 YOUNG PEOPLE ACTIVELY INVOLVED IN PENTA SCHEMES
10,000 YOUNG PEOPLE AND 9,000 FAMILIES AND CAREGIVERS REACHED WITH EDUCATIONAL MESSAGES VIA PENTA YOUNG REPORTERS

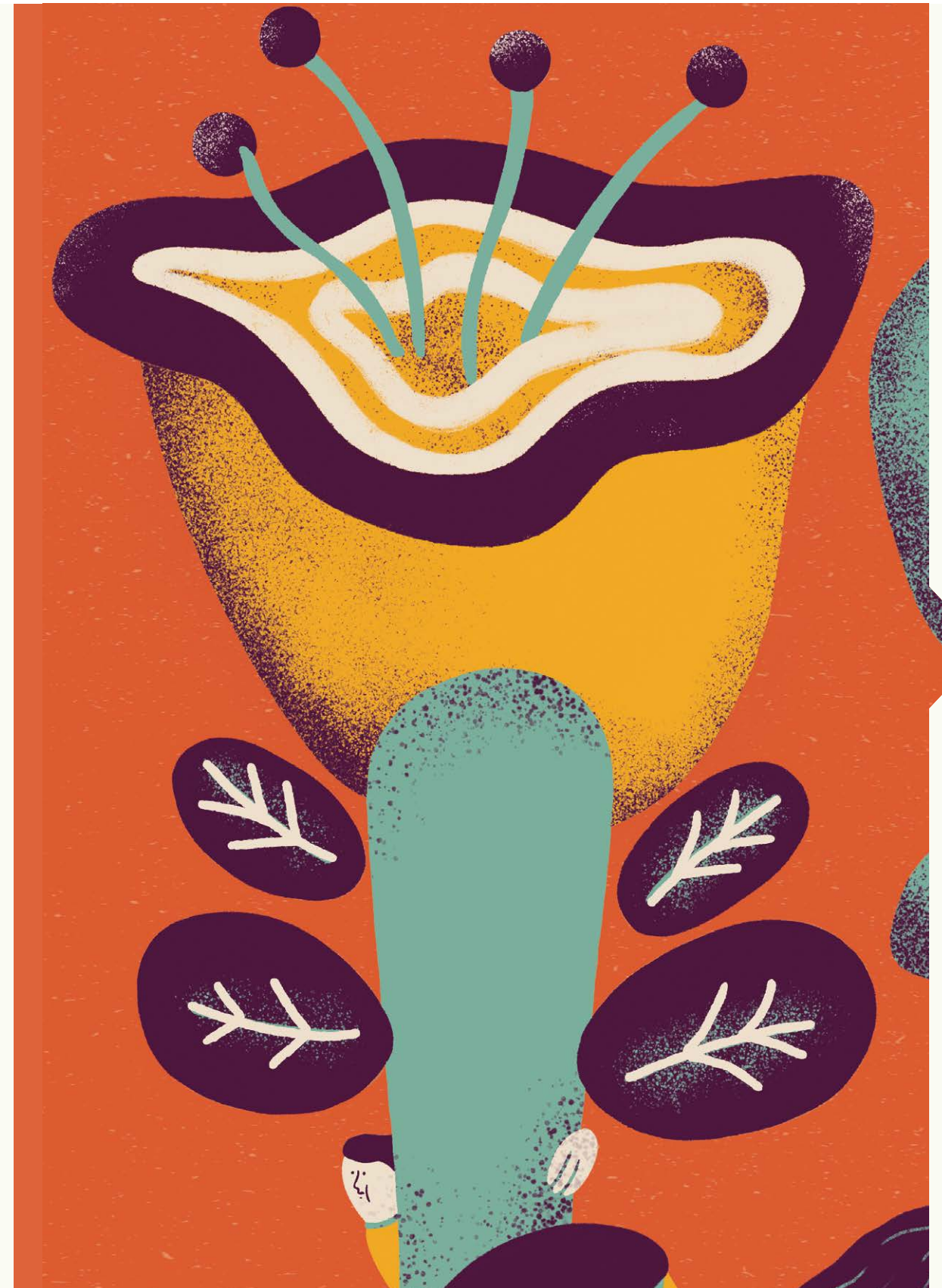
92 PARTICIPANTS IN THE PENTA BRIGHTER FUTURE AWARD
6 GLOBAL WINNERS
30,000 EUROS TOTAL GRANT AWARDED AND PARTICIPATION AT PIM 2024

OUTCOMES

Outcomes

Our progress in realising our vision will be measured by the number of:

- **Infections prevented and treated in children, decreasing mortality, morbidity, DALYs and healthcare costs**
- **Better therapeutic and prevention options for children and in pregnancy**
- **Faster licensing of drugs for paediatric use**



Key Projects 2020-2024

CLINICAL TRIALS

ODYSSEY

A pragmatic strategy trial evaluating the efficacy and safety of a once daily dose of dolutegravir-based antiretroviral therapy compared with the current standard HIV treatment in children and adolescents with HIV

792 RECRUITED

REGION

SSA, Europe

9 PUBLICATIONS

247 CITATIONS

244 SCIENTIFIC CITATIONS
3 (WHO) POLICY CITATIONS

YOUTH TRIAL BOARD ACTIVATED

42 SCIENTISTS INVOLVED

IMPACT

ODYSSEY has shown that a once-daily, single-pill regimen containing DTG is effective in suppressing HIV, even in very young children. This simpler approach to treatment improves how well children stick to their medication, ultimately leading to better health outcomes. Moreover, DTG has shown superior viral suppression compared to the standard-of-care, resulting in better long-term health. This easier treatment also reduces disruption to children's daily lives, improving their quality of life and supporting their growth and development.

PediCAP

A randomised controlled trial to fill the knowledge gaps on antibiotic therapy of community-acquired pneumonia in paediatric age, in terms of optimal duration, oral step-down schedule evaluating effectiveness, safety and selection of antimicrobial resistance

1100 RECRUITED

REGION

SSA

45 SCIENTISTS INVOLVED

IMPACT

PediCAP found that children recovering from severe pneumonia can safely switch from injectable to oral antibiotics earlier, enabling earlier hospital discharge and reducing risks of hospital-acquired infections and antimicrobial resistance, offering a more convenient yet equally effective alternative to current WHO guidelines. [→p. 95](#)

NeoVanc

A multi-centre randomised open label phase IIb study that compared the efficacy, safety and pharmacokinetics of an optimised dosing to a standard dosing regimen of vancomycin in neonates and infants with late onset bacterial sepsis known or suspected to be caused by Gram-positive microorganisms

243 RECRUITED

REGION

Europe

5 PUBLICATIONS

104 CITATIONS

103 SCIENTIFIC CITATIONS
1 (UK NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE/NICE) POLICY CITATIONS

31 SCIENTISTS INVOLVED

IMPACT

NeoVanc was the largest neonatal vancomycin efficacy trial ever conducted. The trial found that a shorter 5-day treatment was not better and may negatively impact hearing in newborns with sepsis.

A NeoVanc long-term follow up study is underway to further investigate this potential hearing signal and evaluate hearing outcomes in babies recruited to the trial. The results of the NeoVanc trial emphasise the importance of ensuring adequately powered trials to identify potential toxicity signals in this population.

SMILE

An open-label, multicentre, randomized, non-inferiority phase 2/3 trial evaluating safety and antiviral effect of a once daily integrase inhibitor administered with Darunavir/Ritonavir compared to standard of care among adolescents and children living with HIV who are also virologically suppressed

317 RECRUITED

REGION

**SSA, Europe,
Latin America**

3 PUBLICATIONS

9 CITATIONS

8 SCIENTIFIC CITATIONS
1 (WHO) POLICY CITATIONS

31 SCIENTISTS INVOLVED

IMPACT

SMILE was the first randomised trial to show that a once-daily dual therapy is as effective as the standard three-drug regimen for children with well-controlled HIV, potentially improving adherence and tolerability.

"We now have an additional treatment strategy for children and adolescents living with HIV thanks to SMILE. This treatment option has already shown to be an effective option for adults, and with these findings, clinicians now have data and proof of the effectiveness of this once-daily alternative for children who are virologically suppressed. The SMILE once-daily regimen is also important in cases when some Nucleoside Reverse Transcriptase Inhibitors (NRTIs) are not tolerated or cannot be taken due to the harm that it would cause the children. Moving forward, we must also carry out this research in other situations such as in children who are on treatment that is failing. This research has already been done in adults and it is important that we also have this data in children".

Alexandra Compagnucci,
SMILE Chief Investigator

OBSERVATIONAL STUDIES

REACH

A collaborative effort to fill the knowledge and data gaps on the HIV epidemic affecting children, adolescents and pregnant women across Russia. It provided new data on long-term antiretroviral therapy toxicity, HIV resistance, Hepatitis C virus and Tuberculosis coinfections and comorbidities in this setting

REGION

East Europe and Russia
25 SCIENTISTS INVOLVED

2 PUBLICATIONS

3 SCIENTIFIC CITATIONS

ZIKAction

An integrated programme of epidemiological, clinical and pathobiological research studies to examine the strength and nature of the association between maternal ZIKV infection in pregnancy and adverse maternal and fetal outcomes, to explain the timing and mechanisms of vertical transmission of ZIKV and to investigate burden and natural history of congenital and acquired paediatric ZIKV infection

REGION

Latin America
46 SCIENTISTS INVOLVED

56 PUBLICATIONS

1098 CITATIONS

1087 SCIENTIFIC CITATIONS
11 (WHO, UNICEF, BRAZILIAN MINISTRY OF HEALTH) POLICY CITATIONS
1 PATENT

EPIICAL

A clinical and experimental platform for the early identification of novel therapeutic strategies for paediatric HIV

319 RECRUITED

REGION

SSA
26 SCIENTISTS INVOLVED

12 PHD FINANCED AND COMPLETED THROUGH EPIICAL

67 PUBLICATIONS

717 CITATIONS

713 SCIENTIFIC CITATIONS
3 (WHO) POLICY CITATIONS
1 PATENT

IMPACT

Driven by the urgent need to improve outcomes for children living with HIV, the collaborative EPIICAL project established four key paediatric cohorts (CARMA, Ucwangingo, EARTH, and CARMA GLOBAL) for in-depth virological and immunological studies. These cohorts, spanning diverse African and European settings, can be used for future research, providing a rich data pool for cutting-edge investigations into paediatric HIV. EPIICAL's impact extends beyond publications; it has laid the groundwork for future cure research, informed treatment guidelines, and fostered a collaborative model that sets a new standard for international scientific endeavors in the fight against paediatric HIV.



My EPIICAL journey

A quest for a cure and a testament to collaboration



By
Alfredo Tagarro
 paediatrician at Hospital Infanta Sofía in Madrid and clinical researcher at Instituto de Investigación 12 de Octubre. He is the coordinator of the EPIICAL EARTH study and co-leads the Penta Respiratory Infections Working Group.

above:
 EPIICAL Consortium meeting in Cape Town (South Africa) in November, 2023

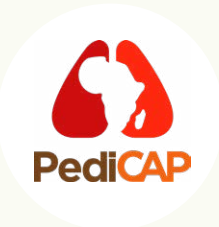
My collaboration with EPIICAL started in 2016, a real turning point for me as a researcher, thanks to my friend and Penta mentor, Pablo Rojo. It was an opportunity to delve into an area I've always been deeply passionate about – HIV – but going a step further: the pursuit of a cure. Joining EPIICAL felt like joining a group of brilliant and inspiring researchers, something like when a young rookie joins a football or basketball team full of great stars. What struck me most was their willingness to share their wisdom and their tolerance for the mistakes of a young researcher like me at that time.

EPIICAL, then and now, is absolutely vital for our research. The HIV pandemic continues to impact children around the world, and it's our ethical and scientific duty to seek not just treatment, but a cure. EPIICAL has put the spotlight on some very important problems that persist in sub-Saharan Africa, such as the persistent high mortality rates

despite early treatment and the complex factors contributing to this. It has also opened up new avenues in immunology, exploring the roles of NK cells and B cell subpopulations and providing significant insights into reservoir behaviour. For example, we are observing that children who start treatment early persistently reach an undetectable reservoir after 2 years of treatment.

The scientific findings of EPIICAL lay the groundwork for new research initiatives, such as targeted treatment for both therapy and cure using broadly neutralising antibodies, therapeutic vaccine, or other approaches. As is often the case in successful collaborations, what made EPIICAL special was the unwavering commitment of scientists, paediatricians, and other healthcare professionals to prioritise the vision of an HIV cure above all obstacles, and their willingness to work together towards this crucial goal for children's health.

Forward momentum: key milestones for Penta in 2024

- 1**
→p. 100
 
PANDEMIC PREPAREDENESS
 Developed an electronic case report form (eCRF) for data collection on mpox in children and pregnant people, in collaboration with ISARIC
- 2**
→p. 95
 
BETTER ANTIBIOTICS
 The PediCAP study demonstrated that a shorter, oral antibiotic treatment for childhood pneumonia is as effective as injectable treatment, enabling earlier hospital discharge in African children
- 3**
→p. 96
 
INNOVATIVE TRIAL DESIGN
 Launched SNIP-AFRICA: Innovative research to rapidly identify effective antibiotics for neonatal sepsis in resource-limited settings, combatting antimicrobial resistance
- 4**
→p. 94
 
INFECTION PREVENTION AND CONTROL
 Developed NeoIPC surveillance kit to enhance Infection Prevention and Control in European neonatal intensive care units

- 5**
→p. 91
 
CLOSE HIV TREATMENT GAPS
 The UNIVERSAL study submitted data to the Food and Drug Administration for approval of a new, child-friendly formulation of Darunavir/Ritonavir (DRV/r)
- 6**
→ GO TO LINK
 
EQUITABLE RESEARCH
 Launched the Brighter Future Award resource centre of best practices for addressing infectious diseases equitably at the grassroots level
- 7**
→ GO TO LINK
 
EDUCATION ON DATA PRIVACY
 Created an animated video to help children and young people understand data privacy (GDPR) when they take part in clinical trials
- 8**
→p. 111
 
PentaTr@ining
 Expanded PentaTr@ining to Middle East and North Africa (MENA) region with a multi-sponsor (UNICEF, WHO, IOM) training workshop in Oman on the topic of Triple Elimination of HIV, syphilis and hepatitis B – creating a ‘train-the-trainer’ legacy for sustainable ongoing regional health programmes
- 9**
→p. 31
 
TOWARDS AN HIV CURE
 Completed EPIICAL, a global platform advancing strategies for long-term HIV remission in early-treated children
- 10**
→p. 56
 
20 YEARS OF PENTA FOUNDATION
 Celebrating 20 years of impact



2. HOW WE OPERATE

The flexible, multidimensional
Penta environment



Penta Foundation: our business model

We operate on a mission-driven model, dedicated to improving the lives of pregnant individuals, infants, children and adolescents affected by infectious diseases, particularly in regions with the greatest need.



Fondazione Penta ETS operates on a **mission-driven model**, dedicated to improving the lives of pregnant people, infants, children and adolescents affected by infectious diseases, particularly in regions with the greatest need. Established in 2004, our core strategy centers on designing and managing impactful biomedical research addressing critical needs in infectious disease. We achieve this by leveraging a global network of leading scientists, researchers, and healthcare

professionals. Through **strategic partnerships** and rigorous **project oversight**, we ensure that research translates into tangible benefits, ultimately reducing the burden of infectious diseases in underserved populations. As a **registered non-profit** with RUNTS, the national single register of third-sector organisations in Italy, we uphold the highest standards of **transparency** and **accountability**, ensuring that **all resources are directed efficiently** towards achieving our mission.

Penta Foundation's governance structure

The Founding body

Fondazione C.A.R.A.P. Onlus is the founding body of Penta and holds the power to appoint the members of the Board of Directors.

The President and the Vice President

The President acts as the legal representative of the Foundation, managing external relations and communication. Furthermore, he convenes and chairs Board of Directors meetings and exercises the powers delegated to him by the Board of Directors. If the President is unable to attend, the Vice President assumes the President's duties.

The Board of Directors

This governing body holds powers of ordinary and extraordinary administration. It is ultimately responsible for ensuring the Foundation operates in accordance with its mission and values. Board members are designated by the Founding Body. Key responsibilities include appointing and revoking the Supervisory Body and the Statutory Auditor, approving financial statement, mission report and the Foundation's budget. Additionally, it implements guidelines outlined in the bylaws for the Foundation's activities and oversees the management of financial assets. The Board resolves acts of ordinary and extraordinary administration and can delegate all or part of its powers to the President or specific members. Board members serve three-year terms. In 2024, they met five times.

With the approval of the Foundation's financial statements as of 31.12.2023, the previous Board of Directors has expired its three-year term and a new Board has been appointed. The current Board of Directors is composed of:

- **Carlo Giaquinto** (President), Paediatrician and Professor of Paediatrics at the University of Padua, Italy
- **Claire Thorne** (Vice President), Epidemiologist and Professor of Infectious Disease Epidemiology at UCL Great Ormond Street Institute of Child Health, University College London, UK
- **Diana Gibb**, Paediatrician and Professor of Epidemiology and Clinical Trials at Medical Research Council Clinical Trials Unit (MRC CTU) at University College London (UCL), UK
- **Elizabeth Robinson**, Indaco Venture Partners SGR, Italy
- **Julia Bielicki**, Professor and Senior Consultant in Paediatric Infectious Diseases at City St George's, University of London, UK and, University Children's Hospital Basel, Switzerland
- **Paolo Rossi**, Immunologist and Professor of Paediatrics at the Children's Hospital Bambino Gesù/ University of Rome Tor Vergata, Italy

The Supervisory Body

Appointed by the Board of Directors for a three-year term, this independent body ensures Penta adheres to legal requirements, its bylaws and proper administrative principles. It also assesses the adequacy of the Foundation's organisational structure and its functioning. Currently, the Supervisory Board is a single member (Dr. Carmine Pallino), who participates in Board meetings.

The Statutory Auditor

BDO Italia S.p.A serves as an auditor, responsible for verifying the accuracy of Penta's financial statements against Italian and international regulations. It is appointed for 3 years.

Details on the Governing bodies' compensation for 2024 are available on the [Penta website](#).

Penta Foundation's compliance

Penta is dedicated to fostering a work environment characterised by fairness, transparency and adherence to the law. This commitment is reflected in our comprehensive approach to ethical conduct.

PRESIDENT OF THE BOARD OF DIRECTORS

Carlo Giaquinto

VICE PRESIDENT

Claire Thorne

SUPERVISORY BODY

Dott. Carmine Pallino

STATUTORY AUDITOR

BDO Italia S.p.A.

FOUNDING BODY

Fondazione
C.A.R.A.P. Onlus

Organisational Model 231

Italian Legislative Decree No. 231/2001 ("231 Decree") establishes a framework for holding organisations accountable for certain offences committed by their representatives in the interest or to the advantage of the organisation. To prevent such occurrences, the Foundation has adopted an Organisation, Management and Control Model ("Penta 231 Model") outlining best practices for all personnel and collaborating parties, as well as defining expected ethical conduct. The Penta 231 Model includes, among others, the **Code of Ethics**, which establishes Penta's ethical principles. Both the 231 Model and the Code of Ethics are regularly updated to reflect any changes in legislation or organisational structure.

Building upon this commitment in 2024, Penta, in collaboration with the MRC Clinical Trials Unit at UCL and the Health Research Authority, further extended its efforts in data protection awareness by co-producing a new animated video specifically designed to help children and young people understand GDPR within the context of participating in clinical trials. This innovative resource, shaped with valuable input from young individuals on the CHIVA Youth Committee and Penta Youth Trials Boards across Uganda, Zimbabwe, South Africa, and the UK, is intended to be shown to young participants before they provide consent. By clearly explaining their rights in an age-appropriate manner, the video empowers them to make informed decisions about their involvement in medical research. This video is now available for research staff to utilise across a range of future studies and disease areas, ensuring that participants of all ages can better understand their data protection rights. → [GO TO LINK](#)

The Board of Directors has appointed a single-member **Surveillance Body for a three-year term** to oversee the effectiveness and ongoing relevance of the Penta 231 Model. This body reports directly to both the Board of Directors and the Supervisory Board.

Data Protection

Penta prioritises personal data protection. We have appointed a **Data Protection Officer** to ensure compliance with data privacy regulations (GDPR). Additionally, we have adopted an internal Privacy Manual which educates all personnel on respecting personal data rights in compliance with data protection regulations.

Code of Conduct

Our Code of Conduct promotes a respectful and positive work environment, emphasising fairness, well-being and responsible communication with colleagues.

Additional Policies

- **Conflict of Interest Policy:** This policy ensures that any potential conflicts of interest are identified, disclosed, and managed appropriately. This protects public trust in Penta's decision-making, operations, and reputation.
- **Fraud Prevention, Anti-Bribery and Anti-Corruption Policy:** This policy outlines Penta's commitment to preventing and prohibiting acts of fraud, bribery and corruption. It ensures compliance with all applicable anti-corruption and anti-bribery laws and regulations.
- **Whistleblowing Policy:** This policy establishes a clear process for receiving, analysing and managing reports of wrongdoing.

Cybersecurity and research

The risks and solutions of Penta



By
Andrea Canton
Penta Foundation
IT Manager

In the current context, cybersecurity is a fundamental pillar for any organization, especially for entities like Penta, whose commitment to health research places it at the center of managing highly sensitive data. Cyber threats are constantly increasing and can have serious consequences for data security and business continuity. For Penta, the protection of sensitive data is crucial to maintaining the trust of funders, partners, and study participants.

The main areas of risk related to cybersecurity that Penta must address include:

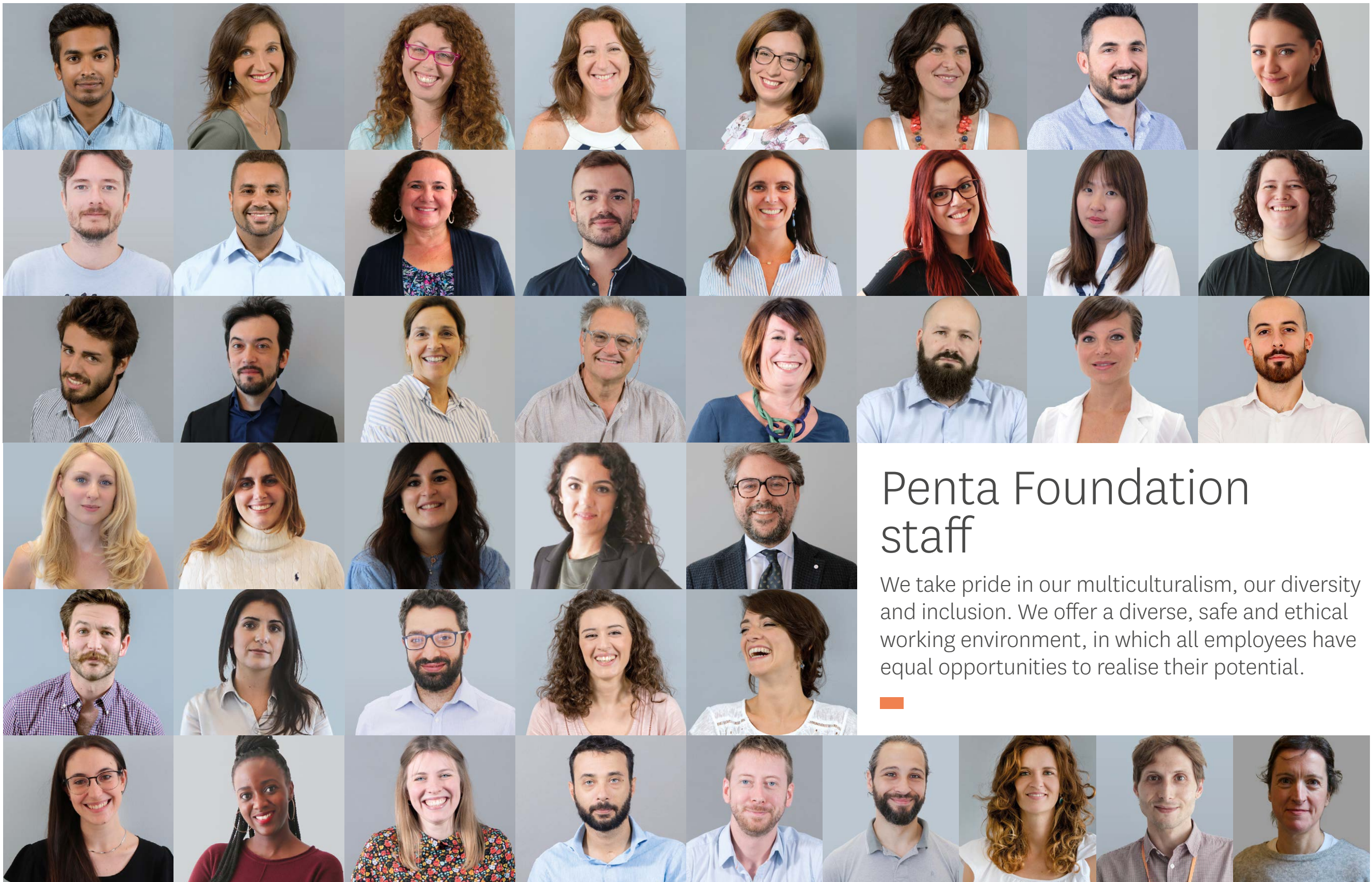
- The potential loss or theft of confidential information. Such an event would irreparably undermine our credibility, with significant legal and economic consequences.
- Cyberattacks, because phenomena such as phishing and ransomware are not just theoretical threats, but concrete dangers capable of paralysing our research activities.
- The security of digital tools used daily by our researchers is a crucial link in the protection chain. Unauthorised access or the compromise of these devices could open dangerous breaches in our IT systems.

The repercussions of such risks on Penta and, consequently, on the scientific community and patients, would be far from negligible. Aware of this delicate situation, the Penta Foundation has undertaken a structured path to strengthen its cyber defenses through concrete and targeted measures:

- Implementing robust access controls for anyone accessing our company files.
- Training our collaborators on best practices in cybersecurity to mitigate the risk of human error, often the primary cause of incidents.
- Continuously monitoring systems, which allows us to detect and respond promptly to potential threats.
- Constantly updating software and security systems to address the continuous evolution of cyber threats.

These initiatives do not represent a mere technical fulfilment but constitute an essential element to ensure the continuity and integrity of our scientific mission. Cybersecurity is, in all respects, a fundamental basis for the success and credibility of the health research we carry out with dedication.





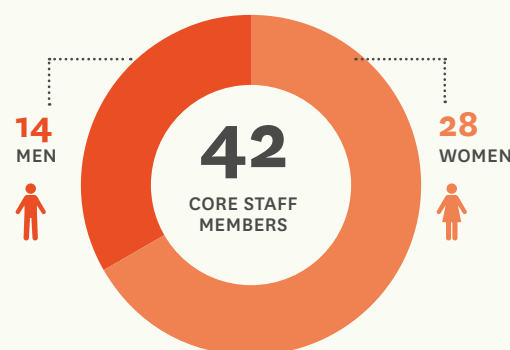
Penta Foundation staff

We take pride in our multiculturalism, our diversity and inclusion. We offer a diverse, safe and ethical working environment, in which all employees have equal opportunities to realise their potential.

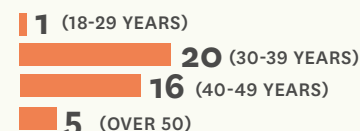


Building a diverse team

COMPOSITION OF THE PENTA FOUNDATION STAFF AS OF 31 DECEMBER 2024

AGE

39.65 AVERAGE AGE
YEARS

NATIONALITYCOMPETENCESQUALIFICATION

9.5%

TURNOVER RATE



92%

PERCENTAGE OF STAFF WITH BACHELOR'S DEGREE



58.3%

PERCENTAGE OF WOMEN IN A LEADING ROLE (LINE MANAGERS AND DEPARTMENT CHIEFS)



100%

RATE OF PERMANENT WORK CONTRACTS ON TOTAL NUMBER OF EMPLOYMENT CONTRACTS

COLLABORATORS

14



8 WOMEN



6 MEN

CONSULTANTS

33



15 WOMEN



18 MEN

TYPE OF EMPLOYMENT CONTRACT

83.3%

35 FULL TIME



20 WOMEN

15 MEN

16.6%

8 PART-TIME



7 WOMEN

1 MAN

Investing in our people: promoting equality and well-being

At Penta, we recognise that our success hinges on the talent, dedication, and well-being of our staff. As part of our 2020-2024 strategy, we are committed to cultivating a diverse, equitable, and inclusive work environment where everyone feels valued and empowered to contribute their best.

One of our key initiatives is actively promoting gender equality at all levels. We utilise a **"blind" recruitment** process, removing identifying information like names, gender and ethnicity from applications during the initial screening stage. This approach mitigates unconscious bias and ensures that the best candidates are chosen based solely on their qualifications and experience.

We prioritise achieving a healthy work-life balance for all employees. We offer **flexible work** arrangements, such as remote work options and adaptable hours, to accommodate individual needs. Generous **parental leave** policies extend to both mothers and fathers, allowing staff to prioritise family responsibilities without compromising their professional growth.

Additionally, we practice **pay transparency** to ensure everyone is compensated fairly based on their role and performance. This transparency allows staff to understand their compensation structure and compare it with colleagues in similar positions.

In 2024, we enhanced our leave policies to provide:

- **50 hours of paid leave to employees** with a certified disability who do not qualify for leave under the Italian law;
- **3 additional days of paid compassionate leave**, extendable to 6 days for employees needing extra time to reach family;
- **3 days of paid leave for caregivers** who are excluded from Italian law (L 104/1992), which, under certain circumstances, guarantees 3 days/month of paid leave for assisting disabled relatives;
- extended the **paternity leave** guaranteed by the Italian law to 25 days.

We foster diversity across our teams, ensuring a broad range of perspectives inform our decisions. This inclusive environment empowers everyone to thrive at Penta.

In 2023, the Gender Equality Working Group (GEWG) and the Equality Officer implemented **awareness-raising** initiatives to educate the Penta Foundation staff on gender equality within the Foundation and, in general, in promoting diversity, equality, and inclusion. This ongoing commitment to fostering a culture of understanding and respect ensures that everyone feels empowered to contribute to a more equitable and inclusive workplace.

Our dedication to gender equality culminated in achieving the **UNI/PdR 125:2022 certification** for our gender equality management system in 2023, affirming our commitment to creating a fair and inclusive workplace.

As Eleonora Brugiolo, Penta Foundation's Equality Officer, highlights, *"The gender equality certification encourages us to continue on this path. It's clear that a more inclusive and flexible work environment contributes to improving people's lives outside of work as well."*

below:
Drawings made by the
children of the
Penta employees



ALEXANDRA



MATILDE



LORENZO



LEONARDO



SEBA



UNI PDR 125
BUREAU VERITAS
Certification



In 2024, we renewed this certification, confirming our achievements and implementing further improvements. Maintaining our 96% score (exceptional for a company with less than 50 employees) motivates us, in daily efforts to foster diversity and inclusion, confident in the positive impact on our employees.

We offer a competitive **total reward system** that encompasses both financial and non-financial benefits. This includes competitive salaries, performance-based rewards, and a comprehensive welfare package. Our “**Penta Welfare Plan**” goes beyond the traditional salary structure, providing a variety of benefits and services designed to enhance employee well-being and create a positive work environment.

In 2023, we launched a new **psychological counselling** service to further support our staff's mental

health and overall well-being. Counselling meetings take place through a secure platform managed by a reputable health facility registered with the National Health Service and supervised by the Order of Psychologists, thus ensuring confidentiality and the safety of user data.

Protecting children is paramount at Penta. We recognise the inherent vulnerability of children and the importance of creating a safe space for them to participate in research or interact with our staff. To uphold this commitment, we have a rigorous **safeguarding policy** that outlines clear procedures to ensure the safety and well-being of children involved in our work or research. This includes guidelines on obtaining informed consent, maintaining confidentiality, and reporting any concerns about a child's safety or well-being.



NOELIA



SOFIA

Our responsibility towards our people

SMART WORKING

100% OF EMPLOYEES

HOURS OF TOTAL WORKING HOURS

28,590 h 44%

BETTER WORK-LIFE BALANCE AND FLEXIBILITY

STUDY PERMITS AND EXAM PREPARATION PERMITS

28%

12 6 WOMEN 6 MEN

MEAL VOUCHERS

100% OF EMPLOYEES ENTITLED

TOTAL INVESTMENT

€ 66,232

INCREASED PURCHASING POWER

EDUCATION CALL

100%

STAFF APPLYING

50%

BUDGET DEDICATED TO WOMEN

ALLOCATED BUDGET

€ 15,000

EDUCATIONAL AREAS
COACHING, PEOPLE MANAGEMENT, VENDORS MANAGEMENT, COMMUNICATION SKILLS, ACCOUNTING, ESG REPORTING

DIVERSITY AND INCLUSION

GENDER EQUALITY WORKING GROUP COMPOSITION

7 6 WOMEN 1 MEN

STORIES FROM PENTA



Ellie Khaw
Penta Foundation
Accountant

Where numbers tell the story

When I joined the Penta family as an Accountant in 2019, Penta was already in the middle of potential growth and expansion. It was the right moment to strengthen its internal organisational structure and tighten up its financial management. Employees were grouped based on their specific role's specializations, and each department operated under a line-manager, overseen by the Senior Leadership Team. New departments were created and today the organisation has seven teams, and each and every one has a crucial role to play.

I had the privilege of participating in the restructuring and implementation of the Enterprise Resource Planning (ERP) system.

Withdrawing all the legacy applications and procedures, the in-house ERP financial system has helped us to standardize and integrate all existing and new financial data, providing real-time financial figures under one platform. Working alongside my talented superiors and learning new financial terms sparked my curiosity and continuous learning. We continue to improve our financial management processes to deliver reliable financial statements to our stakeholders and make informed decisions based on the true financial position of the Foundation, adopting a management style based on trust and accountability.

I am grateful for the supportive work environment that Penta provides!

STORIES FROM PENTA



Giulio Vecchia
Penta Foundation
Project manager

Investing in people, empowering growth: my experience at Penta

Penta is a international organisation, built upon the collaboration between people from diverse backgrounds. Over my eight years with the Foundation's Operations team, I have had the chance to engage with a broad spectrum of partners, each bringing unique roles, experiences, career stages, and cultural perspectives. This stands out as a particularly rewarding part of working here.

Cultivating positive and productive relationships with these partners and within different multicultural contexts requires a blend of skills. We bring together established company principles, individual awareness, with a genuine inclination towards fostering human connections. And in many cases, effective negotiation and relationship management skills are also indispensable tools.

Recognising the importance of these skills, Penta invests in its employees through its annual "Education Call". I was very fortunate to be able to take part in a 2024

people management course funded by this initiative, together with several other colleagues. Delivered over four online sessions, the course provided insights into active listening techniques, public speaking, diplomatic approaches to issue resolution, and effective negotiation strategies.

Working on these techniques has been essential in enhancing my communication effectiveness within our dynamic, multifaceted, and international workplace. From a career perspective, it has equipped me with valuable skills that have also been useful in strengthening Penta's negotiating position, allowing us to prioritise shared objectives over individual interests.

Initiatives like this Educational Call illustrate Penta's commitment to its employee development, fostering a people-first approach and providing essential tools that not only benefit individual career growth but that also contribute to the organisation's success in the global arena.

Building a healthy world for all: our commitment to environmental sustainability

At Penta, we believe in creating a positive impact not just on children's health, but also on the environment we all share. We want our offices to be great places for our staff – and for the planet.

As an international research network, collaboration is key. While face-to-face meetings play an essential role in fostering research, knowledge exchange, and strong partnerships, they also contribute to our carbon footprint. Recognising this, we have implemented a Travel Policy to guide responsible travel practices.

This policy encourages employees and collaborators to:

- Prioritise virtual collaboration tools and reduce unnecessary journeys.
- Minimise long-distance flights.
- Combine meetings to minimise overall travel and maximise efficiency.

- Utilise trains, hybrids, electric vehicles, or low-emission options when travel is necessary.

The introduction of a permanent hybrid work model significantly reduced employee commuting emissions in 2024 (54,508 kg CO₂), compared to the potential emissions of a daily commute scenario (90,846 kg CO₂). Additionally, we prioritise online training opportunities, promoting a better work-life balance while minimising travel's environmental impact.

We engage with our collaborators and suppliers to promote environmentally conscious practices. Our ongoing commitment to sustainability is a core value that guides our operations and inspires our collaborators to embrace a greener approach.

The Penta Foundation: core competencies and 2024 highlights

In 2024, following digital transformations across societies and healthcare systems, we strengthened our capacity to analyse Real-World Data and the resulting Real-World Evidence for medication use, benefits and risks. We also invested in cyber security and harnessed the cloud's potential to create a more secure, more efficient, and more collaborative environment.

Data Management and Infrastructure

The Data Management and Infrastructure (DM&I) Team oversees the entire lifecycle of clinical data within research projects, ensuring efficient and compliant data management. This includes designing and managing Case Report Forms (CRFs), and study databases to meet the specific requirements of each study protocol. The team ensures data quality through robust validation and cleaning processes, addressing discrepancies, and conducting thorough quality control checks. By adhering to regulatory standards such as EMA guidelines and GDPR, the DM&I Team

maintains compliance while producing detailed documentation, including Data Management Plans (DMPs) and Standard Operating Procedures (SOPs). Additionally, the team manages secure data transfers and integration from various sources, fostering seamless collaboration with clinical teams, statisticians, and IT professionals. Leveraging secure and flexible cloud-based technology, the DM&I Team ensures the secure storage, processing, and reporting of clinical data, supporting Penta's commitment to high-quality clinical research.

STORIES FROM PENTA



Penta Foundation's 20th Anniversary

In 2024, the Penta Foundation marked its 20th anniversary, a testament to two decades of tireless dedication to advancing pregnancy and child health worldwide. While the Foundation's impact is evident in the groundbreaking research of the Penta ID Network, the true story lies within the **exceptional team that fuels its success.**

Beyond the strategic navigation of research support—horizon scanning, grant development, and project management—lies **a team driven by genuine passion.** The Padova-based team, a vibrant blend of young professionals, embodies the Foundation's spirit.

What sets this team apart is their unique **blend of expertise and empathy.** They

meticulously uphold the highest ethical standards, ensuring the integrity of every research endeavor, while simultaneously fostering a collaborative and supportive environment. Their **diverse backgrounds and perspectives** enrich the Foundation's work, enabling them to tackle complex challenges with innovative solutions.

This isn't just a team; it's a collective of individuals driven by a shared vision: a healthier future for children starting from their conception. They are **the human engine behind Penta's global reach,** transforming scientific findings into tangible improvements in paediatric care and in pregnancy, and solidifying the Foundation's role as a beacon of hope for children and families worldwide.

Heidrun Hildebrand

Bayer Pharmaceuticals, Paediatric Medicine;
Industry co-Project Lead IMI conect4children

“Working with Penta Foundation for the past 7 years has been a rewarding experience. Your dedication as a trusted partner and engaged coordinator of conect4children has played a crucial role in maintaining the success of this public-private partnership. Your expertise in paediatric infections and dedication to developing new medicines, including vaccines, has had a significant impact on improving the health of children and communities worldwide. Working with us during the Covid-19 pandemic, your unwavering support and collaboration with clinicians, investigators, and patients have been invaluable. Here's to many more years of success and making a difference in the lives of those in need!”

Evelina Tacconelli

Professor of Infectious Diseases, University of Verona; Director of the Infectious Diseases section, Verona University Hospital

“The Penta Foundation represents a model of excellence in paediatric infectious disease research. Collaborating with you is both professionally and personally enriching. Together, we are building a healthier future for generations to come. Happy Birthday!”

on the left page:
Penta Foundation staff celebrate our 20th Anniversary



Programme Operations

Our dedicated Operations team plays a critical role in managing global research projects across various infectious diseases affecting children and pregnant people. From HIV and AMR to pandemic preparedness, the team's expertise spans **project management to clinical and regulatory science**.

Comprising professionals with certified competencies, they ensure sound project management at every stage, from study conception to implementation, through funding procurement and management. Key to their activities is regular **stakeholder engagement** with local teams and sites, regulatory authorities, funders, advocacy groups and patient representatives.

Our Clinical Project Managers work alongside selected Clinical Trial Units (CTUs) and Clinical Research Organisations (CROs) to deliver global trials supporting the authorisation and use of paediatric formulations for the treatment HIV and other infections.

Together with experts from the network, the team provides advice to sponsors for the clinical development of new or repurposed paediatric medicines.

Furthermore, the Operations team supports the Network working groups, ensuring that new ideas arising in the Network's discussions can be transformed in new successful projects, thus contributing to achieving Penta's mission.

above:
Penta Foundation's
Operations team
enjoying their annual
team-building activity

Network, Education and Training (NET)

The NET team brings together training, education and the management of the Penta ID Network to support the development and synergy between key areas. The team collaborates with experts from the extensive Penta ID Network to deliver high quality, interactive and in-depth bespoke training and education courses to healthcare workers and young people across the globe, with a particular focus on resource-limited settings. This is achieved through an innovative approach of combining fully immersive face-to-face courses and engaging e-learning methods, with 'hybrid' delivery modes also proving increasingly effective in the 'post-pandemic' era.

Throughout 2024, we advanced the update and expansion of our teaching curricula and online **PentaTr@ining infrastructure**, successfully delivering freshly revised programmes on **fungal infections, viral hepatitis, HIV and other congenital infections** impacting pregnancy and child health. We extended our training networks to the MENA region through a timely and impactful workshop in Muscat, Oman, while also consolidating recently forged links in Namibia with an inaugural residential course in Windhoek. With a view to longer term sustainability, Penta

has also continued to prioritise the integration and embedding of **capacity strengthening** activities in our projects, particularly in resource-limited settings. We prioritise the meaningful participation of **young people** in the design and delivery of our courses and, more broadly, **we promote and coordinate the involvement of children and young people across all of our work in Penta**.

The NET team provides robust administrative structure and management to the Penta ID Network. In 2024 we continued to buttress the Penta ID Network framework through the coordination of both the Network Engagement Committee and the Scientific Steering Committee. These groups support Penta in ensuring transparency and creating cohesive reporting lines across of all Penta's activities, setting the foundation for a Network that is truly built to last. Building on this momentum, 2024 marks a year of continued growth and purpose. Aligned with our new 5-year strategy, targeted refinements at the working group level will further strengthen and evolve our Network, guaranteeing its long-term sustainability and impact on child health.



Communications

Our diverse and experienced Communications team coordinates all communication activities across Penta's projects and campaigns. Our primary goal is to raise awareness of the unique needs of children and pregnant individuals affected by infections, advocating for their prioritised health and well-being in public health conversations. This is achieved by effectively disseminating Penta's research, broadening its reach and fostering deeper understanding of its impact.

Strengthening stronger relationships with youth and patient groups remains a central focus area. In 2023 and 2024, the Penta Young Reporters, a group of young influencers, used social media to translate complex science into engaging content, demystifying HIV care and raising awareness among their peers.

Building on the success of the Penta Brighter Future Award (BFA)

launched in 2023, a key achievement in 2024 was the launch of the **BFA Resource Centre**. This online platform consolidates valuable resources and inspiring stories of past recipients, fostering greater accessibility and engagement with the BFA initiative and its mission.

Inclusive communication is another cornerstone of the Communications team's philosophy. They proudly endorsed the People First Charter, championing **person-first language** in the field of HIV. This commitment extends far beyond a single disease. The team is dedicated to utilising **non-discriminatory and non-stigmatising language** across all areas of their work. Furthermore, they collaborate with the Gender Equality working group to actively streamline **gender-neutral** language throughout all communications.

above:
Penta Foundation
Communications and
NET teams at their joint
team building activity

Penta BFA Resource Centre

Following the 2024 Penta Brighter Future Award, Penta created the BFA Resource Centre, an online platform for pregnancy and child health advocates. The Centre documents effective strategies used by BFA winners to tackle health inequities at the community level. As the BFA evolves and the collection grows, Penta aims to inspire and equip others, providing a toolbox for translating research into real-world impact.

The following themes have emerged from the BFA 1 collection at the Resource Centre:

- How to engage and **empower communities** to get involved.
- How to create successful collaborations and **partnerships at the grassroots**.
- How to ensure **equitable healthcare access**.
- How to build **robust healthcare infrastructure**.

This Resource Centre is more than just a collection of stories; it fosters a global community of practice, promotes knowledge sharing and accelerates progress towards a healthier future for children worldwide.

[> Go to the Resource Centre](#)

Quality Assurance

Penta is unwavering in its commitment to fostering a research culture centred on quality and impact. We define quality as exceeding expectations in all critical aspects of research, encompassing participant safety and well-being, stringent adherence to regulatory requirements and international standards, and streamlined, efficient operations governed by well-defined and documented processes.

The Penta Quality Management System (QMS) serves as our cornerstone for managing quality. This system functions as an instrument to achieve our intended research objectives, guarantee compliance with all requirements and expectations, and continuously drive improvement within our research practices.

We hold ourselves accountable to the highest standards and expect the same level of commitment from all our collaborators. This ensures the integrity and ethical conduct of all research conducted under the Penta umbrella.



Finance and Administration

At Penta, we prioritise transparent and sound financial management practices. This includes strict adherence to both national and international standards, fostering a culture of responsible resource allocation. Our dedicated Finance and Administration team plays a critical role in ensuring the efficient and effective use of financial resources.

Legal

The legal team plays a critical role in ensuring the Foundation's legal compliance. They collaborate closely with all internal teams to support day-to-day operations. This includes providing institutional legal support, liaising with the Data Protection Officer, Surveillance Body, and external legal advisors to guarantee adherence to all applicable legal requirements. The team combines legal expertise with knowledge of European funding regulations. Comprised of certified professionals, they ensure robust legal management and coordination by drafting, negotiating, and managing contracts, providing internal legal guidance and supporting the legal design - including the privacy aspects - of projects and clinical trials both private and public funded. In the context of EU-funded projects, the

team additionally supports the implementation of grant agreements, consortium agreements and their amendments. They ensure overall administrative coordination and legal management, including guiding partners and maintaining liaison with funders.

In 2024, the legal team notably supported the Foundation's response to the Italian Data Protection Authority's (Garante Privacy) invitation to participate in drafting new ethical rules for processing personal data in statistical or scientific research. The Foundation's inclusion in the technical working group is a valuable opportunity, reflecting Penta's commitment to enhancing the efficiency of scientific research.

above:
Penta Foundation
Finance team at their
annual team building
activity

Organogram

Our forward-thinking leadership team comprises dedicated, focused and experienced individuals who work hand in hand with each other and the Penta staff to make a difference for all our stakeholders.



PENTA FOUNDATION PRESIDENT

Carlo Giaquinto



VICE PRESIDENT

Claire Thorne



CHIEF PROGRAM OFFICER

Laura Mangiarini

- NETWORK, EDUCATION AND TRAINING
- PROGRAM OPERATIONS
- EPIDEMIOLOGY AND RWD SCIENCE
- DATA MANAGEMENT AND INFRASTRUCTURE



CHIEF FINANCE AND ADMINISTRATION OFFICER

Luigi Comacchio

- ADMINISTRATION
- FINANCE
- LEGAL
- QUALITY ASSURANCE & AUDITING



CHIEF PEOPLE, COMMUNICATIONS AND CULTURE OFFICER

Giuseppe Bonura

- IT
- HR
- COMMUNICATIONS

Penta ID Network

The Penta ID Network forms the foundation of our work in Penta. With the skills, experience and expertise of all our Network members, we develop and deliver world class research and training to drive understanding and good practice around the management of infections in infants, children, adolescents and during pregnancy.

The Penta ID Network reaches almost every corner of the world, with members from Asia, Africa, the Americas and Europe, and has grown steadily since its initial set up in Europe back in 1991. Our members are clinicians, researchers and healthcare professionals, who cover a great depth and breadth of expertise in paediatric infectious diseases.

We leverage this diversity in conducting life-changing research and cutting-edge training programmes – all with the aim to improve the lives of pregnant people and children through the generation and translation into practice of new scientific knowledge.

Throughout 2024:

- HIV & viral infections
- Serious bacterial infections and antimicrobial resistance
- Infection in pregnancy and vertical transmission

- Neglected and emerging childhood infections

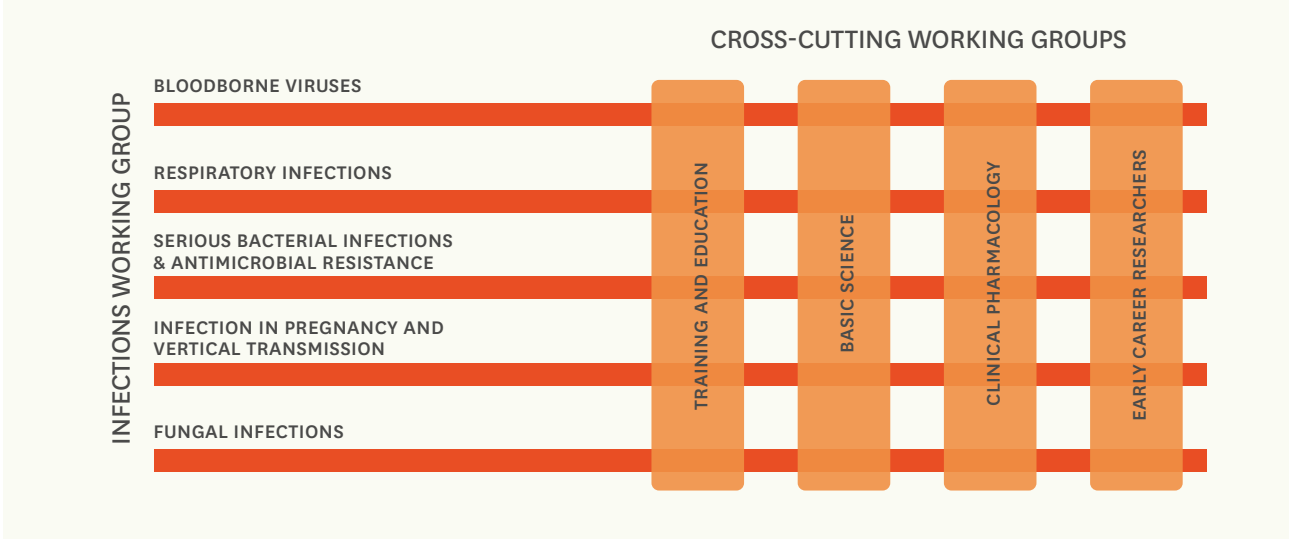
To this end, our **Infections Working Group** led the development of new research concepts, training programmes and activities within each of these scientific areas.

Specifically, the working groups focused on:

- Bloodborne viruses
- Respiratory infections
- Serious bacterial infections and antimicrobial resistance
- Infection in pregnancy and vertical transmission
- Fungal Infections.

To support and complement our Infections Working Group, we have established cross-cutting working groups in: Training and Education, Basic Science, and Clinical Pharmacology. Additionally, an Early

on the right page:
Penta ID Network
members at PIM 2024
in Monopoli (Italy)



Career Researchers working group is dedicated to young researchers pursuing careers in paediatric infections.

Crucially, a Scientific Steering Committee, comprising leads from each Penta working group and regional representatives from Africa, Asia, and

Latin America, ensures a coordinated approach across all our activities. This committee fosters brainstorming, unifies approaches to projects, supports initiative coordination, and serves as a forum for addressing issues, sharing updates, and identifying opportunities

Early Career Researchers

Inspiring a new generation of research leaders in infectious diseases in paediatrics and during pregnancy

Within the Penta ID Network, a key focus is on fostering the involvement of early career researchers in the working groups to ensure the Network's sustainability. In 2021, we set up an Early Career Researcher (ECR) working group, open to all ECRs in the Penta ID Network. This group provides an opportunity for members to share ideas, learn from one another, and access peer support. One of the central aims of the ECR working group is to support the growth and development of the next generation of leaders in paediatric infectious disease. Within this group we have:

- **Developed a Penta Mentoring Programme** with the purpose of connecting ECRs with experienced mentors to provide guidance and encourage professional development. In 2024, the pilot phase of the Penta Mentoring Programme was piloted and will be expanded in 2025.
- **Promoted peer support through the Penta Café programme:** This initiative creates an environment

where ECRs can present research proposals and ideas in a welcoming, informal atmosphere to receive constructive feedback and cultivate collaboration.

- **Identified the training needs of ECRs** and matching them with existing training opportunities. The goal is to equip ECRs with the necessary skills and knowledge to advance their careers, strengthen their research capabilities, and enhance their contributions to the field of paediatric infectious diseases.
- **Collaborated with PentaTr@ining** to support the development of an advocacy paper on Penta's training impact, and supported various training courses through their active participation.
- **Supported in grant proposal writing skills.** In 2024 Penta supported Early Career Researchers in submitting a COST proposal, the first such submission driven by this working group.

STORIES FROM PENTA



Melania Kowatch and Valeria Bajura
Penta Foundation Network,
Education and Training team

Penta Mentoring Programme: reflections on a successful pilot phase

The Penta Early Career Researchers (ECR) Mentoring Subgroup launched the **pilot phase** of the Penta Mentoring Programme in 2024. This initiative connected our ECRs with experienced researchers from **the Penta ID Network**, fostering the development of future research leaders. Through structured mentorship, mentees and mentors partnered to set achievable career goals, address challenges, and build professional confidence.

The pilot phase successfully paired **8 mentor-mentee pairs**, providing valuable opportunities for professional development, knowledge exchange, and personalised guidance tailored to the needs of ECRs. This initial phase yielded crucial insights, helping us refine our approach for future editions.

Positive feedback from both mentors and mentees highlights the programme's significant value:

- **Mentee:** "I have really enjoyed my meetings with my mentor. She has expertise that closely aligns with my PhD. She is very kind and supportive, and I feel comfortable opening up about my difficulties."

- **Mentor:** "I feel like I am helping my mentee think about the bigger picture - what is important to focus on for her career rather than just immediate deadlines. She comes to meetings prepared with topics to discuss, which is fantastic."

- **Mentee:** "My mentor's guidance on project management has significantly enhanced my ability to prioritise tasks and meet deadlines effectively, encouragement helped me step out of my comfort zone, which has made me more confident in public speaking and decision-making."

- **Mentor:** "Es una experiencia gratificante. Al ser mi primera vez como mentor, sentía algo de miedo, pero a medida que pasaron las reuniones, me di cuenta de toda la experiencia que puedo aportar a mi aprendiz. Ambos nos beneficiamos." ("It is a rewarding experience. As it was my first time as a mentor, I felt a bit nervous, but as the meetings progressed, I realised how much experience I could share with my mentee, and we both benefited.")

The success of the pilot phase reinforces our commitment to expanding and improving the Penta Mentoring Programme. We will integrate the lessons learnt to enhance the experience for future participants. We look forward to welcoming new mentors and mentees into the next phase, ensuring ECRs receive the support they need to excel.

Building an inclusive network

Our Network members are involved in all aspects of Penta's work. We keep our members connected through a variety of engaging activities, fostering collaboration, knowledge-sharing, and a strong sense of community. Both online and face-to-face scientific meetings provide platforms for members to exchange knowledge, discuss research findings, and collaborate on critical issues in pregnancy and paediatric infectious diseases. Our "Penta Aperitivo" webinars offer focused knowledge exchange opportunities and interactive discussions on key topics. We maintain open communication channels with our members, keeping them informed of the latest developments, research initiatives, and Network activities.

In 2022 we designed a **new Network governance structure** to ensure greater transparency, facilitate collaboration, and support the Network's continued expansion. This resulted in a more streamlined membership process and cohesive reporting line structure.

As part of this structure, we redesigned the Scientific Steering Committee. This Committee plays a vital role in fostering a coordinated approach across Penta's working groups and clinical areas. The Committee comprises leads from each Penta working group and regional representatives from Africa, Asia and Latin America, supporting the coordination of initiatives and serving as a forum to address issues, risks and share updates and opportunities.

We have also established the **Network Engagement Committee (NEC)**. The NEC is responsible for ensuring member engagement by designing and implementing initiatives that promote interaction and collaboration. The NEC also manages membership applications and tracks the Network's expansion, ensuring its continued growth.

STORIES FROM PENTA



Matteo Bason
Penta Foundation
Education manager

Penta Aperitivo Webinars: connecting the global infectious disease community

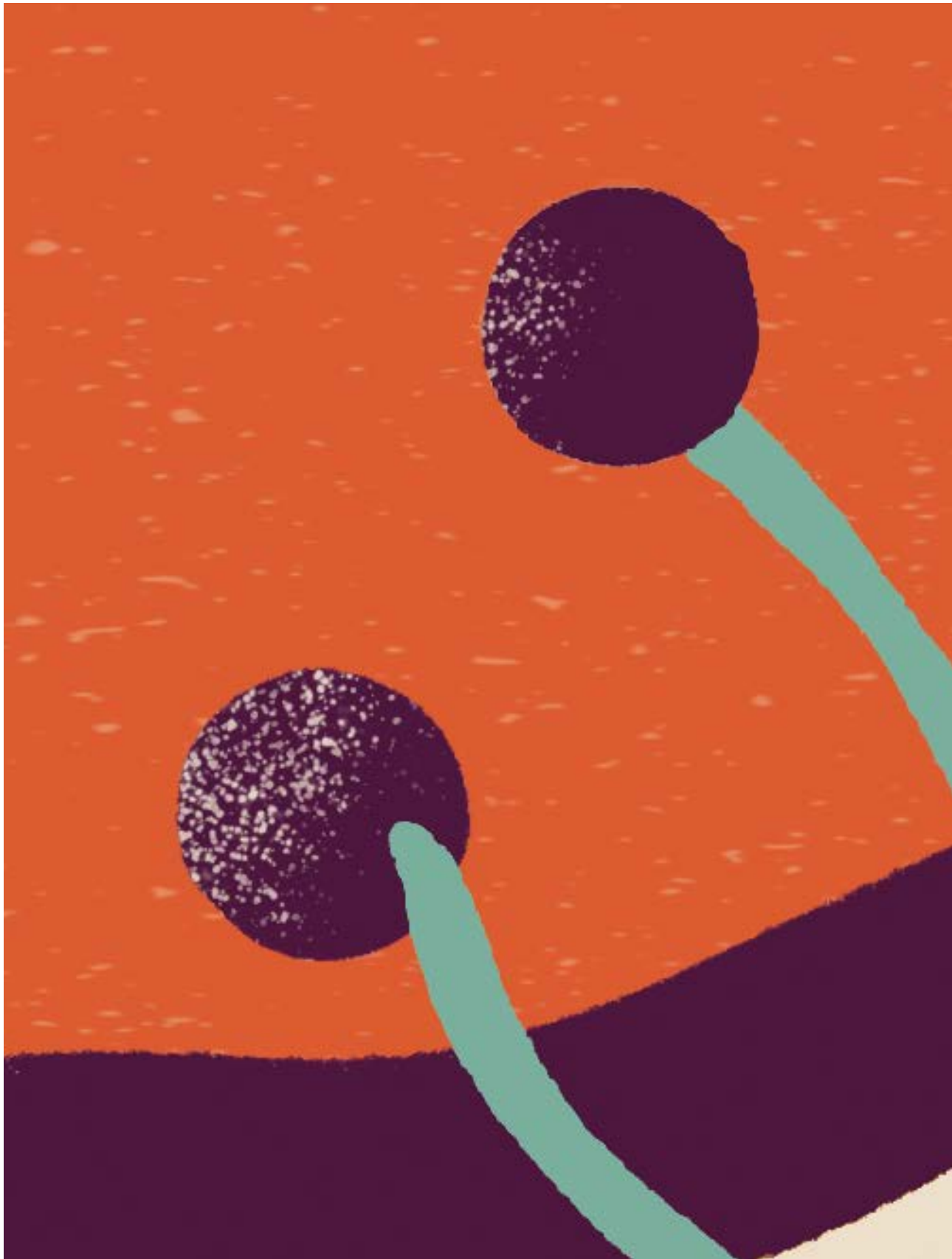
The Penta Aperitivo webinars serve as a valuable platform for healthcare professionals and researchers interested in the latest advancements in infectious diseases affecting children and pregnant individuals. Covering a broad range of topics, these sessions provide insights into prevention and management, while also showcasing Penta's initiatives, projects, and studies. Participants gain a unique opportunity to engage with the Penta ID Network and explore the benefits of being part of our global community.

In 2024, we hosted seven webinars featuring international experts, both within and beyond

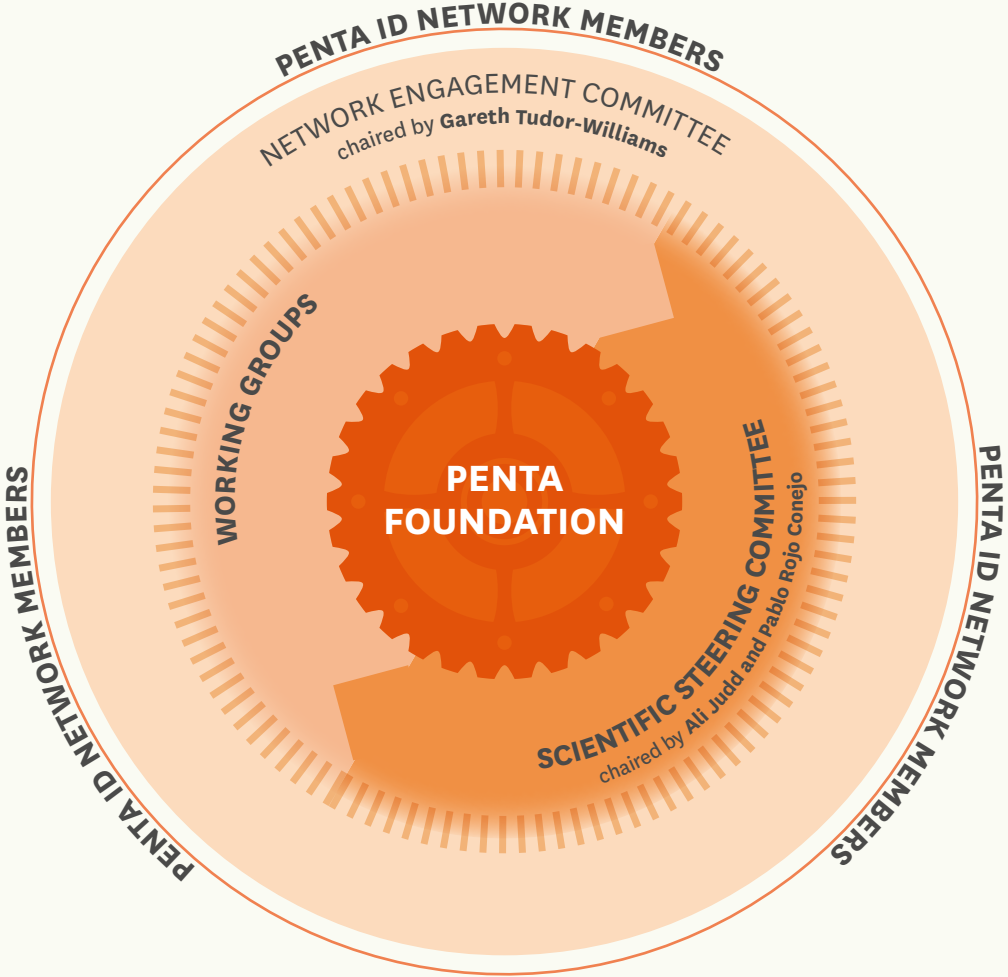
the Penta ID Network. A novelty of the format was to provide the opportunity to Early Career Researchers to present their work and their "fresh" perspective on the field, fostering engagement through panel discussions and audience participation. The webinar topics addressed some of the most pressing issues in infectious diseases affecting children and pregnant people. We explored how to translate scientific research into practical solutions for healthcare settings, discussed innovative approaches for engaging the public in scientific studies, and examined new strategies to enhance the diagnosis

of tuberculosis in children. Other sessions focused on the latest findings regarding antiretroviral treatments for pregnant and breastfeeding people, addressed the challenges of monitoring and preventing neonatal sepsis in diverse healthcare settings, investigated the global spread of fungal infections in children and their impact across different regions.

With each session, the Penta Aperitivo series confirmed to be a dynamic, interactive and collaborative space for knowledge exchange. As we look ahead to 2025, we remain committed to expanding our reach and supporting the global ID research community.



Penta's
Ecosystem



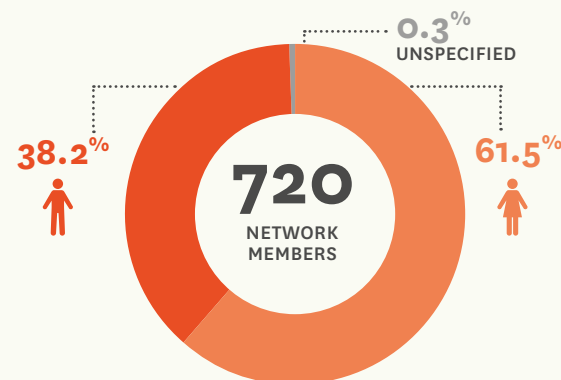
Building an inclusive Network

A diverse landscape of expertise in pregnancy and child health research

AS OF 31 DECEMBER 2024

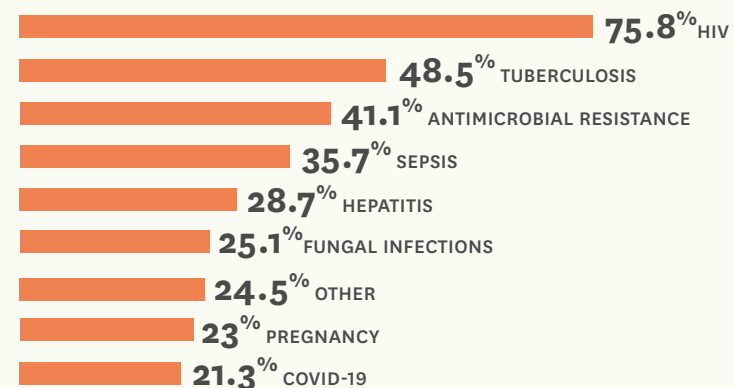
NETWORK MEMBERS

+21,4% INCREASE RATE IN 2024

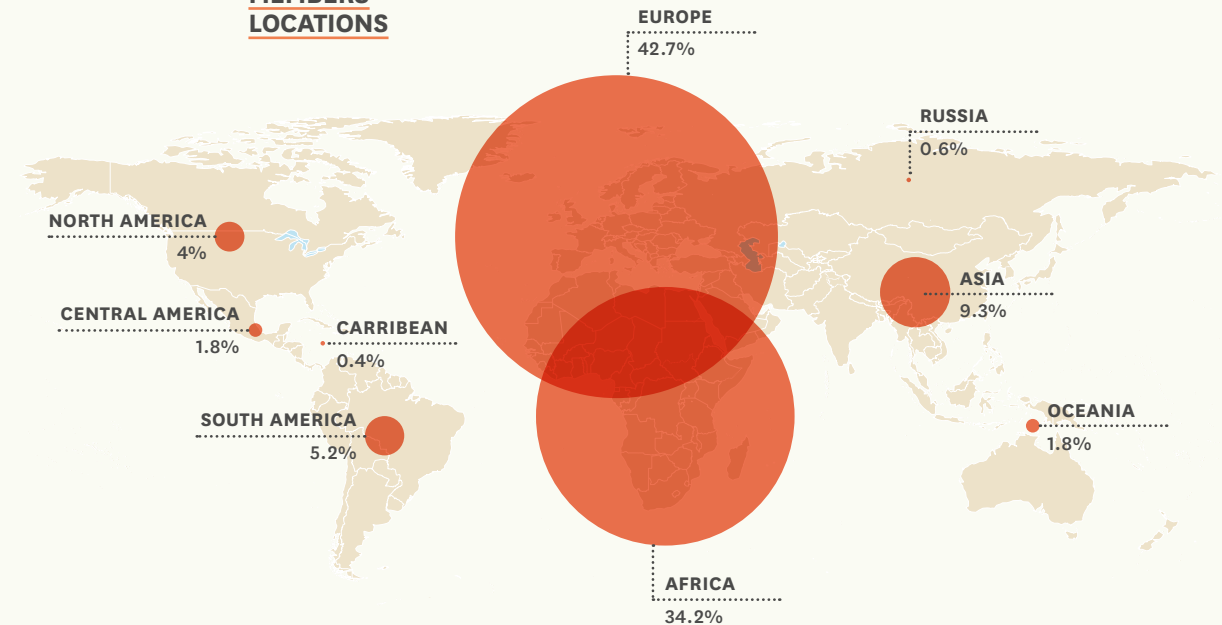


31.8% EARLY CAREER RESEARCHERS

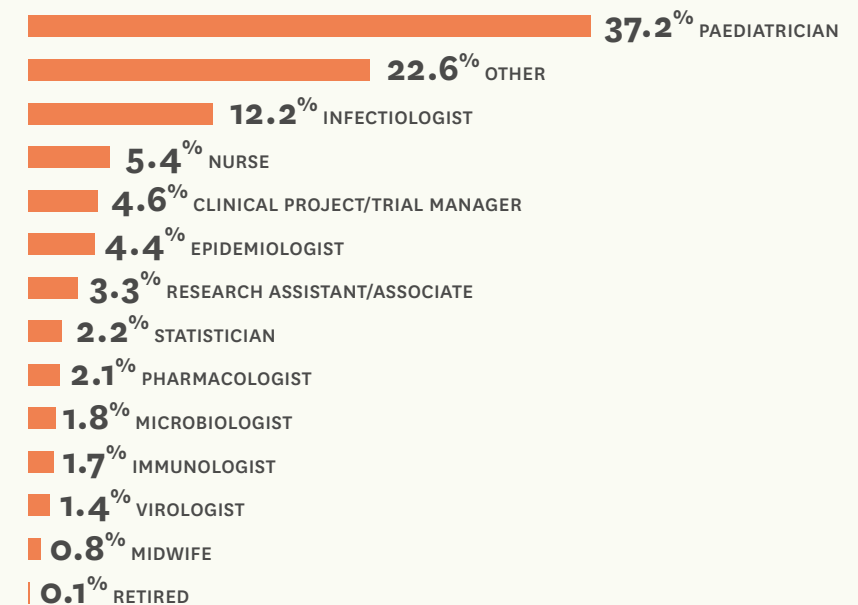
CLINICAL AREA OF INTEREST



MEMBERS LOCATIONS



PROFESSION



Our stakeholders

Our mission is our guiding light and cannot be accomplished by us alone. We actively seek out and promote partnerships, resources, and input from our stakeholders to accelerate efforts to advance our mission and achieve lasting impact.

PATIENTS, THEIR FAMILIES AND CAREGIVERS INVOLVED IN OUR STUDIES

BY VOLUNTARILY PARTICIPATING IN OUR RESEARCH, PATIENTS, ALONG WITH THEIR FAMILIES AND CAREGIVERS, CONTRIBUTE TO A BRIGHTER FUTURE FOR THEMSELVES AND THEIR COMMUNITIES

PRIVATE AND PUBLIC

THEY PROVIDE FINANCIAL SUPPORT FOR RESEARCH EFFORTS

EMA, FDA, WHO

THEY ACT AS A SAFEGUARD FOR ETHICAL AND RESPONSIBLE RESEARCH, BY ENSURING STUDIES ARE DESIGNED TO MINIMIZE RISKS TO PARTICIPANTS WHILE MAXIMIZE THE POTENTIAL BENEFITS

MINISTRIES OF HEALTH AT LOCAL, NATIONAL AND INTERNATIONAL LEVEL

THEY BRIDGE THE GAP BETWEEN RESEARCH AND REAL-WORLD APPLICATION, ENSURING PENTA'S RESEARCH EFFORTS CONTRIBUTE MEANINGFULLY TO IMPROVING PUBLIC HEALTH

CROS, CTUS, OTHER RESEARCH NETWORKS, PROJECT PARTNERS

THEY ARE KEY PLAYERS IN RESEARCH UNDERTAKINGS THROUGH CO-PLANNING, SHARING KNOWLEDGE AND EXPERTISE, TEST AND APPLY INNOVATION

BOARD OF DIRECTORS, SUPERVISORY BOARD, SCIENTIFIC STEERING COMMITTEE

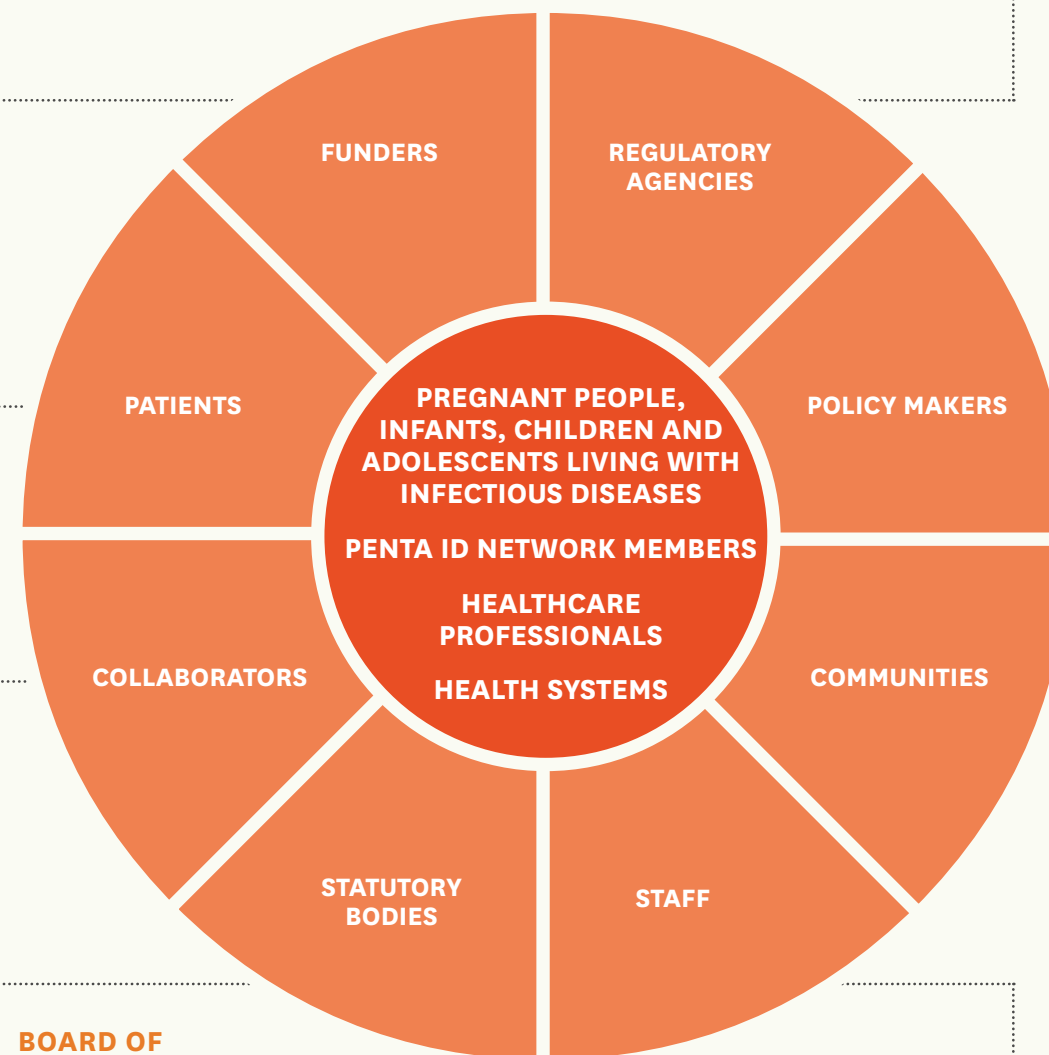
THEY DEFINE THE STRATEGY, PROVIDE GUIDANCE, MONITOR OUTCOMES

PENTA FOUNDATION STAFF

THEY PLAY A CENTRAL ROLE IN COORDINATING AND IMPLEMENTING RESEARCH AND LIAISING WITH STAKEHOLDERS

COMMUNITY GROUPS, PATIENT ASSOCIATIONS

BY SHARING THEIR LIVED EXPERIENCE, THEY OFFER CRITICAL INSIGHTS INTO THE NEEDS AND CHALLENGES FACING THE PATIENT POPULATION TARGETED BY OUR RESEARCH



Our key partners

Driven by an unwavering commitment to improving health in pregnancy and paediatrics, Penta promotes innovation through collaborative research and capacity building to accelerate positive impact. We achieve this by forging strategic partnerships with leading organisations worldwide, leveraging the expertise of international collaborators to drive impactful research agendas.

Our clinical research hinges on long-standing collaborations with renowned clinical trial centres: MRC CTU at UCL, UK, Institut National de la Santé et de la Recherche Médicale (INSERM), France and Program for HIV Prevention and Treatment (PHPT), Thailand.

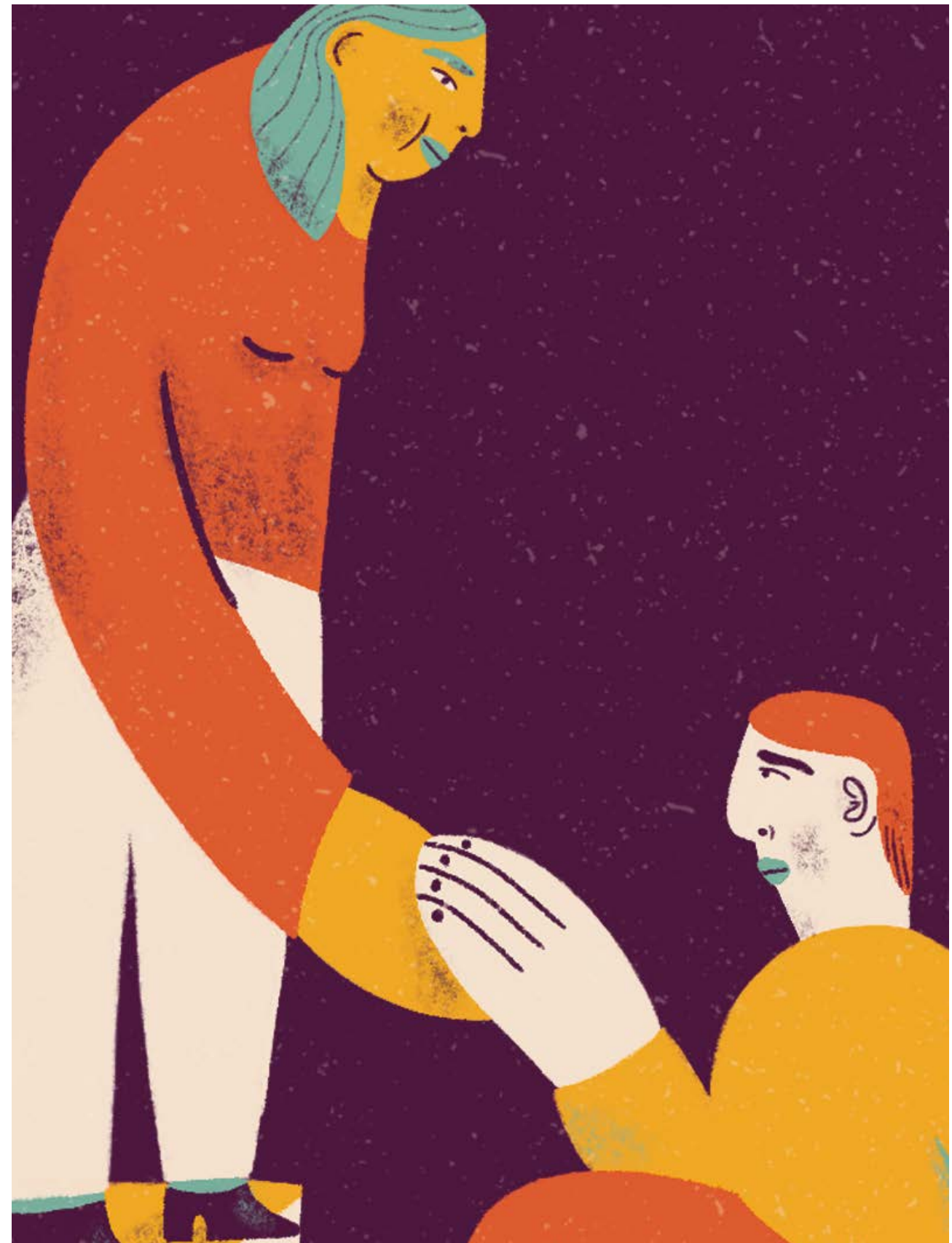
Our dedication to children's health extends beyond clinical trials. We actively participate in larger initiatives and programmes such as:

- **Global Accelerator of Paediatric Formulation – GAP-f**, a WHO Network hosted within the Research for Health Department in the Science Division, aimed at addressing the paediatric treatment gap. Within this partnership, we lead the Clinical Research working group, facilitating

all the clinical research activities in the GAP-f portfolio.

- **Global Antibiotic Research & Development Partnership (GARDP)**, which focuses on tackling drug-resistant infections in children by accelerating antibiotic development.
- **ORCHESTRA, VERDI, CoMeCT**, aimed at preparing the EU to face future pandemics.
- **c4c**, building a pan-European network for conducting trials in paediatrics.

In Italy, collaborations with **Ospedale Pediatrico Bambino Gesù (OPBG)** in Rome, the **University of Padova** and the **University of Verona** ensure our research translates into practical solutions and accessible medicines.



In Africa, we have formalised collaborations with the **Joint Clinical Research Centre (JCRC)** and **Makerere University** – John Hopkins University Research Collaboration (MUJHU), to ensure the delivery of the best care to Ugandan children.

We also collaborate with Doctors with Africa **CUAMM**, a Non-Governmental Organisation based in Italy, to develop programmes to protect vulnerable communities in Sub-Saharan Africa.

We are proud members of the:

- European Network of Paediatric Research at the European Medical Agency (**Enpr-EMA**).
- WHO's Paediatric Antiretroviral Working Group (**PAWG**) and Paediatric Antiretroviral Drug Optimization (**PADO**).

We leverage platforms to broaden our research impact such as:

- EPPICC (European Pregnancy and Paediatric Infections Cohort Collaboration), which comprises 5 pregnancy cohorts in 4 countries and 15 paediatric cohorts in 13 countries in Europe and Thailand. By sharing scientific expertise and resources, the EPPICC cohorts collect safety data on antiretrovirals after their market rollout.
- EPIICAL, an international collaboration aimed at increasing

immunological and virological knowledge to implement immunotherapies for long-term viral remission in children.

- Vac4EU (Vaccine monitoring Collaboration for Europe), a community for scientific debate and study implementation around COVID-19 vaccines, where we advocate for the needs of children.

We signed a collaboration agreement with **IAVI** to expedite treatment development for critical childhood diseases, with a focus on identifying and developing innovative monoclonal antibodies to treat and prevent HIV in children.

We are also a member of **BBMRI** (European research infrastructure for biobanking and biomolecular resources in health and life sciences) and **EPTRI** (European pediatric translational research infrastructure) to enhance research funding opportunities and develop paediatric medicines.

Additionally, we signed a Memorandum of Understanding (MoU) with **LAB-Net** to foster collaboration and optimise the utilisation of clinical research outputs.

Furthermore, we signed the **2022 Rome Action Plan** to intensify our commitment to scaling up prevention, diagnosis, and treatment of paediatric HIV and TB.

STORIES FROM PENTA

Nina Ferencic

MA, PhD, formerly Senior Adviser on HIV and Young People's Health and Development, UNICEF Regional Office for Europe and Central Asia

Dr Ruslan Malyuta

Paediatric AIDS Specialist, UNICEF Headquarters

A decade of impact: Penta and UNICEF's partnership for children's health in Eastern Europe and Central Asia

For a decade, UNICEF and Penta have been collaborating to strengthen national healthcare systems in Eastern Europe and Central Asia.

Through joint training programmes, Penta and UNICEF have strengthened the capacity of hundreds of healthcare providers, leading to significant improvements in prevention, treatment, and support for children and adolescents living with HIV and co-infections such as tuberculosis. These programs have been highly valued not only for delivering state-of-the-art knowledge but also for challenging stereotypes, reducing stigma, and addressing human rights violations

associated with HIV infection. The collaboration has also been instrumental for rolling-out World Health Organization clinical guidelines.

The UNICEF-Penta collaboration has created valuable networking opportunities among health professionals in the region. This has been appreciated by the children and their parents, who have experienced enhanced quality of care and support.

Heartfelt thanks to Penta for our ongoing partnership and for our shared commitment to the well-being of children now and in the years to come.



3. ACTIVITIES

Not just clinical trials,
but **cohort** and **pregnancy**
studies, educational and
training programmes
and **big data**

Advancing research on pregnancy and child health in 2024



Chiara Messina
Penta Foundation
Head of Program
Operations

Building upon its established legacy, Penta's collaborative and innovative research unfolds through partnerships with academia, industry, and the wider community to address the persistent challenges posed by infectious diseases in pregnant people, infants, children, and adolescents.

A key highlight of 2024 was Penta's commitment to build a coordinated preparedness action in response to future pandemics. This resulted in key initiatives participation such as CoMeCT and BE READY NOW, aiming at improving coordination across Europe for clinical research in infectious diseases. Penta's commitment is to ensure the prioritisation of underserved populations, such as pregnant individuals and children, within this initiative. As coordinator, Penta spearheaded the PIPELINE project, set to launch in 2025. This initiative will establish a pan-European network of pregnancy and infancy

sites, enabling prompt responses to emerging new infection threats through site preparation for clinical studies and a master protocol adaptable for these populations.

Penta's efforts in Africa have also been noteworthy in 2024, particularly with the successful conclusion of the PediCAP trial for the improvement of outcomes for children hospitalised with pneumonia, which provided evidence for reducing the burden on patients, families and healthcare systems. This achievement marks another significant milestone in Penta's commitment to reducing antimicrobial resistance in children.

In the area of HIV, 2024 marked also the conclusion of the innovative EPIICAL project, an eight-year initiative that provided invaluable insights into virological and immunological dynamics, particularly in relation to early antiretroviral treatment response and discontinuation. The

groundwork by EPIICAL has paved the way for the new ENABLE project, which expands research into innovative HIV treatments for children living with HIV. This transition ensures continuity in Penta's commitment to addressing the challenges faced by HIV-affected families.

In 2024 significant efforts were also devoted to the registration of new paediatric formulations. Penta prepared and coordinated the submission to the US Food and Drug Administration (FDA) of the modelling and simulation data to support the dossier for the approval of a child-friendly, fixed-dose combination of Darunavir/Ritonavir for the treatment of HIV in children, along with Clinton Health Access Initiative (CHAI). This effort reflects our commitment to ensure that medications are tailored with the correct dosage and formulation specifically for children, adopting state of the art methodology to advance paediatric HIV treatment options.

In support of all the above and the work to come, the Penta Research Environment (PRE) continued to be an essential resource, facilitating data sharing across various research initiatives and allowing researchers to analyse data seamlessly, fostering collaboration and accelerating evidence generation.

Penta's activities in 2024 reflected our dedication to innovative research, collaborative efforts, and meaningful partnerships. As the organisation continues to evolve, we reinforce our contribution to advancements in pregnancy and child health.

Current research portfolio

Developing impactful research on prevention, diagnosis and treatment of infections in children and in pregnancy, infancy, childhood and adolescence.

HIV AND VIRAL INFECTIONS
SERIOUS BACTERIAL INFECTIONS AND
ANTIMICROBIAL RESISTANCE
NETWORK BUILDING
NEGLECTED AND EMERGING
CHILDHOOD INFECTIONS

HIV AND VIRAL INFECTIONS

We generate evidence to optimise HIV treatment, prevention, and cure strategies, improving outcomes for children exposed to the virus, towards the 2030 elimination goal.

ODYSSEY

A randomised trial of dolutegravir (DTG)-based antiretroviral therapy (ART) vs standard of care (SOC) in children with HIV infection starting first-line or switching to second-line ART

Overall objectives

To assess the efficacy and toxicity of dolutegravir plus 2 NRTI (Nucleoside Reverse Transcriptase Inhibitors) versus standard of care among HIV positive children and adolescents

from 2014 until 2025

Grant amount € 15,764,263

Funder ViiV Healthcare

Penta's Role SPONSOR

DOLOMITE

Dolutegravir in pregnant people and exposed infants in Europe

Overall objectives

To assess the safety, effectiveness and "real-world" outcomes of DTG use in pregnant people living with HIV and their babies

from 2017 until 2025

Grant amount € 3,139,242

Funder ViiV Healthcare

Penta's Role COORDINATOR

D3

A randomised non-inferiority trial with nested pharmacokinetics (PK) to assess DTG/3TC fixed dose formulations for the maintenance of virological suppression in children with HIV infection aged 2 to <15 years old

Overall objectives

To assess whether DTG/3TC is non-inferior to Standard of Care, consisting of an anchor drug (NNRTI, PI or INSTI) and 2 NRTIs, in terms of virological suppression

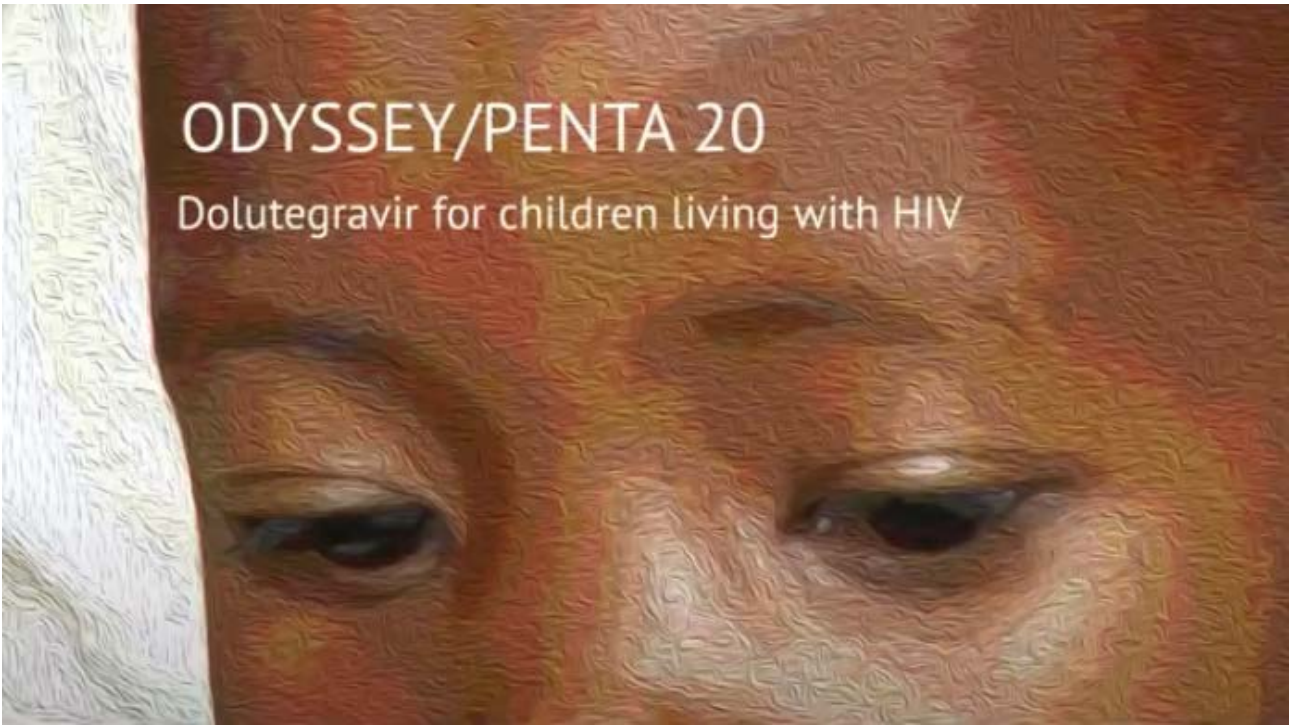
from 2020 until 2026

Grant amount € 15,930,645

Funder ViiV Healthcare

Penta's Role SPONSOR

on the right page:
Still from the
ODYSSEY study film



EMPIRICAL

Empirical treatment against cytomegalovirus and tuberculosis in severe pneumonia in HIV-infected infants: a randomised controlled clinical trial

Overall objectives

To develop a clinical trial to evaluate whether empirical treatment against cytomegalovirus and tuberculosis improves survival of infants with severe pneumonia and living with HIV

from 2019 until 2025

Penta budget € 571,420

Grant amount € 7,680,619

Funder European Commission – EDCTP2

Penta's Role PARTNER

EPIICAL

Early treated Perinatally HIV Infected individuals: Improving Children's Actual Life

Overall objectives

To implement novel strategies to obtain long-term viral remission in children early treated for HIV

from 2020 until 2024

Grant amount € 8,502,850

Funder ViiV Healthcare

Penta's Role COORDINATOR and SPONSOR

EPPICC

CABOTEGRAVIR STUDY

Pregnancy and Neonatal Outcomes following Prenatal Exposure to Cabotegravir Long Acting (CAB LA): data from EPPICC

Overall objectives

To evaluate the use of CAB in pregnant people, describe the maternal characteristics, estimate the frequency of adverse pregnancy-neonatal outcomes and the perinatal transmission rates; assess proportion of viral suppression achievement

from **2021** until **2027**

Grant amount **€ 1,030,575**

Funder **ViiV Healthcare**

Penta’s Role **COORDINATOR**

DOLUTEGRAVIR STUDY

Clinical outcomes of children and adolescents with HIV taking DTG in Europe and Thailand: an EPPICC study

Overall objectives

To investigate the uptake, effectiveness, and safety of DTG in infants, children and adolescents in "real world" clinical settings across Europe and Thailand. Results will help assess the impact of the increased use of DGT-based regimens to inform future policy and practice

from **2022** until **2025**

Grant amount **€ 2,005,380**

Funder **ViiV Healthcare**

Penta’s Role **COORDINATOR**

TENOFOVIR ALAFENAMIDE FUMARATE (TAF) STUDY

Effectiveness and safety of TAF based therapy in children and adolescents living with HIV in Eastern and Western Europe: an EPPICC study

Overall objectives

To assess whether use of TAF-containing regimens to treat children and adolescents living with HIV is associated with lower renal and bone adverse events and similar immunological and virological outcomes compared to Tenofovir disoproxil, and increased gain in Body Mass Index

from **2022** until **2024**

Grant amount **€ 802,705**

Funder **Gilead Sciences, Inc.**

Penta’s Role **SPONSOR**

RENAL IMPAIRMENT STUDY

Renal impairment among children and adolescents living with HIV: an Epidemiology of Pregnancy and Paediatric Infections International Cohort Collaboration study (EPPICC Renal)

Overall objectives

This study will assess the occurrence of renal impairment and associated risk factors in children and adolescents living with HIV followed-up in routine HIV care in EPPICC

from **2024** until **2027**

Grant amount **£ 1,103,200**

Funder **GlaxoSmithKline Research & Development Limited**

Penta’s Role **COORDINATOR**

DOLOMITE EPPICC STUDY

Pregnancy and Neonatal Outcomes following Prenatal Exposure to Dolutegravir in Europe

Overall objectives

Characterise the population of pregnant people taking DTG-based regimens by trimester of exposure, describe frequency of adverse pregnancy and neonatal events, the proportion of pregnant people on DTG with undetectable viral load and the vertical transmission rates

from **2024** until **2029**

Grant amount **£ 846,995**

Funder **ViiV Healthcare**

Penta’s Role **COORDINATOR**

HVRRICANE

Phase I, Proof of Concept, Open-Label, Randomised Clinical Trial to Evaluate the Safety and Effects of Using Prime-boost HIVIS DNA and MVA-CMDR Vaccine Regimens with or without Toll-like Receptor 4 Agonist on HIV Reservoirs in Perinatally HIV Infected Children and Youth

Overall objectives

To explore whether HIVIS DNA and MVA-CMDR vaccination will lead to a reduction in HIV reservoir markers as a result of vaccine-induced immune responses

from **2018** until **2026**

Grant amount **\$ 543,506**

Funder **Henry M. Jackson - Foundation and Penta**

Penta’s Role **PARTNER**

LATA

Long-Acting Treatment in Adolescents

Overall objectives

To find out whether taking long-acting injectable medicines every 8 weeks is as effective and safe as taking tablet HIV medicines every day, and if it improves the quality of life of adolescents living with HIV

from **2023** until **2026**

Penta budget **£ 83,111**

Funder **Janssen**

Penta’s Role **PARTNER**

SHIELD

A multicentre, open-label, single-arm trial to evaluate the safety, pharmacokinetics and antiviral activity of fostemsavir in combination with optimised background therapy (OBT) in HIV-1 infected children and adolescents who are failing their current combination ART and have dual- or triple-class antiretroviral (ARV) resistance

Overall objectives

To evaluate the safety of 24 weeks of treatment with fostemsavir + OBT in at least 60 HIV-1 infected children and adolescents aged 6 to < 18 years and weighing at least 20kg who are failing their current antiretroviral treatment and have dual-or-triple-class resistance

from 2020 until 2027

Grant amount € 12,622,959

Funder ViiV Healthcare

Penta's Role SPONSOR

UNIVERSAL

Pharmacokinetic and safety studies of new antiretroviral formulations: expediting UNIVERSAL first and second line regimens for all children living with HIV in Africa

Overall objectives

To develop two complementary paediatric antiretroviral fixed dose combinations for infants and children newly diagnosed with HIV initiating ART, and children on first line therapy that is failing and need to switch to a new treatment regimen, as well as monitoring long-term safety. This work will fully address the main treatment gaps for CLWHIV in Africa

from 2021 until 2025

Penta budget € 1,619,218

Grant amount € 3,999,819

Funder European Commission – EDCTP2

Penta's Role COORDINATOR

UP-ART

Ugandan Paediatric Anti-Retroviral Treatment study on long term outcomes on dolutegravir in children and adolescents living with HIV in Uganda

Overall objectives

To assess the uptake and long-term effectiveness of DTG in children and adolescents in real-world clinical settings in Uganda, using data from the UP ART cohort

from 2024 until 2027

Grant amount £ 1,051,200

Funder GlaxoSmithKline Research & Development Limited and ViiV Healthcare

Penta's Role COORDINATOR

THRIVE

Transforming Advanced HIV Disease CaRe in LMICs through Comprehensive and Equitable Access: Empower Locally, Catalyze Impact Globally

Overall objectives

Reduce mortality among adults and children living with HIV by enabling access to critical prevention, screening, and treatment commodities, and centering local leadership and community-owned solutions to find and serve people living with advanced HIV disease where they are

from 2024 until 2026

Penta budget \$855.942

Grant amount \$ 3,037,588

Funder UNITAID

Penta's Role PARTNER

STORIES FROM PENTA



Alessandra Nardone
Penta Foundation
Senior Clinical Project Manager

My journey with
UNIVERSAL: a step
closer to revolutionising
paediatric HIV treatment

When I was assigned as a Clinical Project Manager in the UNIVERSAL project in 2021, I knew we were working on something important, even though I could not have envisioned such an impact at that time. The objective was clear: to develop two child-friendly, fixed-dose combinations (FDC) for HIV treatment, one of which was Darunavir/Ritonavir (DRV/r). This was a priority identified by the WHO's Global Accelerator for Paediatric Formulation (GAP-f) in 2019, through a panel of HIV experts (PADO).

In February 2024, a crucial moment arrived: we submitted the UNIVERSAL DRV/r pharmacokinetic modelling and simulation analysis to the US FDA. This submission represented a significant step, providing data to support the FDA's decision on the new DRV/r FDC registration.

For me, this was more than a professional milestone. It was a privilege. As a Penta

employee, I coordinated the collaborative work between our network experts from PHPT, Assistance publique - Hôpitaux de Paris (AP-HP), and CHAI, and presented the application to the FDA. It was the first time for Penta to lead on an FDA submission.

In March 2025, the FDA approved our modelling. This approval was a landmark step towards making the new DRV/r FDC available. This fixed-dose combination could revolutionise the approach to paediatric HIV treatment offering smoother dosing regimens, potential improvement in adherence and minimised number of pills children with HIV need to take.

My participation in the UNIVERSAL project gave me the true sense of collaborative efforts for advancing paediatric HIV treatments. It reinforces Penta's commitment to developing better treatments for children globally.

YOUNG REPORTERS

Overall objectives

To increase access to the latest HIV research and policy among children and young people living with HIV and monitor the influence and impact this information has on them. The project will create a team of empowered and highly skilled young influencers who can translate science into effective social media content and better inform their peers about HIV care

from 2022 until 2024

Grant amount € 214,418

Funder ViiV Healthcare & Gilead

Penta’s Role COORDINATOR

BREATHHER Plus

A randomised open-label 3-arm, 96-week trial evaluating the efficacy, safety and acceptability of weekends off dolutegravir-based ART and monthly long-acting injectable ART compared to daily dolutegravir-based ART in virologically suppressed children and adolescents living with HIV in sub-Saharan Africa

Overall objectives

To compare short cycle therapy (five days on, two days off) dolutegravir-based antiretroviral therapy to daily dolutegravir-based ART in virologically suppressed adolescents living with HIV in sub-Saharan Africa

from 2019 until 2025

Penta budget € 88,187

Grant amount € 7,401,327

Funder European Commission – EDCTP2

Penta’s Role PARTNER

SERIOUS BACTERIAL INFECTIONS AND ANTIMICROBIAL RESISTANCE

With a focus on the vulnerable, we are actively improving the treatment and prevention of serious bacterial infections in infants and children, addressing the critical challenges of neonatal sepsis and antimicrobial resistance.

NeoIPC

Establishing innovative approaches for optimal infection prevention of resistant bacteria in NICUs by integrating research, implementation science and surveillance in a sustainable global platform

Overall objectives

To evaluate and implement IPC activities in neonatal intensive care by applying innovative methodology for IPC intervention trials from design to analysis, embedding both trial conduct and non-trial IPC activities within an implementation framework and fostering IPC engagement in neonatal intensive care

from 2021 until 2026

Penta budget € 3,185,688

Grant amount € 9,999,817

Funder European Commission – Horizon 2020

Penta’s Role PARTNER and SPONSOR

PediCAP

Impact of duration of antibiotic therapy and of oral step-down to amoxicillin or co-amoxiclav on effectiveness, safety and selection of antimicrobial resistance in severe and very severe childhood community-acquired pneumonia (CAP): a randomised controlled trial

Overall objectives

To optimise antibiotic treatment for children aged 3 months to 10 years hospitalised with severe/very severe community-acquired pneumonia in South Africa, Uganda, Mozambique, Zambia and Zimbabwe

from 2019 until 2025

Penta budget € 1,021,862

Grant amount € 6,997,077

Funder European Commission – EDCTP 2

Penta’s Role COORDINATOR and SPONSOR

next pages:
Parents in a NICU taking part in a NeoIPC project training video
PediCAP Consortium meeting in Johannesburg (South Africa), February 2024
SNIP-AFRICA project kick-off meeting in Johannesburg (South Africa) in January, 2024



NeoIPC: leading the fight against hospital-acquired infections in newborns

Hospital-acquired infections are a major threat to newborns in neonatal intensive care units (NICUs), especially those who are born preterm, due to their weak immune systems. Effective infection prevention and control (IPC) measures are crucial for reducing infection rates and improving survival and long-term health outcomes.

Penta is at the forefront of neonatal IPC through the NeoIPC project, a European initiative driving innovation in neonatal IPC and tackling AMR. A key component of the project is the NeoIPC surveillance toolkit, a powerful resource that helps NICUs track hospital-acquired infections in high-risk newborns more effectively. By simplifying and standardising data collection, it allows hospitals to monitor infection rates, compare their performance with other NICUs and implement targeted IPC interventions.

NeoIPC offers a comprehensive suite of free resources for surveillance in neonatology, including protocols, data collection sheets, training, video tutorials and reference materials. These tools empower healthcare teams to take a proactive approach to infection prevention and control, ensuring that NICUs can adopt best practices to improve their patients' health outcomes. Designed for flexibility and scalability, the NeoIPC surveillance toolkit is already being introduced in diverse healthcare settings, from Europe to sub-Saharan Africa and South America.

By building a global network of NICUs, NeoIPC is making significant strides in neonatal care and forging a united front against AMR.



PediCAP study: transforming childhood pneumonia treatment in Africa

Pneumonia remains a leading cause of childhood illness and mortality, particularly in resource-limited settings across Africa. The PediCAP study, a multi-national collaboration, has delivered groundbreaking results that promise to transform how we approach this life-threatening condition.

The PediCAP-A trial, conducted across five African countries, enrolled over 1100 children with severe pneumonia. The study challenged the standard treatment approach, which typically involves a five-day course of injectable antibiotics requiring prolonged hospital stays. PediCAP's innovative research explored the effectiveness of transitioning children from injectable antibiotics to oral antibiotics (amoxicillin or amoxicillin-clavulanate) once they showed clinical improvement.

The results are highly promising: PediCAP demonstrated that this switch to oral antibiotics is equally effective and offers significant advantages. Children were able

to leave the hospital sooner, with an average reduction of one day in their hospital stay. Furthermore, the study established that a total of four days of antibiotic treatment, combining the initial injectable phase and the subsequent oral phase, is generally sufficient for recovery. This shorter treatment duration is safe, effective, and represents a more child-centered approach.

The impact of PediCAP's findings is substantial. Earlier hospital discharge alleviates the strain on families and healthcare systems, reduces costs, and minimises the risk of hospital-acquired infections. The use of readily available oral antibiotics like amoxicillin further enhances accessibility and affordability. By optimising pneumonia treatment, PediCAP is contributing significantly to improved child health outcomes and a more efficient use of healthcare resources in Africa. This research paves the way for updated treatment guidelines and better care for children with pneumonia.



SNIP-AFRICA: pioneering innovative solutions to combat antimicrobial resistance in children

AMR is a silent pandemic, disproportionately affecting children in resource-limited settings. In 2019, AMR claimed 1.27 million lives globally, with a staggering one in five deaths occurring among children under five. This crisis is compounded by the fact that newborns, a highly vulnerable population, are often excluded from clinical trials, resulting in a critical lack of data on effective treatments. Furthermore, antibiotics recommended by the World Health Organization are increasingly ineffective against drug-resistant bacteria.

Recognizing this urgent challenge, Penta, through the SNIP-AFRICA project, is leading the charge in pioneering innovative research to address life-threatening infections like neonatal sepsis in Africa.

SNIP-AFRICA aims to revolutionise the management of these infections by establishing a clinical research platform to support adaptive trials in Africa. Current methods for determining the most effective antibiotic regimens are inefficient, leaving children vulnerable to suboptimal treatments.

SNIP-Africa is breaking new ground, utilising surveillance activities, pharmacokinetic studies, and a cutting-edge trial design that allow for the simultaneous comparison of multiple treatment options, expediting access to better treatments for children.

This innovative approach is crucial for resource-limited countries, where AMR has the most devastating impact. By including patients from these regions in our studies, we ensure that new and existing antibiotics are evaluated in the populations that need them most. The expected impact is profound: providing evidence-based rankings of effective antibiotic regimens for neonatal sepsis, leading to improved treatment guidelines and, ultimately, a significant reduction in neonatal mortality and better long-term outcomes for sepsis survivors.

SNIP-AFRICA, in collaboration with other successful Penta projects on AMR like PediCAP, is not just conducting research; it is building a foundation for sustainable improvements in child health across Africa.

SNIP-AFRICA

Severe Neonatal Infection Adaptive Platform Trials in Africa

Overall objectives
To constitute a sustainable platform with an appropriate governance structure spanning the global South and North for implementation of adaptive trials for severe childhood infections, with focus on neonatal sepsis

from 2023 until 2028
Penta budget € 1,414,901
Grant amount € 7,168,901
Funder European Commission – EDCTP3
Penta’s Role COORDINATOR

Team-COACH

Training and education in antimicrobial stewardship (AMS) and infection prevention and control (IPC) in children

Overall objectives
To create a Network of centres across different South European countries – Spain, Italy, and Greece – receiving training via an innovative platform for capacity building and improving practices in Infection Prevention Control (IPC) and antimicrobial stewardship (AMS) in the paediatric inpatient and outpatient settings, including secondary and primary healthcare services

from 2023 until 2025
Penta budget € 261,829
Grant amount € 1,966,833
Funder European Union
Penta’s Role PARTNER

VALUE-Dx

The value of diagnostics to combat antimicrobial resistance by optimizing antibiotic use

Overall objectives
To facilitate and accelerate the rigorous assessment and implementation of new diagnostic technologies into healthcare settings, by establishing the infrastructure, methods, processes and approaches needed to understand, evaluate, assess, and demonstrate the multi-faceted value of diagnostics, and overcome the associated barriers to their widespread adoption and use

from 2019 until 2024
Penta budget € 1,088,420
Grant amount € 14,125,708
Funder European Commission – Innovative Medicines Initiative - IMI2
Penta’s Role PARTNER AND SPONSOR OF THE ADEQUATE STUDY

DESIGN OH AMR

DESIGNing the European Partnership on One Health AMR

Overall objectives
To define priorities for the upcoming Horizon Europe calls on AMR, with Penta actively advocating for a strong focus on paediatric research within this critical area

from 2021 until 2025
Grant amount € 1,051,000
Funder Joint Programming Initiative on Antimicrobial Resistance, Stockholm, SE, JPIAMR
Penta’s Role PARTNER

NETWORK BUILDING

We are committed to nurturing a more effective clinical research landscape, facilitating the development and availability of appropriate drugs and dosages for pregnant individuals, infants, children, and adolescents.

c4c - conect4children

COLlaborative Network for European Clinical Trials For Children

Overall objectives

To develop a large, collaborative paediatric network that will facilitate the development of new drugs and other therapies for the entire paediatric population in Europe

from **2018** until **2024**

Penta budget **€ 10,925,212**

Grant amount **€ 154,387,606**

Funder **European Commission – Innovative Medicines Initiative – IMI2 JU**

Role **COORDINATOR**

ECRAID-Base

European Clinical Research Alliance on Infectious Diseases

Overall objectives

To establish a coordinated and permanent European infrastructure for clinical research on infectious diseases

from **2019** until **2025**

Penta budget **€ 250,000**

Grant amount **€ 29,969,875**

Funder **European Commission – Horizon 2020**

Penta's Role **PARTNER**

CoMeCT

COordination MEchanism for Cohorts and Trials

Overall objectives

Enhance Europe's clinical research preparedness and response capacity to infectious disease outbreak with pandemic potential through sustained strategic and scientific coordination of adaptive platform trials and cohort studies

from **2023** until **2026**

Penta budget **€ 206,000**

Grant amount **€ 3,000,000**

Funder **European Commission – Horizon Europe**

Penta's Role **PARTNER**

GAP-f

Global Accelerator for Paediatric Formulations

Overall objectives

To enhance the coordination and accelerate the prioritisation, investigation, development, introduction, and safe rollout of high-quality medicines in optimal formulations for children

from **2022** until **2024**

Grant amount **\$ 47,355**

Funder **WHO**

Penta's Role **PARTNER**

NEGLECTED AND EMERGING CHILDHOOD INFECTIONS

Through collaborative efforts, we are advancing COVID-19 treatment and care, while simultaneously building crucial research preparedness to safeguard pregnancy and child health against future emerging infections.

VERDI

SARS-CoV-2 variants Evaluation in pRegnancy and paeDIiatrics cohorts

Overall objectives

To improve understanding of the epidemiology, prevention and treatment of SARS-CoV-2 variants of concern and mpox among children and pregnant people, and to prioritise children, pregnant people and high-risk individuals in pandemic preparedness for future infectious disease outbreaks. The evidence generated by VERDI will allow rapid delivery of recommendations on the best strategies to control viral spread in paediatric populations, as well as on optimised clinical management and treatment of COVID-19 and mpox in children and pregnant people

from **2021** until **2025**

Penta budget **€ 1,504,727**

Grant amount **€ 15,395,599**

Funder **European Commission – Horizon Europe**

Penta's Role **PARTNER AND SPONSOR OF THE Mpox PAEDIATRIC AND ADOLESCENT CLINICAL STUDY**

ORCHESTRA

Connecting European Cohorts to Increase Common and Effective Response to SARS-CoV-2 Pandemic

Overall objectives

To create a new pan-European cohort built on existing and new large-scale population cohorts in European and non-European countries, to advance knowledge on the control of COVID-19 infection. The data sharing infrastructure will allow data to be made available throughout Europe and beyond, shaping the continuously evolving public health and vaccination strategies

from **2020** until **2024**

Penta budget **€ 1,100,000**

Grant amount **€ 29,799,685**

Funder **European Commission – Horizon 2020**

Penta's Role **PARTNER**

VERDI: Synergising expertise – Penta and ISARIC advance equitable pandemic preparedness

In 2024, Penta strategically partnered with ISARIC, the International Severe Acute Respiratory and emerging Infection Consortium, to address critical data collection gaps during infectious disease outbreaks. This collaboration expands ISARIC's currently available tools on mpox in adults to capture essential data in underrepresented populations: children, adolescents and pregnant people.

By combining ISARIC's infrastructure with Penta and the VERDI project's expertise, including experts from Africa, the partnership aims to develop **globally accessible case report forms** for mpox in pregnancy and childhood. This will provide researchers and clinicians worldwide with **standardised, high-quality case report forms**, ensuring equitable, data-driven pandemic responses.

The adaptability of these case report forms enables their application to various infectious diseases, fostering **a robust global health framework**. This alliance highlights the importance of collaborative efforts in developing effective and inclusive pandemic preparedness strategies.

PFIZER-BIONTECH PASS C4591021

Post Conditional Approval Active Surveillance Study Among Individuals in Europe Receiving the Pfizer BioNTech Coronavirus Disease 2019 (COVID-19) Vaccine

Overall objectives

To determine whether an increased risk of prespecified AESI exists following the administration of at least one dose the Pfizer-BioNTech COVID-19 vaccine

from **2021** until **2024**

Penta budget **€ 940,500**

Grant amount **€ 7,594,618**

Funder **Pfizer Inc**

Penta's Role **COORDINATING CENTRE**

PFIZER-BIONTECH PASS C4591038

Post-Authorisation Active Surveillance Study of Myocarditis and Pericarditis Among Individuals in Europe Receiving the Pfizer-BioNTech Coronavirus Disease 2019 (COVID-19) Vaccine

Overall objectives

To describe the clinical course (treatment, survival, hospitalisations, long-term cardiac outcomes) of myocarditis and pericarditis among individuals diagnosed with myocarditis and/or pericarditis after receiving at least 1 dose of the Pfizer-BioNTech COVID-19 vaccine and among individuals diagnosed with myocarditis and/or pericarditis who had no prior COVID-19 vaccination, using a cohort study design

from **2022** until **2024**

Penta budget **€ 142,369**

Grant amount **€ 1,939,547**

Funder **Pfizer Inc**

Penta's Role **COORDINATING CENTRE**

PFIZER-BIONTECH PASS C4591052

Post-Authorisation Safety Study of Comirnaty Original/Omicron BA.1 and Comirnaty Original/Omicron BA.4-5 in Europe

Overall objectives

To determine whether there is an increased risk of pre-specified adverse events of special interest following the administration of Comirnaty Original/Omicron BA.1 or Comirnaty Original/Omicron BA.4-5 compared with not receiving any COVID-19 bivalent vaccine

from **2022** until **2025**

Penta budget **€ 6,110**

Grant amount **€ 41,945**

Funder **Pfizer Inc**

Penta's Role **COORDINATING CENTRE**

PREGINPOXVAC - EDCTP

Maternal And Infant Safety And Immunogenicity In A Phase 3, Open-Label, Randomised, Vaccine Trial Of A Two-Dose Mpox Vaccine

Overall objectives

Assess the safety and immunogenicity of the MVA-BN vaccine in pregnant women

from **2024** until **2027**

Penta budget **€ 190,000**

Grant amount **€ 1,599,327**

Funder **European Commission – EDCTP3**

Penta's Role **PARTNER**

PREGINPOXVAC - CEPI

Maternal And Infant Safety And Immunogenicity In A Phase 3, Open-Label, Randomised, Vaccine Trial Of A Two-Dose Mpox Vaccine

Overall objectives

Assess the safety and immunogenicity of the MVA-BN vaccine in newborns and infants

from **2024** until **2028**

Penta budget **\$ 408,611**

Grant amount **\$ 7,000,000**

Funder **CEPI**

Penta's Role **PARTNER**

PROMISE

Preparing for RSV Immunization and Surveillance in Europe

Overall objectives

To conduct systematic reviews to consolidate all available published and unpublished data at global level to address current gaps in RSV epidemiology and to synthesise evidence to inform development of novel severity score for RSV infection in young children

from **2021** until **2024**

Penta budget **€ 53,750**

Grant amount **€ 7,024,387**

Funder **European Commission – Innovative Medicines Initiative - IMI2**

Penta's Role **PARTNER**

RBDCOV

RBD Dimer recombinant protein vaccine against SARS-CoV-2

Overall objectives

To test the efficacy, tolerability, and safety of two new vaccines against different variants of COVID-19 based on the outstanding data generated using a recombinant protein (Receptor Binding Domain (RBD) adjuvanted with very well-established adjuvant, MF59 by the consortium

from 2021 until 2025

Penta budget € 250,000

Grant amount € 9,779,211

Funder European Commission - Horizon Europe

Penta's Role PARTNER

Science4Pandemics

Science4Pandemics

Overall objectives

To develop a digital platform to educate the public on the prevention and management of pandemics. Targeting the adolescent population in particular, the project will use gamification and artificial intelligence to enhance the public's understanding of this field

from 2022 until 2024

Penta budget € 83,396

Grant amount € 1,238,904

Funder EIT Health

Penta's Role PARTNER

VACCELERATE

European Corona Vaccine Trial Accelerator Platform

Overall objectives

Pan-European backbone for the acceleration of phase 2 & 3 COVID-19 vaccine trials. The overall objective is to connect all European stakeholders involved in vaccine development to provide a pan-European platform for clinical trial design and conduct

from 2021 until 2024

Penta budget € 25,000

Grant amount € 11,999,997

Funder Horizon Europe

Penta's Role SUBCONTRACTOR



above:
Advert of the Science4Pandemics videogame

An ever-increasing number of research activities

2024



2023



2022

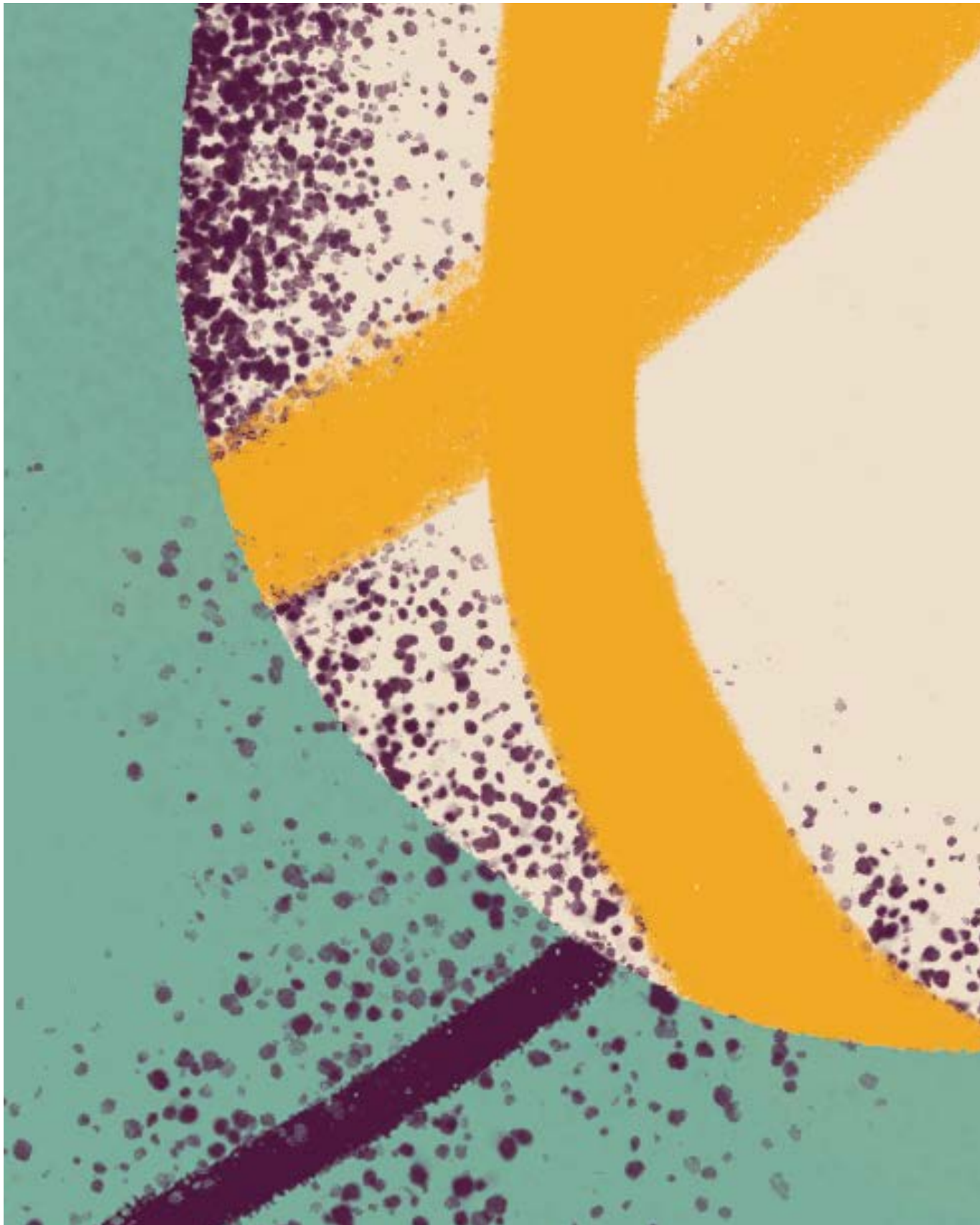


2021



2020





Youth engagement & participation

We actively integrate young people's perspectives into the planning, design, and implementation of our studies, acknowledging their unique understanding of their needs. In 2024, we expanded our efforts to include their voices significantly.



Patients – including children and adolescents – must be involved in research, not as passive beneficiaries, but as leaders and influential drivers. At Penta, we engage and communicate with the communities for whom we optimise treatment, believing they deserve a say in their health and the research around their treatments. Conversations with young people and their families provide essential insight into cultural acceptability and barriers to medications. This defines our approach to **ethical** and **meaningful** patients and community involvement.

Over recent years, we have developed models that position young people centrally in our research, thus ensuring their meaningful input. This is accomplished through consultation, collaboration, and co-production in areas such as:

1. Community educational materials
2. Training materials for the Penta ID Network
3. Policies and guidelines
4. Communication campaigns
5. Wider representation of young people across Penta's work.

In 2024, we reinforced our commitment to youth engagement and participation in ongoing projects, fully adopting a patient-centered approach to our research.

Penta's **Youth Trial Boards** (YTBs) have been running since 2017 as a platform to engage young people in clinical research. Through interactive, youth-friendly, activity-based training, YTBs bridge the gap between complex science and the young people directly affected. Within YTBs, young people take part in workshops, discussions, and creative activities to develop trial materials (logos, posters, patient information sheets, and recruitment videos). They also provide feedback on how research can be made more youth-friendly and accessible. This model has become a standard practice across Penta, implemented in countries like Uganda, Zimbabwe, and South Africa, and in HIV-focused clinical trials.

Building on the success of YTBs, Penta introduced **youth participation in our Trials' Steering Committees** (TSCs), providing insight into trial decision-making processes.

Penta's Young Reporters programme, empowering young health communicators, trains young people to translate scientific information into accessible content for their peers. Through hands-on training, they learn to simplify research findings for social media platforms, creating posts, articles, and digital content. In 2024, we launched a second edition, recruiting three new young reporters and retaining three young people from the previous edition as mentors.

"I am a YTB member from South Africa. First of all, I would like to thank Penta for the great opportunity they gave me to go to Cape Town to attend the conference, to be able to gain more information about research and to experience Cape Town... In the conference I learnt so many things: to be able to believe in myself, to take my treatment accordingly, to keep my body healthy and I think I will talk and share my experience and share my knowledge with others on what I have learnt in the conference."

"YTB has had a huge impact on the site. It has opened our eyes more and made us to be more open minded about young people's opinions and their ideas, because we have realised that young people do have a voice and when they are given the correct platform to express themselves, they can teach the health workers as well as others about what they need in their life and what they need in the management of their condition not only HIV but their living lifestyle in general."

YTB co-coordinator South Africa

Equipped with essential communication skills, they engaged in conferences (IAS 2024, the International Workshop on HIV Paediatrics 2024, International Workshop on Adolescence Sexual and Reproductive Health and Rights, and HIV 2024), collaborated with researchers, and shared accurate health information within their communities. Their work has reached many young people through social media, sparking conversations and increasing awareness of paediatric and adolescent infectious diseases.

In collaboration with WHO, the Global Network of young people living with HIV, IAS, Elizabeth Glaser Pediatric AIDS Foundation, Zvandiri, ViiV Healthcare and leading paediatric clinical trials (C4C, D3, ODYSSEY, Breather Plus and LATA), we developed **Quality Standards for the meaningful and ethical participation of children and young people in research**. A youth-friendly version was created in 2023.

Empowering young minds through research

Youth engagement and participation in Penta's research and training

YOUTH ENGAGEMENT SCHEMES IN OUR STUDIES



YOUTH TRIAL BOARDS & YOUTH REPRESENTATION AT TRIAL STEERING COMMITTEES

YOUNG REPORTERS

ADVISORY GROUPS

PENTATR@INING

YOUNG PERSONS INVOLVED IN OUR ACTIVITIES

30

YOUTH TRIAL BOARD MEMBERS FROM ZIMBABWE, UGANDA AND SOUTH AFRICA

4

YOUNG REPRESENTATIVES TO TRIAL STEERING COMMITTEES FROM UGANDA AND SOUTH AFRICA

6

YOUNG REPORTERS FROM UK, UGANDA, SOUTH AFRICA, BRAZIL, INDIA AND THAILAND

AGE VARIED BETWEEN

15 AND 21

GENDER



5

YOUNG PEOPLE SPEAKING AT PENTATR@INING COURSES

STORIES OF IMPACT

This article was written by the Penta Young Reporters

Penta's Young Reporters at the International Workshop on Pediatrics and HIV 2024

Arriving at the International Workshop on Pediatrics & HIV 2024, it was a wild mix of nerves and excitement. We were about to be surrounded by experts, who spend their careers understanding and fighting the virus we live with every day. As Young Reporters, we were determined to grab what we could understand and share it with other young people who needed this info.

Anna Yakutsk from UNAIDS made us feel that we were not alone, but part of a global community. As she spoke about progress in paediatric HIV, the importance of testing and treatment access, we thought, managing the meds is one thing, but the emotional and social challenges can feel overwhelming. A Day 2 session on youth-friendly HIV services showed us how much those services can actually help.

One session that really clicked was on why children's HIV meds sometimes stop working. Dr. Natella Rakhmanina broke it down so we actually understood what "treatment failure" means. It made us want to figure out how to

help young people talk to their doctors about this, and get the support they need.

We have much to celebrate as new treatments become available, but for some of us, these are not options and this disappointment can be heavy to hold. But Natella helped us understand this better and not feel ashamed about medicine resistance.

One of us was on the Youth Panel, sharing our stories – diagnosis, switching treatments, the whole journey. We all felt proud to see the panel share experiences that are faced by many of us living with HIV. The spirit of resilience and advocacy shone through the session.

We were nervous and did not understand all of the science details. But it was a good experience. It gave us hope, made us understand our challenges better, and a determination to advocate for ourselves and others living with HIV. And we're taking this knowledge back to our friends, because it's made a real difference.



PentaTr@ining

Delivering bespoke education and training programmes for frontline healthcare providers, ensuring high-quality patient care and clinical research.





Penta remains committed to providing expert training in paediatric infections as part of its goal to improve clinical care and health outcomes for children and families and to ensure robust high-quality clinical assessment as part of its trials. Since 2013, **young people living with HIV** have become increasingly involved in the design and delivery of our training programmes. Growing up with HIV or other paediatric infectious diseases carries with it specific challenges. Issues such as social stigma and mental health, status disclosure, drug adherence, and doctor-patient/family communication

continue to be crucial learning topics, which further underlines the importance of meaningful engagement with young people in all our training programmes.

We also continually seek to expand capacity building by ensuring that **new investigators are trained** and supported to carry out research and are able to design their own studies. The [WHO Toolkit](#) for research and development of paediatric antiretroviral drugs and formulations, developed in collaboration with Penta, was a major step towards this. Moreover, Penta provides [HIV Treatment guidelines](#)

“Overall, this is the best course I have ever attended! Very friendly, inspiring and approachable speakers – made so many new friends. I know so much more than when I started the course. I could write an essay about how wonderful this experience was. Thanks to all the Penta team!”

“Thank you very much for this learning experience – your enthusiasm is contagious!!”

PentaTr@ining Delegates

for clinicians and other healthcare professionals. Our current guidelines were released in November 2024 in conjunction with [European AIDS Clinical Society \(EACS\)](#), and act as a concise reference document to guide antiretroviral choices for children and adolescents with perinatally acquired HIV. The guidelines continue to undergo revisions by the writing committee, with the next major update scheduled for 2025.

Starting in 2005, **PentaTr@ining** is an in-depth training platform designed to provide specialist knowledge for healthcare workers caring for

children, adolescents, young people and pregnant individuals living with infectious diseases. Our pioneering training infrastructure has integrated innovative distance learning methods together with interactive face-to-face courses. Having carried out 87 programmes to date, Penta is able to tailor and deliver its high-quality training for a range of settings – with a particular focus on resource-limited regions around the globe.

HIV services remain in a phase of recovery following the COVID-19 pandemic, with the 2024 UNAIDS report [“The Urgency of Now: AIDS at](#)

above:
Delegates at the
PentaTr@ining
residential course
in Rome (Italy), 2023

a [Crossroads](#)” highlighting faltering of progress globally in combatting the HIV epidemic. Reduced access to HIV care raises specific problems for the care of pregnant people, for early diagnosis and treatment initiation in young children and for the management of patients with significant immune suppression. For this reason, it has remained crucial to ensure that training needs of healthcare workers caring for vulnerable populations continue to be met. Whilst seeking to maximise the benefits and efficiencies that arose with online meetings during the pandemic, there remain elements that are better served by face-to-face workshops, especially for mentorship, case discussion, community engagement and establishing lasting networks.

In response to one of the fastest growing regional epidemics in the world, and to coincide with and promote the recently developed WHO/ UNICEF-led publication [“Progress Report and Roadmap on Elimination of Mother-to-Child Transmission of HIV, Syphilis and Hepatitis B in the Middle East and North Africa/ Eastern Mediterranean Region”](#), we conducted our first ever residential course in Muscat (Oman). The strategic and constructive approach to this workshop, whereby 11 participating regional countries developed customized action plans targeting key focus areas, has been instrumental

towards ensuring the long-term sustainability and effectiveness of vertical transmission elimination efforts in the MENA region. Penta also carried out a bespoke HIV training course in Windhoek (Namibia) for the first time – building on the substantial success of our online programme for Nambian delegates held in 2021, and solidifying vital new training links within the Penta ID network. In another first for PentaTr@ining, in September our long-standing partners at the University of Padua (Italy) warmly hosted the residential component of our upgraded flagship hybrid course ‘HIV & other Congenital Infections’.

As Penta’s research activity continues to grow and evolve in response to the changing needs of children and pregnant people living with infectious diseases, so do our training priorities. In 2024, we delivered freshly updated editions of our immensely popular new online clinical training programmes “Fungal Infections in Paediatrics” and “Viral Hepatitis in Children”, reaching delegates working in even the remotest settings around the world. As we look to 2025 and beyond, our ambitions remain to widen our network and teaching portfolio in other priority subject areas, such as infection prevention and control in healthcare settings, advanced HIV disease (‘STOP-AIDS’), and social stigma among young people.

Finally, a key strategic aim of our training courses is to foster meaningful and verifiable change in professional practice in our delegates and their institutions over the long term. Throughout 2024, we continued our implementation of targeted **“Impact Assessment”** surveys to gather crucial information from our delegates concerning actual changes in their professional practice, overcoming specific barriers to effective treatment, improving patient outcomes, as well as on the development of local and international networks and capacity strengthening.

To date, individual PentaTr@ining courses have been funded by sponsorship from UNICEF, ESPID, EuroCoord, WHO, the Italian Latin American Institute (IILA), delegate fees and by independent medical educational grants from pharmaceutical companies. In 2024, Penta received endorsement and/or funding for training programmes from the following organisations:

- UNICEF: Institutional contract for training services for the hybrid course: “Elimination of Mother-to-Child-Transmission of HIV, Syphilis and Hepatitis B Capacity Building Training for the MENA Region”
- ViiV Healthcare: Independent Medical Education Grant for the hybrid course “PentaTr@ining Namibia 2024”

- ESPID: Training and Education Workshop Awards for the following courses: “HIV & other Congenital Infections”, “Fungal Infections in Paediatrics” and “Viral Hepatitis in Children”
- Medical Research Council Centre for Medical Mycology (MRC CMM) at the University of Exeter: Ongoing partnership and support for the online course “Fungal Infections in Paediatrics”.
- KEDRION BioPharma: Ongoing partnership and support for the online course “Viral Hepatitis in Children”
- University of Padua: Ongoing partnership and support for the hybrid course “HIV & other Congenital Infections”
- Delegate fees: Penta received delegate fees from participants of the following courses: “HIV & other Congenital Infections”, “Fungal Infections in Paediatrics” and “Viral Hepatitis in Children”

STORIES OF IMPACT



Eiman Alblooshi
paediatric ID consultant
Tawam Hospital Abu Dhabi, United Arab Emirates

More than training: global synergies and nurturing the next generation of experts

In 2022, as I concluded my fellowship in South Africa, I had the opportunity – thanks to my programme director, Prof. Moherndran Archary – to participate as a faculty member in the online PentaTr@ining course “Fungal Infections in Paediatrics” for the first time. This experience was unique, and showed me the tangible effort that goes into making a complex topic visually engaging and accessible, with insights from experts worldwide.

Beyond the training content, what stood out most was the welcoming team at Penta – their commitment to inclusivity, bringing together perspectives from diverse healthcare settings around the globe. The online format allowed me to engage with participants from a multitude of different countries, some of which I had to look up on a map!

Each subsequent online programme, such as “PentaTr@ining: AMR Online Course”, reinforced my sense of belonging to this community of dedicated professionals. The interactive discussions were shaped not only by faculty members, but also by highly engaged participants. Their varying experiences and ideas brought true depth to every discussion, sharing relevant topics and exploring practical solutions together. In 2023 I returned home to the United Arab Emirates, a country known for its diversity, where I grew up hoping to share something valuable with people around the world. As someone who is passionate about medical education, PentaTr@ining has provided me with the platform to fulfil one of my personal goals – educating healthcare professionals across different regions. Then in 2024,



taking part in the residential course “The Regional Elimination of Vertical Transmission of HIV, Syphilis, and Hepatitis B Capacity Building Training” as a PentaTr@ining speaker was an eye-opening experience. This timely workshop held in Muscat, Oman offered deep insights into healthcare systems across the Middle East and North Africa region. Hearing local experts discuss their challenges, strategies, achievements, and future plans provided a valuable perspective on the realities of maternal and child health in that region of the world. Connecting with professionals from UNICEF, WHO Regional Office for the Eastern Mediterranean, and Penta at the event and witnessing the harmony and synergy among these organisations reinforced the power of our unified dedication in driving meaningful

impact and change and I am so grateful for these opportunities to connect with leading experts, exchange knowledge, and work toward our shared goal of improving paediatric infectious disease healthcare worldwide.

above:
PentaTr@ining course delegates in
Windhoek (Namibia), July 2024

PENTATR@INING

Since we started

87

TRAINING COURSES
DELIVERED TO **9,000+**
HEALTHCARE WORKERS FROM
40+ COUNTRIES

TYPE OF PROFESSIONALS TRAINED

MAINLY PAEDIATRICIANS

OTHERS INCLUDE:

- EPIDEMIOLOGISTS
- GENERAL PRACTITIONERS
- HEALTH PROGRAMME ADVISORS
- LAB TECHNICIANS
- MEDICAL STUDENTS
- NURSES
- NUTRITIONISTS
- OBSTETRICIANS-GYNECOLOGISTS
- OTHER PHYSICIANS
- PATIENT GROUPS
- PHARMACISTS
- PSYCHOLOGISTS
- RESEARCHERS
- SOCIAL WORKERS

COURSES HAVE BEEN DELIVERED IN:

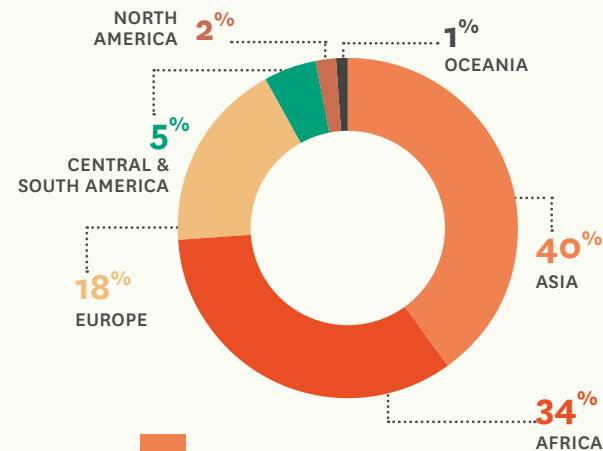
- ENGLISH
- SPANISH
- RUSSIAN
- FRENCH
- PORTUGUESE
- GEORGIAN
- UZBEK
- ARABIC

PENTATR@INING

In 2024

OVER
800

DELEGATES FROM MORE THAN
60 COUNTRIES
PARTICIPATED IN OUR
PENTATR@INING COURSES IN 2024



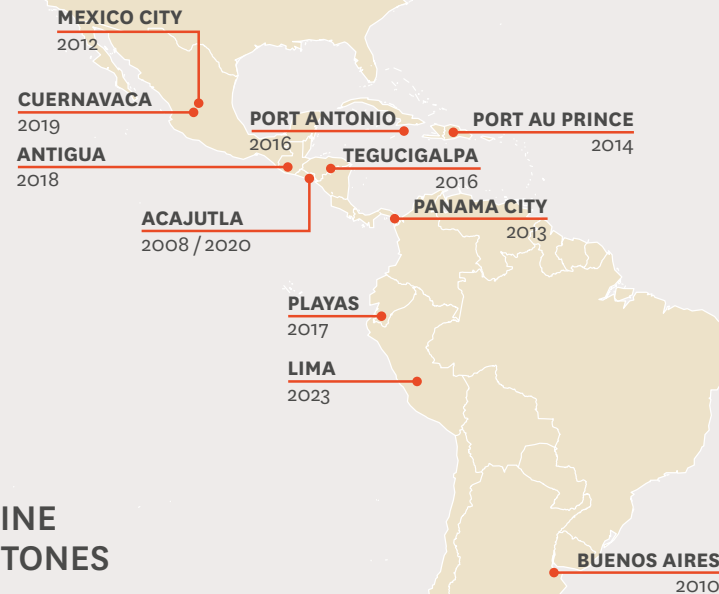
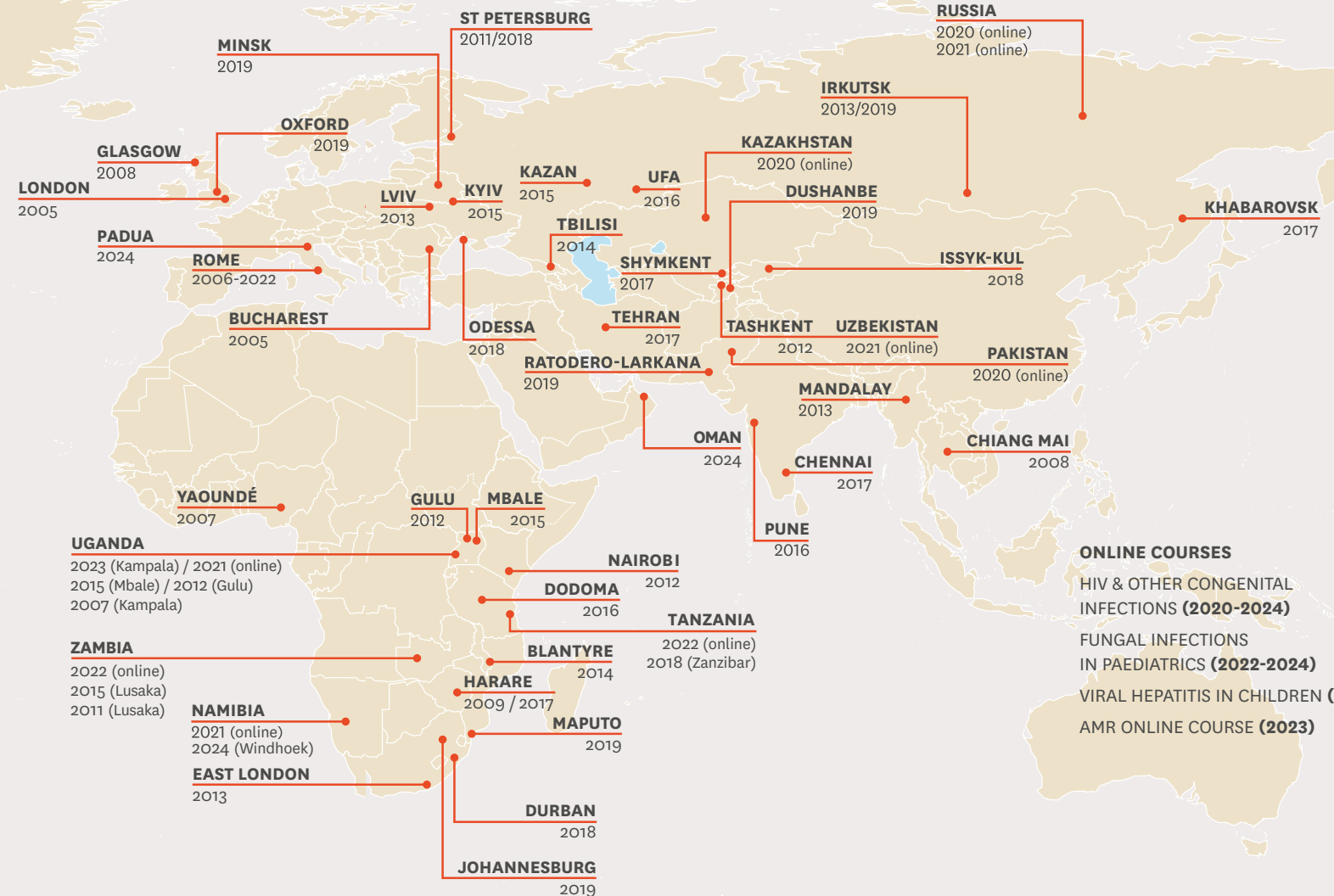
OUR PROGRAMMES IN 2024
ADDRESSED **A WIDE RANGE
OF PAEDIATRIC INFECTIOUS
DISEASES**, WITH OUR
PARTICIPANTS BEING TRAINED ON
TOPICS SUCH AS:

- HIV (INCL. OPPORTUNISTIC
INFECTIONS, MENTAL HEALTH)
- CONGENITAL INFECTIONS
- INVASIVE FUNGAL INFECTIONS
- VIRAL HEPATITIS
- HEALTH PROGRAMME MANAGEMENT



PENTATR@INING

Map

TIMELINE
MILESTONES

ONLINE COURSES

HIV & OTHER CONGENITAL INFECTIONS (2020-2024)

FUNGAL INFECTIONS IN PAEDIATRICS (2022-2024)

VIRAL HEPATITIS IN CHILDREN (2022-2024)

AMR ONLINE COURSE (2023)

PENTATR@INING



What is our impact?

IN **2024** WE CONTINUED TO MEASURE MEANINGFUL IMPACT AND ENDURING CHANGES IN PRACTICE AMONG PARTICIPANTS OF OUR PENTATR@INING COURSES.

TO DATE, WE HAVE COLLATED KEY DELEGATE FEEDBACK AND DATA FROM A TOTAL OF **13 TRAINING COURSES** HELD SINCE 2019.

Has the training course increased your confidence in applying these guidelines?



Has your own professional practice changed in any way since the training?



Have you had the opportunity to share acquired knowledge and help train your own colleagues?



Has your institution begun implementing changes in day-to-day practice as a result of the training?



How would you rate the overall quality of the course?



How would you rate the overall relevance of the course?





4. THE FUTURE: CHALLENGES AND OPPORTUNITIES

Looking ahead

Building on a remarkable past five years, marked by significant achievements and the agility to navigate a dynamic global landscape, Penta is poised to amplify its impact in the years to come. Our reflections on the 2020-2024 period have yielded valuable lessons: the critical importance of **adaptability** in responding to emerging health crises, the extended impact achieved through **strategic partnerships and network expansion**, and the lasting value of **investing in research infrastructure** like the EPIICAL platform and c4c.

These insights have shaped our strategy for the next five years (2025-2029), which remains faithful to our ethos: translating rigorous research into tangible solutions that improve global health outcomes for pregnant individuals, infants, children, and adolescents. Our efforts will be guided by three main strategic pillars:

1. NURTURING A VIBRANT AND COLLABORATIVE INTERNATIONAL RESEARCH NETWORK

Our network community is one of our greatest strengths. We will broaden our collaborations to further strengthen our research capacity and advance infectious diseases research in pregnancy and paediatrics, ensuring equitable contribution from underrepresented regions in Asia, Africa and the Americas.

2. GENERATING SCIENTIFIC EVIDENCE TO INFORM GUIDELINES AND POLICIES AND TO IMPROVE HEALTH OUTCOMES FOR PRIORITY RESEARCH AREAS AND POPULATIONS

We have identified key priorities for our research on prevention and management of infections in pregnant people, infants, children and adolescents organised into four dedicated working groups:

- HIV and viral hepatitis;
- Serious bacterial and fungal infections;
- Congenital and perinatal infections;
- Respiratory infections.

Across all our priority research areas, we will foster the implementation of innovative methodologies supported by experts from our Clinical Pharmacology and Basic Science Working Group. We will promote knowledge exchange and strengthen local research capacity through our comprehensive Education and Training programme, and expand our Early Career Researchers programme to cultivate the next generation of scientific leaders.

3. PREPARING TO ADDRESS (RE) EMERGING INFECTION THREATS

Recent global events underscore the persistent threat of new and re-emerging infections, exacerbated by environmental change, conflicts, and globalisation. We recognise that pregnant individuals, infants, children, and adolescents are at even higher risk of poorer health outcomes and greater inequities in such scenarios.

Penta's strategic focus in the next five years will be to consolidate, harmonise and expand existing research capacity

to enable a rapid targeted, effective and equitable research response to these threats. We will build upon the foundations laid in 2020-2024 to champion the specific needs of our target populations within ongoing and developing European and international research preparedness initiatives. By mobilising our network, we will identify critical preparedness questions relevant to these populations and ensure an effective response to (re-) emerging infection threats.

Underpinning all our efforts will be a strengthened engagement with local communities, young people, patients, and their families. We will prioritise their needs and actively integrate their perspectives into every stage of our work, from initial conception to final implementation.

Our overarching strategy remains focused on generating robust scientific evidence to inform guidelines, policies, and ultimately, practice. Penta is steadfast in its advocacy for equitable access to healthcare across all our activities and deeply committed to engaging with affected and at-risk communities to maximise our impact on global health.

The Penta's 2025-2029 Strategy Workplan is now available at [→ GO TO LINK](#)

European collaboration: fortifying research preparedness for future health challenges



By
Evelina Tacconelli
University of Verona, Italy – Coordinator of ORCHESTRA and Partner of VERDI, CoMeCT, and PIPELINE

The recent global COVID-19 pandemic has starkly revealed the necessity for a fortified research preparedness framework. Projects like ORCHESTRA and VERDI, and the most recent CoMeCT and PIPELINE, are at the forefront, exploring innovative strategies to swiftly counteract emerging and re-emerging infectious diseases in adult and paediatric populations. ORCHESTRA, for example, has generated high-quality evidence on the long-term effects of SARS-CoV-2 infection, highlighting the importance of standardised and prospective data collection across diverse populations, while VERDI, prioritising pregnant people and children, showed the essential role of epidemiological and clinical research in these populations for the development

of clinical recommendations on SARS-CoV-2 and mpox infections. Moving forward, **research preparedness** is further developed under the umbrella of the coordination infrastructures of the CoMeCT project, supporting seamless data exchange across international borders. A major lesson learnt from these experiences is that **translating research outcomes into tangible health policies is paramount during a pandemic** and essential to enable rapid and effective responses, particularly in underserved populations usually not involved in major observational and interventional trials. Penta clearly shows itself to be a crucial catalyst, guaranteeing the children's unique needs are always addressed comprehensively.

A pivotal aspect of these projects, particularly ORCHESTRA and VERDI, has been the concurrent research conducted on children and adults. This parallel approach has proven invaluable, revealing age-dependent variations in disease progression and treatment efficacy. For example, the discovery of differing inflammatory responses in children versus adults during COVID-19 directly influenced the development of tailored therapeutic strategies. Similarly, serological data from paediatric and adult individuals was the backbone to support tailored vaccination schedules and public health campaigns.

The significance of **collaborative endeavors** between diverse institutions cannot be overstated. By pooling expertise, resources, and data, we can forge a resilient framework to **safeguard** public health against future epidemics. Crucially, the active involvement of major stakeholders like the European Centre for Disease Control and Prevention, European Medicines Agency and WHO in the projects proved to be vital. Their continuous collaboration within the projects ensured that research findings were rapidly translated into actionable public health recommendations.

These collaborations exemplify **the sustainability of European research investments**, where data and insights are shared across networks, informing policy and practice at both regional and global levels. This interconnected approach strengthens Europe's ability to respond effectively to health crises, ensuring long-term benefit from the research conducted.

However, beyond the data and policy implications, the true engine driving these projects is the unwavering enthusiasm and dedication of the involved research teams. ORCHESTRA and VERDI, working in close synergy, have demonstrated the power of collaborative spirit in tackling critical research gaps. PIPELINE, leveraging the valuable experience gained from its predecessors, is poised to further enhance our understanding of infectious diseases with epidemic and pandemic potential. CoMeCT, acting as a coordinating hub is ensuring the development of sustainable research pathways. This interconnectedness and collaborative drive, fueled by the passion of the researchers, underscores **the vital role of human dedication** in ensuring the success and long-term impact of European research investments.



5. FINANCIAL RESULTS

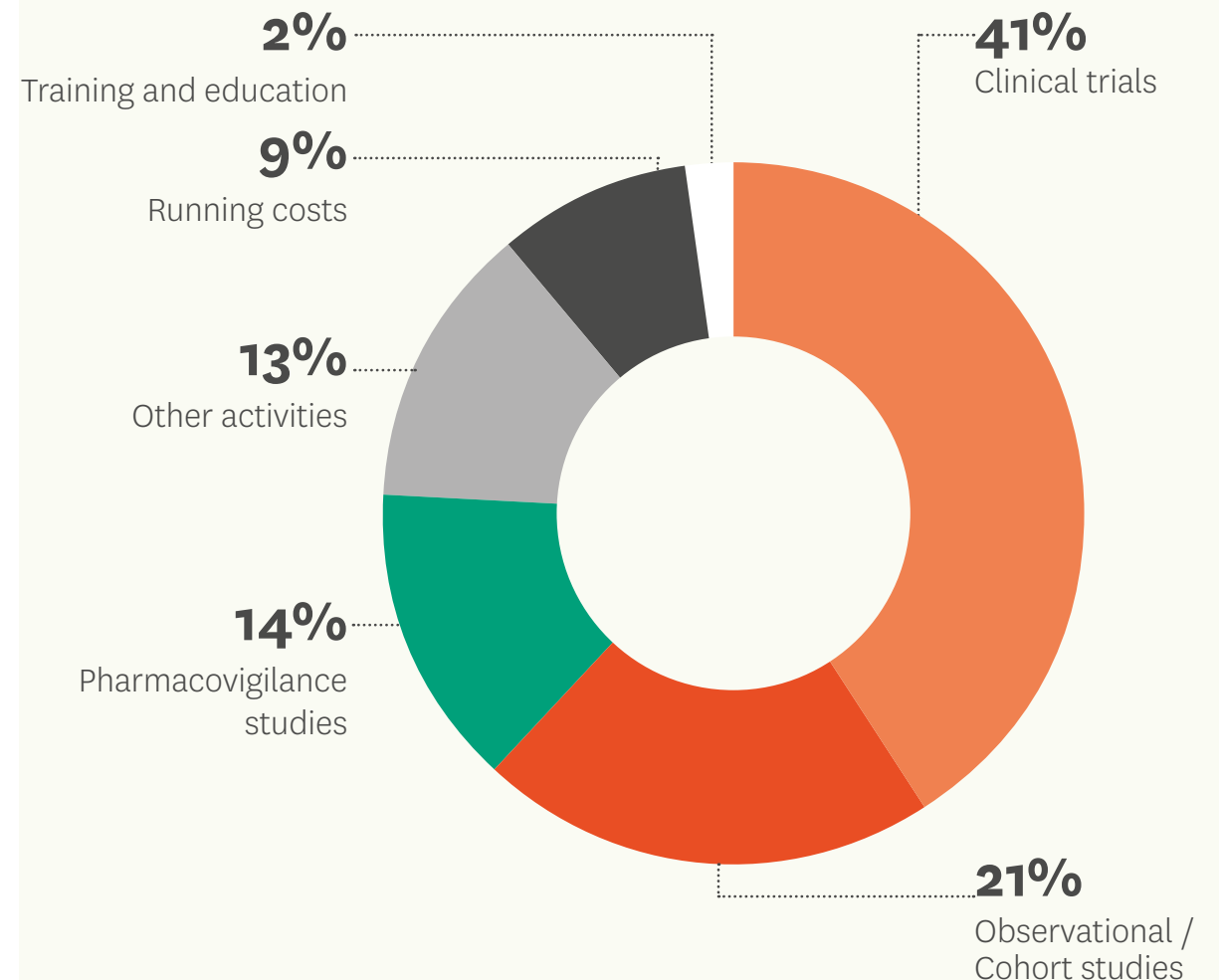
Penta is an **independent organisation** funded by a diverse range of public and private contributors, including international organisations. This allows us to maintain our independence and pursue research priorities that address **critical global health challenges**

As our funding distribution reflects, HIV remains a central focus for Penta. However, the emergence of other infections with pandemic potential has spurred significant research activity in this area. Additionally, we continue to dedicate substantial resources to advancing research on AMR and fostering collaboration through network building initiatives.

Our resources are primarily directed toward study-related activities, particularly the implementation of clinical trials and cohort studies. This ongoing research directly translates into advancements in paediatric infectious diseases.

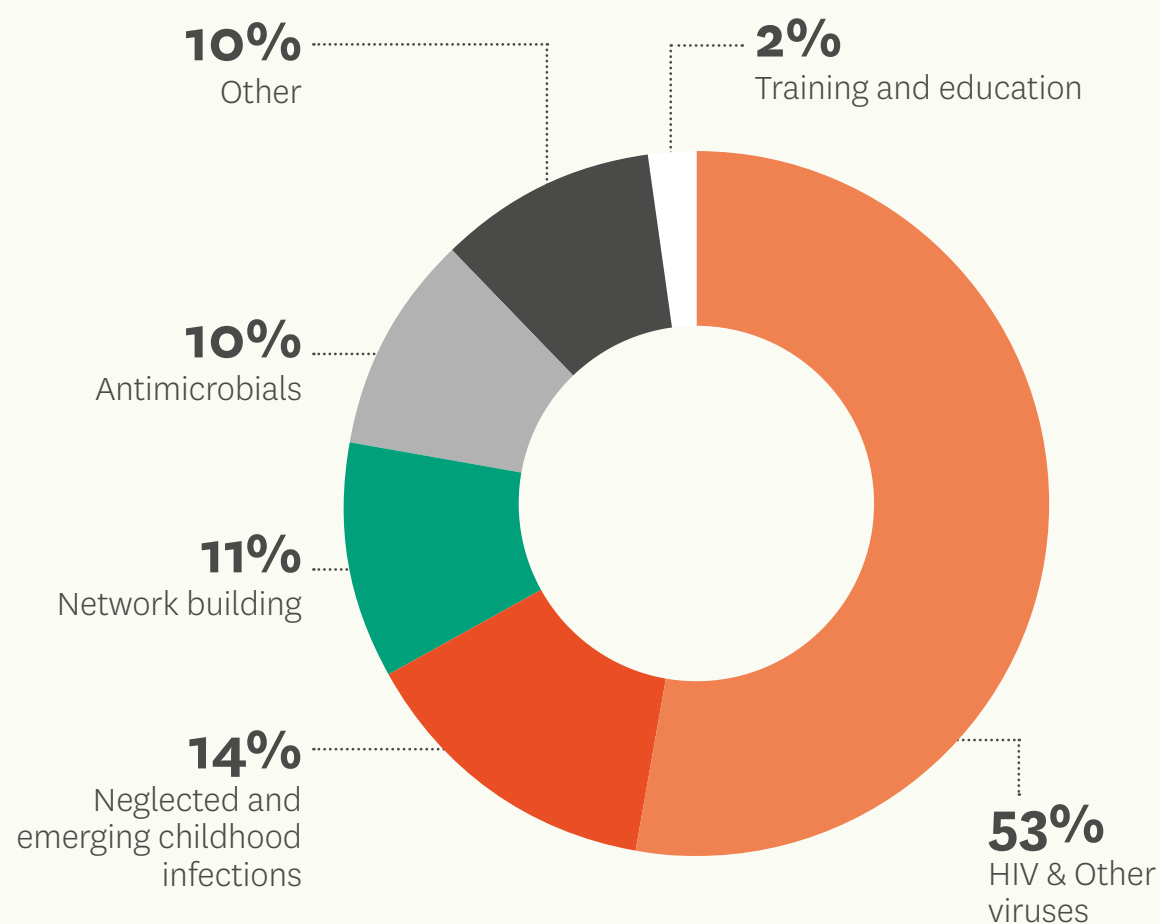
Penta benefits from strong partnerships with a variety of funding sources. Private entities and international organizations contribute the majority of our funding, reflecting our commitment to cross-sector collaborations.

Expenses by type of activity



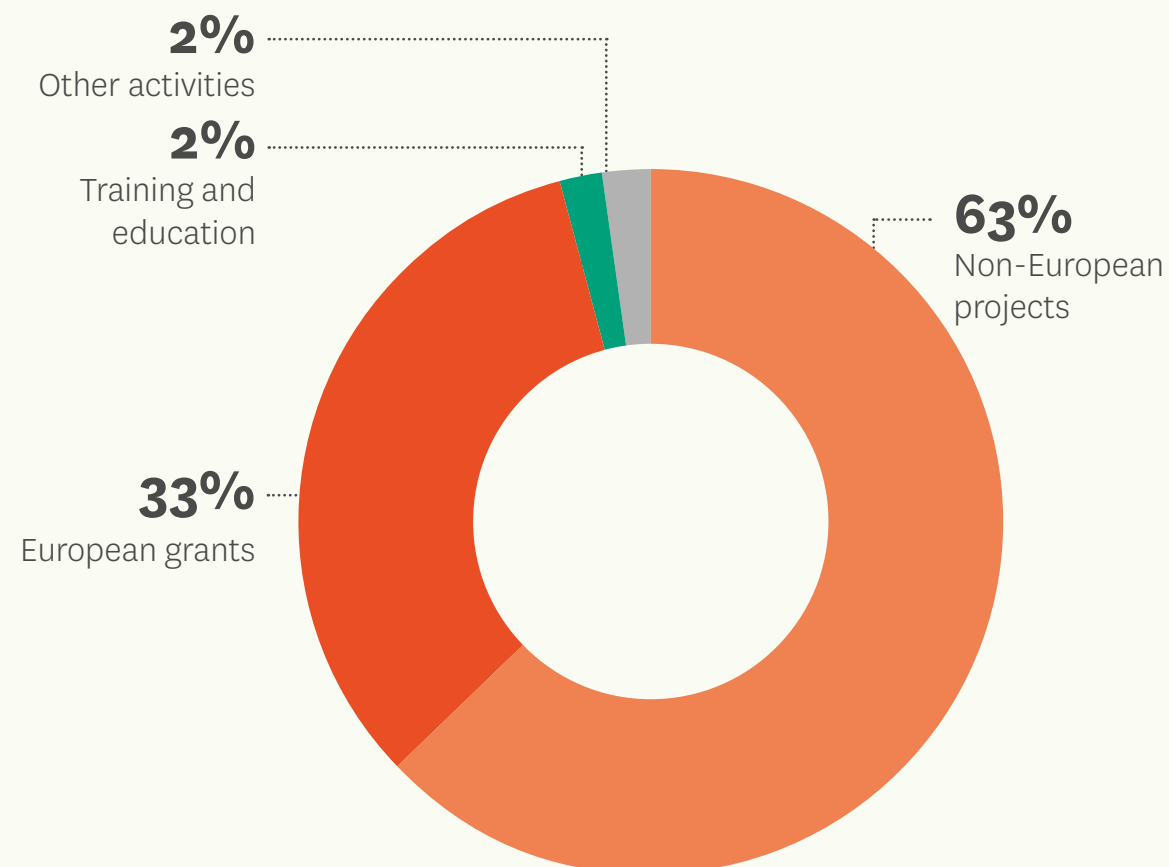
THIS CHART ILLUSTRATES THE PERCENTAGE DISTRIBUTION OF OUR RESOURCE ALLOCATION ACROSS DIFFERENT ACTIVITIES FOR 2024. AS THE DATA INDICATES, A SIGNIFICANT PORTION OF OUR RESOURCES ARE DIRECTED TOWARDS THE IMPLEMENTATION OF CLINICAL TRIALS AND COHORT STUDIES.

Revenues by research area



THE CHART SHOWCASES THE EVOLVING LANDSCAPE OF PENTA'S RESEARCH FOCUS. CONSISTENT WITH PREVIOUS YEARS, HIV REMAINS THE PRIMARY FOCUS OF OUR RESEARCH. HOWEVER, A STEADY INCREASE IN OTHER AREAS IS EVIDENT, REFLECTING OUR STRATEGIC RESPONSE TO EMERGING PUBLIC HEALTH THREAT.

Revenues by funder



AS THIS CHART ILLUSTRATES, PENTA BENEFITS FROM STRONG PARTNERSHIPS WITH A VARIETY OF FUNDING SOURCES. PRIVATE INSTITUTIONS CONTRIBUTE THE MAJORITY OF OUR FUNDING, REFLECTING OUR COMMITMENT TO CROSS-SECTOR COLLABORATION. THE EUROPEAN COMMISSION REMAINS A KEY PUBLIC SECTOR PARTNER.

Methodological note

This report adheres to the "Guidelines on how to write Third Sector organisations' Social Report" outlined in the Italian Ministry of Labour and Social Policies Decree of July 4, 2019. Social reporting measures, discloses, and emphasises accountability to stakeholders for an organisation's social impact.

This report offers stakeholders clear and transparent information regarding Penta's social and environmental responsibilities, social goal pursuit, and achievements during the fiscal year January 1, 2024, to December 31, 2024. Whenever possible, year-on-year comparisons are provided.

The Penta environment encompasses multiple entities with a shared vision: the Penta Foundation (Italian legal entity) and the Penta ID Network (clinicians, researchers, and healthcare professionals in 94 countries). This report presents a unified picture while acknowledging the distinct characteristics of the Foundation and its partner entities.

The Penta Foundation's Communications Team coordinated document design and content selection, with input from all staff. Data was sourced from Penta's Contacts Institutions Projects Database, accounting system, and Gender Equality Plan and strategic contributions from Penta ID Network members, including scientific information, study findings, and background data.

The report and financial statements comply with Italian regulations and relevant accounting principles. The Board of Directors approved them on 28 April 2025. BDO S.p.A. audited the Foundation's financial statements, certifying a fair and accurate representation of the financial position as of December 31, 2024, and the year 2024's operational results and cash flows.

Stories featured in this report were collected throughout 2024, highlighting the contributions of numerous individuals to Penta's success. This reflects our growing focus on stakeholder engagement, human capital development, and creating impact for our communities.



Penta's Social Report is published annually. For more information, please contact us at communication@pentafoundation.org or visit our website penta-id.org/who-we-are/annual-reports/

This report adheres to the principles of the Italian Ministry of Labour and Social Policies Decree of July 4, 2019 (relevance, completeness, transparency, neutrality, clarity, truthfulness, data verifiability, period competence,

comparability, reliability, and third-party autonomy), as well as Penta's core values of collaboration, diversity and inclusion, research equity, team spirit, responsibility, and transparency.

Notes

.....

.....

.....

.....

.....

.....

.....

.....

.....

.....

.....

.....

.....

.....

.....

.....

.....

.....

.....

.....

.....

.....

.....

.....

.....

.....

.....

.....

.....

.....

.....

.....

.....

.....

.....

.....

.....

.....

.....

.....



concept and design

bcvassociati.it

illustration

Giulia Dall'Ara

photos

Penta Foundation



Penta

Child Health Research



UNI PDR 125
BUREAU VERITAS
Certification



Fondazione Penta ETS

Corso Stati Uniti 4, 35127, Padova, Italy

VAT 04150680280

info@penta-id.org

www.penta-id.org

