



# Penta

Child Health Research

## Annual Social Report **2022**



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# Letter to our stakeholders

Dear friends,

You know, at Penta we strongly feel our responsibility towards the world. With this Annual Social Report, we want to share with you some reflections on what role we play in our communities, how we are working to create a diverse workforce and how we manage our impact on the environment.

What underpins our mission is the awareness that health is a right, not a privilege, and that everyone, especially the most fragile, has the same right to access the best treatments available and to participate in decisions that affect their lives. **Equality and Social justice** are topics that call on everyone, at the level of political action, and also of organisational practices. And we are determined to play our part.

In 2022 we made **inclusion and diversity** mainstream themes in the way we operate. We know from experience that an inclusive company is a better performing company and is more likely to achieve better economic results. Therefore, we understand diversity and inclusion as strongly connected with the results we obtain.

Operating within a complex system of relationships, we have remained committed to getting communities well informed and passionately interested in what Penta is up to, because **people are at the heart of everything we do**. But this is not enough. We also encourage and support the **active engagement** of children, adolescents, and other participants in our studies, so we can better understand where to direct our efforts, help participants overcome barriers to participation and co-produce new knowledge. This is what facilitates the development of prevention, diagnoses and treatment strategies in an impactful way. Nonetheless, participation for us means filling the gap between science and communities and nurturing our mission about the next steps for research. Because research that does not question whether, when, and how their work can be translated in the real world and impact the lives of real people, is by all means ineffective research.

We have **strengthened the dialogue with our stakeholders**, making it a definitively distinctive element of our way of operating. We have thus been able to gather essential information to understand the changes underway and stay close to the organisations with which we carry out our studies. In low-resource settings we are supporting our research sites and help strengthen their capacity to run their own studies. **Capacity building** is a cornerstone of our strategic action.


For more than three decades, Penta has been unwavering in our commitment to improving the health of mothers and children around the world. We serve these populations, including the most vulnerable groups, through a network of more than 460 researchers, scientists and healthcare professionals dedicated to painting a brighter future and making a real impact on their lives.

There are many people to thank for making Penta what it is today. Thank you to the Penta staff members for your hard work and commitment, to our partners and collaborators, who have helped us protect our most fragile populations by ensuring they receive the best medicines, vaccines and other interventions that science has to offer and to the families and children in our studies. Thank you all for continuing to work with us.

*Carlo Giaquinto,*  
on behalf of  
Penta Foundation Board of Directors





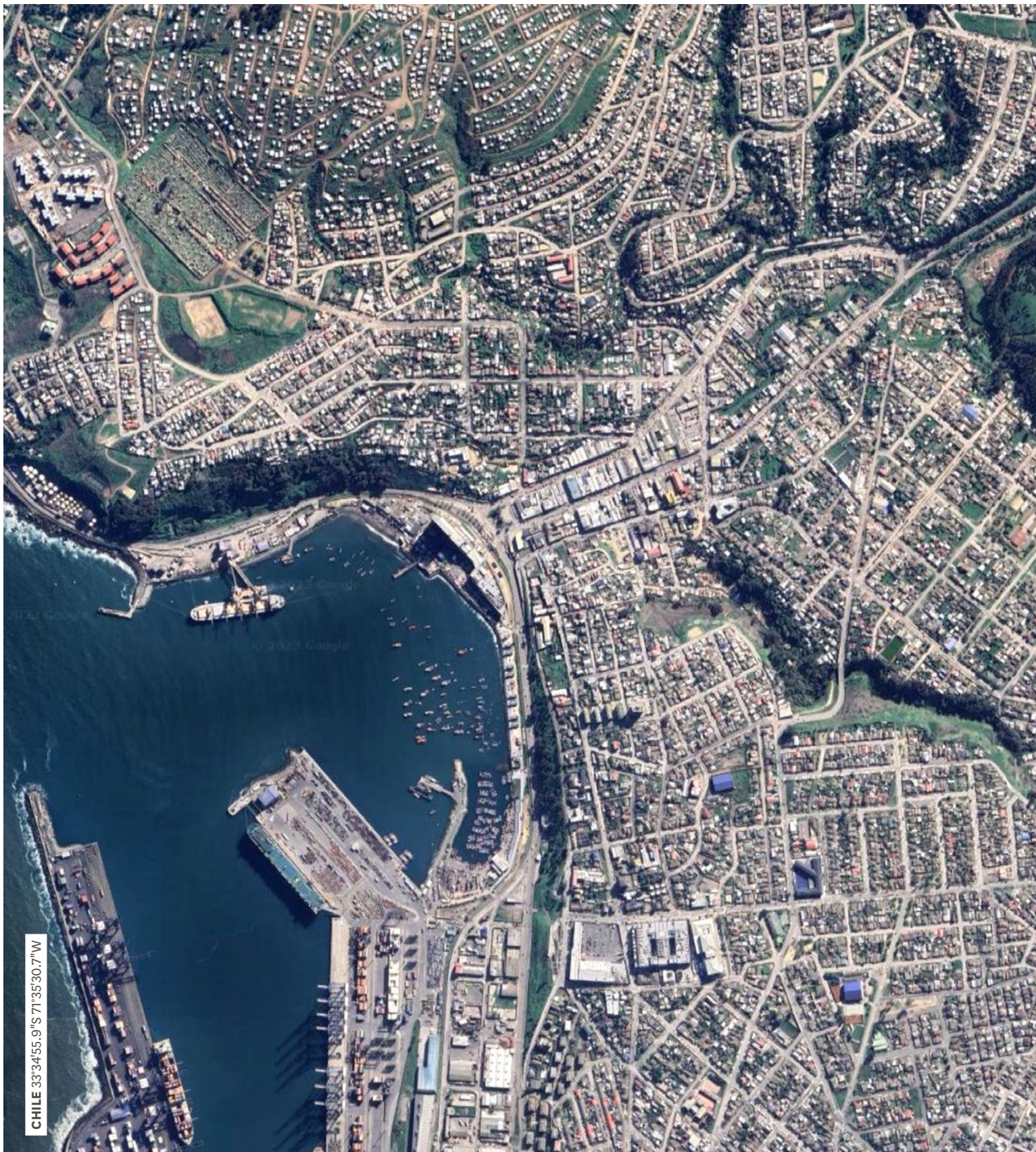
An aerial photograph of a city, likely Dublin, Ireland, showing a dense urban area with a river (the Liffey) flowing through it. The city is characterized by a mix of residential buildings, green spaces, and industrial areas. The river is a prominent feature, with several bridges crossing it. The surrounding area includes more urban development and some open land.

Who is Penta? We are people from all walks of life with different backgrounds and unique lived experiences. But as different as we are and regardless of what we see when we look outside our windows, we are unified in our belief that children and pregnant people should not have to wait years to receive the best medications.

We are where the medicines are needed, where the people who need these medicines are and where we can make a meaningful impact on health outcomes. So, regardless of where our planes, buses or trains depart from, whether we see skyscrapers or green pastures, bustling streets or hushed walkways, we aspire to see healthy children, healthy pregnancies, positive health outcomes and a brighter future for global child and maternal health.

With the pictures you will find in this Annual Social Report, we hope you see who we are, what we hope for through our studies and the values that unite us, because we are Penta people.





# 1.

## ABOUT US

We are a **global, independent, scientific collaboration** devoted to determining and implementing the best ways to **prevent, diagnose and treat diseases in children**



## Our vision

**To be at the forefront of clinical science that improves prevention, diagnosis and treatment of infections in children**



## Our mission

**To build a global network that conducts excellent research to help health systems achieve optimal outcomes for children**



## What makes us unique

**One network  
One vision  
One voice**



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

## Our values

**Sharing,  
collaboration  
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 children.

## Our guiding principles

**Diversity and inclusion, team spirit, responsibility, transparency**



As an international collaborative platform coordinating and undertaking research designed to improve child health and combat infections – we include and respect investigators throughout our Network. Making space for all those passionate about our mission is something we pride ourselves on - we seek to create a genuine platform for teams to build a body of research that contributes to children's wellbeing.



# Our journey continues

We are on an exciting journey to transform the prevention and treatment of infections in children.

Thirty-two years ago, Penta started with a shared passion of like-minded scientists who wanted to ensure that children were not left behind in the treatment of HIV/AIDS. Today, many are working hard to ensure that this idea not only spreads around the globe, but extends to other diseases beyond HIV.

The Paediatric European Network for Treatment of AIDS (PENTA) was established

in 1991 as a collaboration between paediatric HIV centres in Europe. The primary aim of the Network was to undertake **independent clinical trials**, which focused on questions specific to children and complemented others working in this research space.

Over time, as the Network started to grow beyond HIV clinical trials and observational studies, Penta

became an ideal platform to generate, develop and support research and training activities – and thus the **Penta Foundation** was born.

Recognising that other infections in children were similarly neglected, in 2011, Penta evolved into **Penta ID** (Infectious Diseases), extending its research (both clinical and basic) to other paediatric infectious diseases. With the growing

threat of antimicrobial resistance, Penta has since built an ambitious and unique research agenda to address strategic questions in both treatment and prevention for newborns and children.

In 2021, the fight against COVID-19 became an important focus for us; as central to our scientific strategy, we pulled together our Network members and collaborators to investigate

the impact of SARS-CoV-2 on maternal and child health reflecting our belief that only through joining our resources and experience with partners can we advance our knowledge and inform strategies for 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, with a view to build **research preparedness for future emerging** pathogens with pandemic potential, harnessing the power of real word data.

As we continue to accelerate towards truly becoming the leading experts in maternal and child health research, we will keep being guided by the values and behaviours that underpin everything we do.

From our initial focus on HIV to the inclusion of other infectious diseases

**1991**

**Penta**  
Paediatric European Network for Treatment of AIDS

**2004**

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

**2011**

**Penta ID**  
Extension of the Network to address other Infectious Diseases

**2020**

**Penta ID Network**  
Launch of the 5-year scientific strategy

**2021**

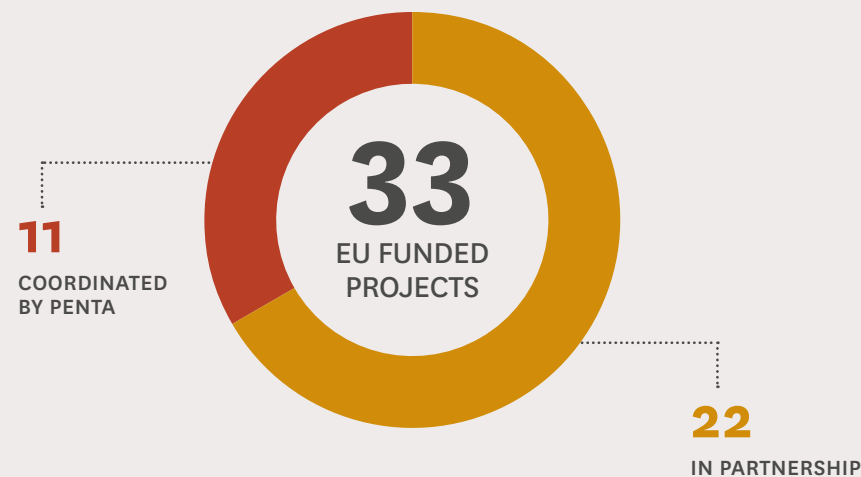
**Penta turns 30**  
Start of the Brighter Future conversations

**2022**

**From COVID-19 to mpox**  
Towards research preparedness for pathogens with pandemic potential



# Since we started



MORE THAN  
**50,000**  
WOMEN AND CHILDREN ENROLLED  
IN OUR STUDIES

CONTRIBUTION TO REGISTRATION OF  
**ARV FORMULATIONS**  
FOR PAEDIATRIC HIV GLOBALLY

**42**  
STUDIES

**7** POST-MARKETING SAFETY STUDIES  
CONDUCTED THROUGH THE  
**EPPICC NETWORK**

PENTA **HIV GUIDELINES**  
GLOBALLY RECOGNISED

OVER  
**260**  
PEER-REVIEWED SCIENTIFIC  
ARTICLES

MORE THAN  
**110**  
SITES IN  
**31**  
COUNTRIES ENGAGED  
IN OUR STUDIES

JOINT ACTIVITIES WITH  
**ADULT NETWORKS**

RESEARCH **PREPAREDNESS**  
**PLATFORM** FOR EMERGING  
INFECTIOUS DISEASES

SUBSTANTIAL SCIENTIFIC  
CONTRIBUTION TO THE  
**WHO AWARE**  
**ANTIBIOTIC BOOK**  
THE **1<sup>st</sup>**  
GLOBAL GUIDELINES ON  
ANTIBIOTIC USE

OVER  
**460**  
MEMBERS IN OUR  
NETWORK GLOBALLY

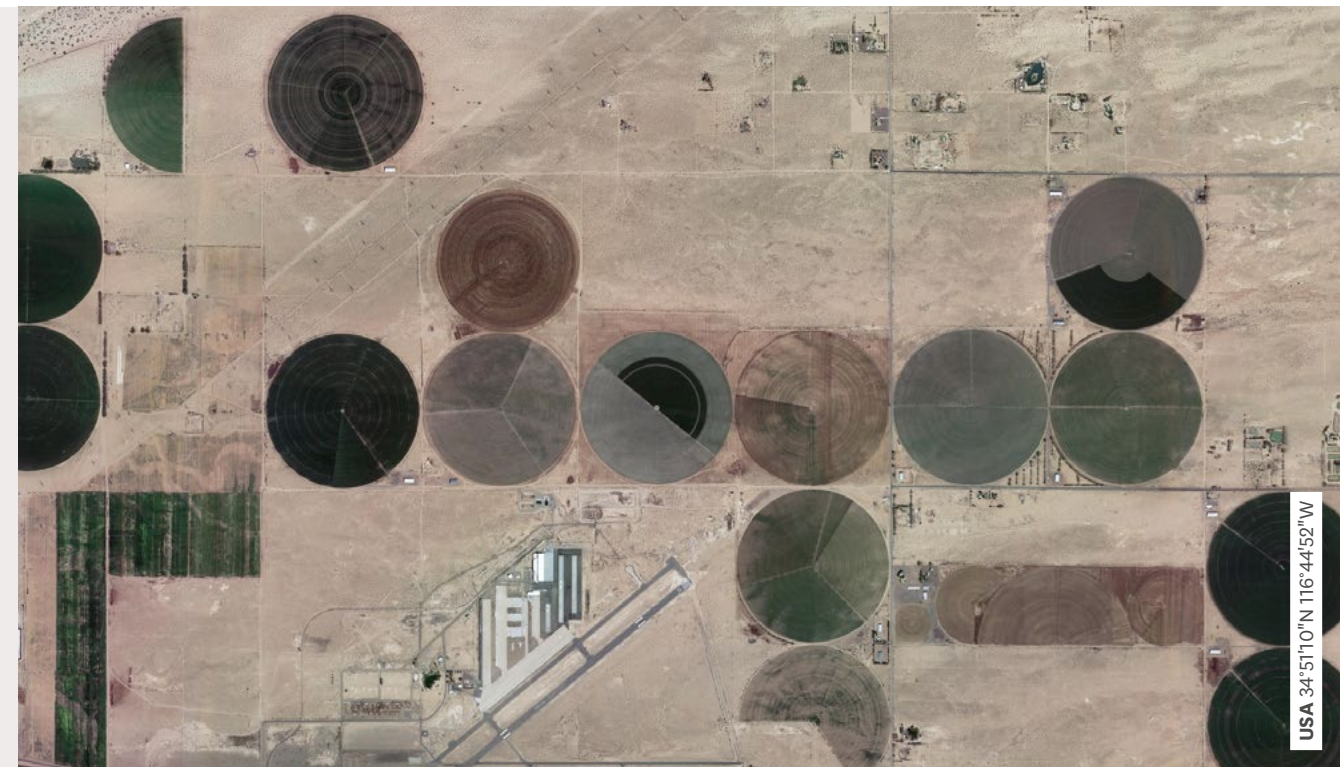
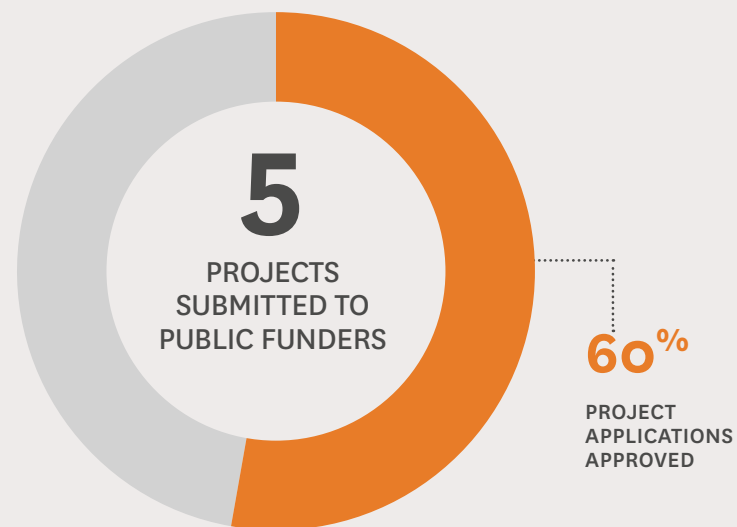
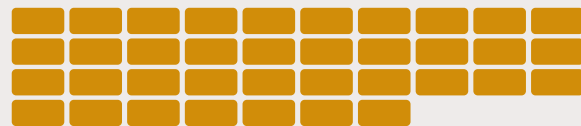
NETWORK OF PREGNANCY AND  
PAEDIATRIC COHORT COLLABORATION  
INVOLVING OVER  
**16** **IN EUROPE,**  
**THAILAND,**  
COUNTRIES **SOUTH AFRICA**



# 2022 at a glance

37

PENTA PROJECTS  
AND STUDIES



USA 34°51'10"N 116°44'52"W

4

PENTATR@INING COURSES  
HELD, DELIVERING A TOTAL OF  
**112.5 HOURS** OF LEARNING

MORE THAN

800

HEALTHCARE PROFESSIONALS  
FROM OVER **60** DIFFERENT  
COUNTRIES TRAINED



# An interview with Elizabeth Robinson

**Elizabeth Robinson,**  
member of Penta  
Foundation Board of  
Directors, Italy

**What did you see in Penta that led you to believe that there is potential for innovation and growth?**

I believe there is a huge potential for innovation and growth in Penta. Infectious diseases are becoming an increasing global health issue and we have seen huge advances in innovative medicines including the new vaccine technologies used effectively for COVID-19. However, children and pregnant women were among the last to have access to these. Penta can play a key role in accelerating access to innovated medicines through its dedication to paediatric clinical trials.

**What is the value of Penta? And why is independent research an asset for the medical community?**

Mothers and children are particularly vulnerable populations for infectious diseases, however they are often left out of the traditional pharmaceutical industry sponsored clinical trials for the regulatory approval of new medicines. Penta's dedication and long history of activity in the area of paediatric clinical trials is essential in this neglected area.

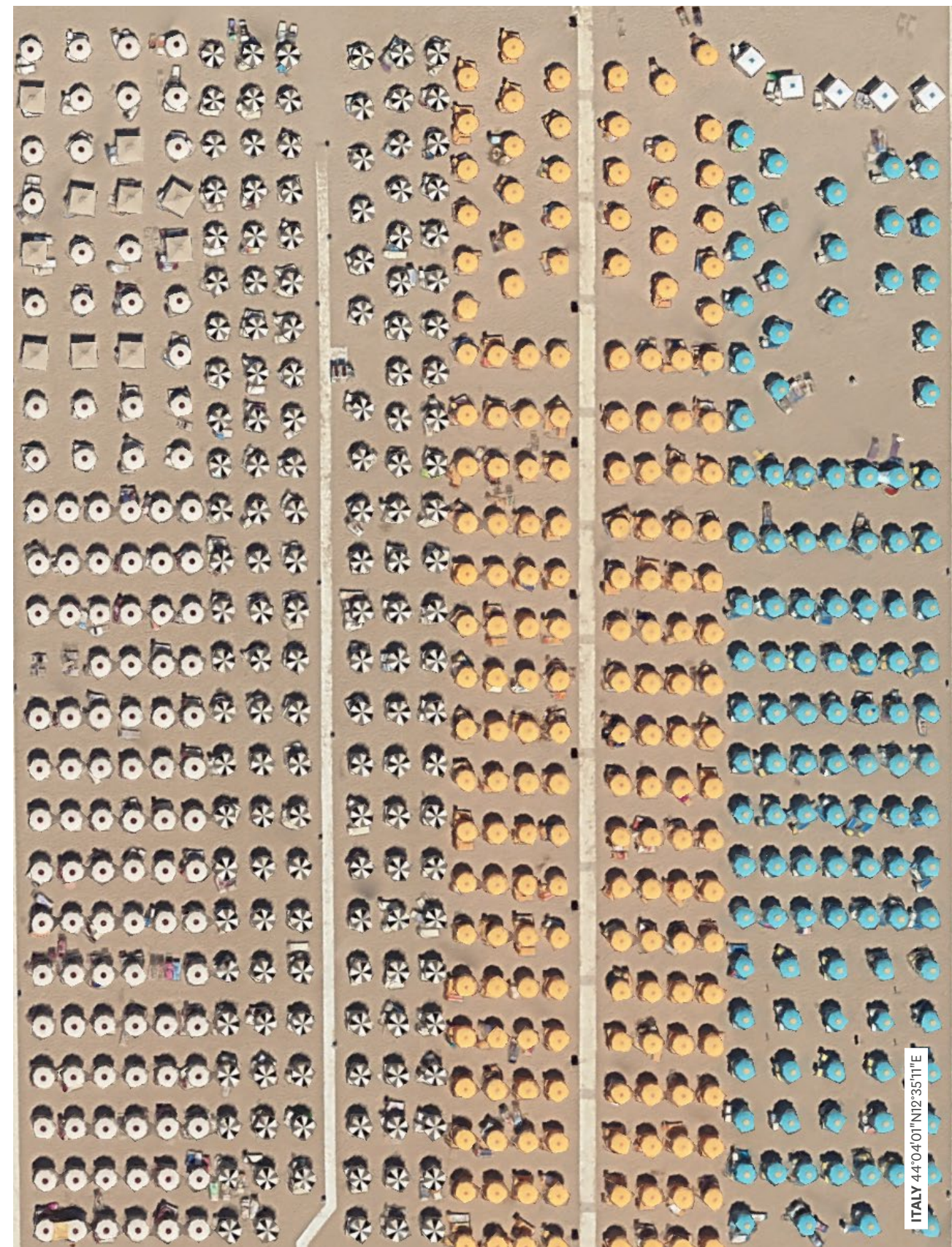
The historic dedication of Penta as an independent research network has made significant progress toward the availability of HIV medication for children and we are also seeing the positive impact in the other disease areas where Penta is working.

The work of Penta has also shed new light on the

different ways in which diseases affect small children compared to adults.

**How do you see the future of Penta? What challenges and what opportunities are there on the horizon to achieve Penta's vision of better health for mothers and children?**

I see Penta expanding its research into new areas of infectious diseases and into the area of antimicrobial resistance. A continuing challenge is to engage the regulators in order to facilitate clinical trials in children and mothers. A further challenge is to incentivise the pharma industry to address the paediatric and pregnant women population much earlier in drug development.





# Why our research matters?

## INFECTIOUS DISEASES

Globally, **INFECTIOUS DISEASES**, including pneumonia, diarrhoea, malaria and sepsis remain **THE LEADING CAUSES OF DEATH FOR CHILDREN 1 MONTH TO 9 YEARS OF AGE**. (WHO)

## HIV

In 2021, there were **1.7 MILLION CHILDREN YOUNGER THAN 15 YEARS LIVING WITH HIV** globally, of whom 84% live in sub-Saharan Africa. If untreated, children living with HIV experience the highest **RISK OF MORTALITY IN THE FIRST 5 YEARS OF LIFE**. Children have persistently lower ART coverage globally as compared to adults. (UNAIDS)

## NEW HIV INFECTIONS

Despite the global campaign to eliminate vertical transmission, children are still acquiring HIV during pregnancy, delivery, or breastfeeding, **WITH 160,000 NEW INFECTIONS GLOBALLY IN 2021**.

Most of the new HIV infections among children occurred because adolescent girls and women **COULD NOT ACCESS OR CONTINUE WITH HIV TESTING**, prevention and treatment services throughout pregnancy and breastfeeding. (UNAIDS)

## LOWER RESPIRATORY TRACT INFECTION

**LOWER RESPIRATORY TRACT INFECTION IS THE LEADING INFECTIOUS CAUSE OF DEATH AMONG CHILDREN UNDER 5**, killing approximately **800,000 CHILDREN A YEAR**. In many parts of the world, a child dies from pneumonia every 39 seconds even though the disease is entirely preventable and can be easily managed with antibiotics. (UNICEF)

## TUBERCULOSIS

Tuberculosis is a disease that the world knows how to prevent and treat. Yet, every day over **600 CHILDREN UNDER THE AGE OF 15 DIE FROM** – nearly a quarter-million each year. Most of these deaths occur among children under the age of 5. (UNICEF)

## ANTIMICROBIAL RESISTANCE

Antibiotic resistance is growing and killing many more people of all ages than previously known: in 2019 alone, **NEARLY 1.3 MILLION DEATHS WERE CAUSED BY BACTERIAL ANTIMICROBIAL RESISTANCE (AMR)**, including nearly 140,000 deaths in newborns. (GARDP)

## HEPATITIS C

An estimated **3.3 MILLION CHILDREN ARE LIVING WITH CHRONIC HEPATITIS C INFECTION**, with 20 countries accounting for 80% of all cases among children 0–18 years of age. (GAP-F)

## LACK OF NEW ANTIBIOTICS

**THERE ARE VERY FEW NEW ANTIBIOTICS UNDER DEVELOPMENT TO REPLACE ANTIBIOTICS THAT NO LONGER WORK**. The latest discovery of a new antibiotic class that has reached the market was back in 1987. (ReAct)

## FUNGAL INFECTIONS

Invasive fungal infections are threatening the most vulnerable, newborns and children, including those prematurely born 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. (WHO FUNGAL PPL)

## IMPACT OF COVID-19 ON CHILDREN AND LONG COVID

Children and adolescents remain at low risk of **SARS-COV-2 INFECTION AND COVID-19 MORTALITY**, accounting for 0.4% of overall deaths. However, those who experience severe COVID-19 are more likely to develop **LONG-TERM SYMPTOMS**, such as fatigue, respiratory problems, dizziness, muscle weakness and chest pain. (UNICEF)



# Our objectives for the period 2020-2025

At the heart of our studies is our desire to improve the health and wellbeing of mothers and children across the world. We are committed to making the best treatments available to children in the disease areas in which we are active. We can count on a unique and ever-growing network of investigators, who are leading champions for child health.

## 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 of 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

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

Infections prevented and treated in children, decreasing mortality, morbidity, disability-adjusted life years & healthcare cost

Better therapeutic and prevention options for children and in pregnancy

Better and faster licensing of drugs for paediatric use





UGANDA 3°30'54"N 34°08'09"E

## STORIES OF IMPACT



**Philippa Musoke,**  
Penta ID Network ODYSSEY  
Co-investigator in Uganda

### ODYSSEY trial: Improving the lives of children living with HIV

ODYSSEY's results on dolutegravir (DTG) have been a game changer in many places in Africa. DTG has been found to work well, have fewer side effects, and be safe for children to take with other drugs. Additionally, it is taken only once a day and there are now formulations that are appropriate for very young children, right down to three kilos, making it **an ideal solution for families** who struggle with getting their children to take their medication regularly. With DTG, children have a better chance of suppressing the virus, **growing well and living a healthy life.**

Until recently, DTG was only available for adult use. There wasn't knowledge of the recommended dosage for children, even though we knew it was one of the better drugs for treating HIV, because it was potent and rapidly

reduced the viral load. Paediatric versions of older anti-HIV drugs were difficult for children to take and did not reduce the viral load very well, making successfully treating HIV in children difficult. But now, **the lives of children and young people living with HIV have been improved.** Thanks to ODYSSEY, we now know that DTG can be given to our children safely, in the appropriate dosage and that it is better than the older drugs.

The ODYSSEY trial was undertaken collaboratively and globally in Africa, Asia, and Europe. This not only improved the efficiency of the study but also helped ensure that the results were more widely applicable across different regions. **It also fostered a sense of teamwork and camaraderie among the members, which was essential for the success of the trial.**



## STORIES OF IMPACT



**Linda L. Lewis,**  
Clinton Health Access  
Initiative, US

### ODYSSEY trial: Closing the gap on paediatric antiretroviral therapy

Children living with HIV in low- and middle-income countries have historically waited many years for newer, more effective, or safer medicines to treat their HIV infection. This lag in availability of optimal medicines has been due to slow development of paediatric formulations by innovator pharmaceutical companies, slow enrolment of initial paediatric clinical trials, and resulting limited clinical data to allow treatment guidelines consensus. The randomised comparison of dolutegravir (DTG)-based treatment and standard treatment in the ODYSSEY study for both initial and second-line therapy provided data to support regulatory approval of a dispersible paediatric formulation and clinical experience to support international guidelines and use in low- and middle-income countries.

The Penta-sponsored ODYSSEY study, conducted in collaboration with ViiV Healthcare, collected

critical pharmacokinetic (PK), safety, and efficacy data in children living with HIV taking the new paediatric formulation. The PK data combined with data from another paediatric clinical trial were submitted to both the U.S. Food and Drug Administration and the European Medicines Agency and contributed to approval of the dispersible DTG tablet worldwide. The study also showed that, in a large, geographically diverse group of children, DTG-based regimen led to improved viral suppression, less treatment failure, and an excellent safety profile in children living with HIV compared to either protease inhibitor- or non-nucleoside reverse transcriptase-based therapy commonly used in LMIC. The success of the ODYSSEY study has allowed rapid development of generic paediatric DTG dispersible tablets and adoption of an optimal DTG-based regimen for children living with HIV in low- and middle-income countries.

## 1. ABOUT US

# ODYSSEY: a landmark clinical trial

ODYSSEY trial started in 2015.  
The long term follow up ends in 2024

IN **2019** THE WORLD HEALTH ORGANIZATION INCORPORATED THE DATA FROM ODYSSEY INTO THEIR DOLUTEGRAVIR (DTG) DOSING RECOMMENDATIONS FOR CHILDREN WITH HIV

IN **2020** DATA FROM THE ODYSSEY TRIAL CONTRIBUTED TO REGULATORS APPROVING A 5MG DISPERSIBLE TABLET FOR YOUNG CHILDREN IN BOTH USA (FDA), EUROPE (EUROPEAN MEDICINES AGENCY) AND OTHER COUNTRIES

RESULTS FROM ODYSSEY SUPPORT CURRENT WHO GUIDELINES, WHICH RECOMMEND DTG-BASED TREATMENT AS THE FIRST CHOICE FOR ALL CHILDREN OVER 4 WEEKS OF AGE LIVING WITH HIV

AS OF JULY 2022,  
**60 COUNTRIES**  
HAVE ADOPTED DTG-BASED REGIMENS AS THE PREFERRED TREATMENT OPTION FOR ALL CHILDREN LIVING WITH HIV

IN **2020** THE U.S. FOOD AND DRUG ADMINISTRATION (FDA) APPROVED USE OF THE ADULT DTG TABLETS FOR CHILDREN WEIGHING AT LEAST 20KG

IN **2022** THE U.S. FDA APPROVED A DISPERSIBLE, FIXED-DOSE DTG COMBINATION FOR CHILDREN WEIGHING BETWEEN 10 AND 25KG

RESULTS FROM A SUBSTUDY OF ODYSSEY SHOW THAT CHILDREN BEING **TREATED FOR TUBERCULOSIS AND HIV** AT THE SAME TIME CAN SAFELY TAKE DTG TWICE A DAY

THE EXPANSION OF EASY-TO-TAKE, CHILD FRIENDLY REGIMENS HAS RESULTED IN RISING RATES OF HIV VIRAL SUPPRESSION AMONG CHILDREN LIVING WITH HIV AND RECEIVING TREATMENT

(SOURCE: UNAIDS GLOBAL AIDS MONITORING 2022)





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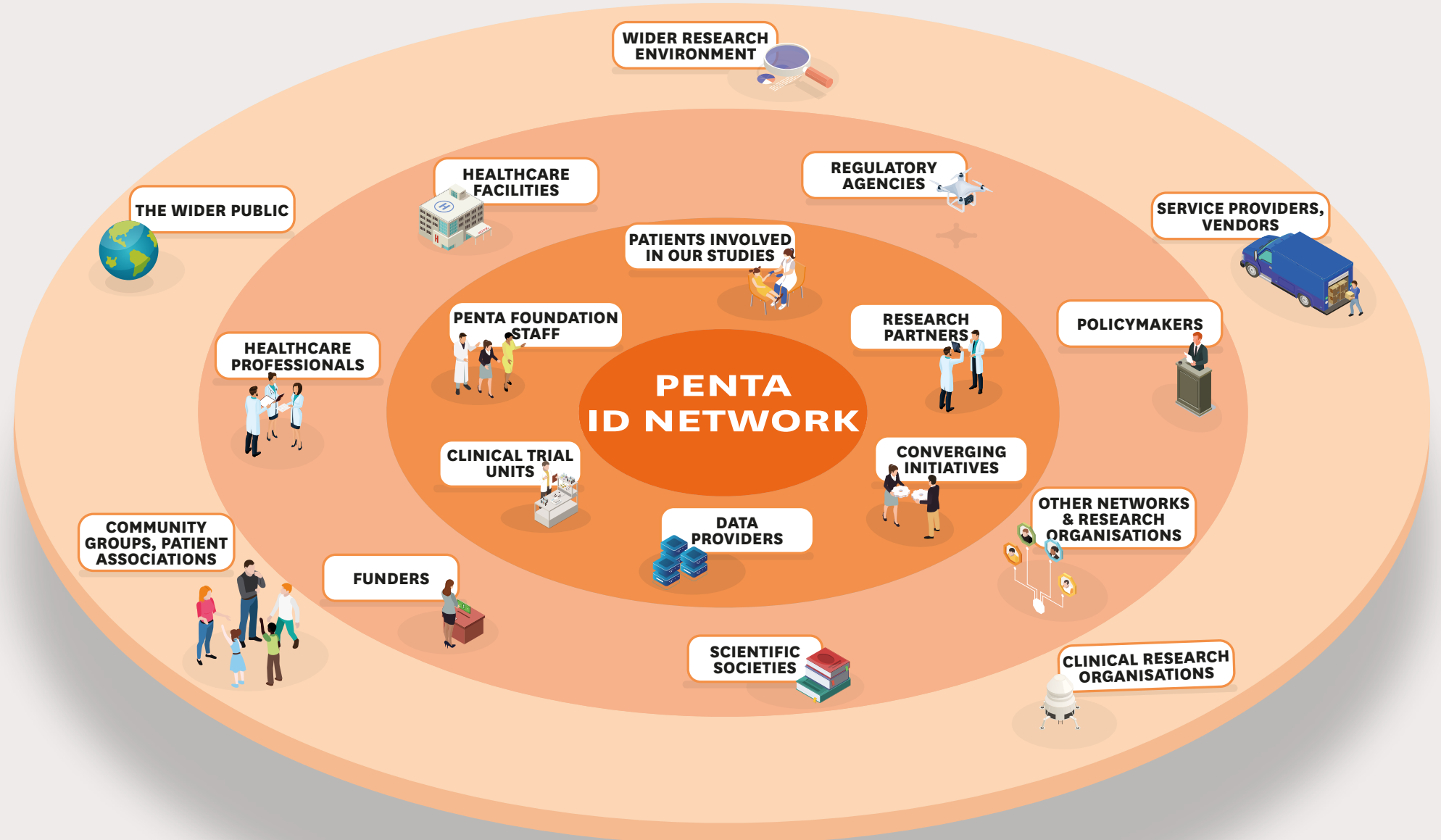
## 2. HOW WE OPERATE

The flexible,  
multidimensional,  
**Penta environment**



# Our Stakeholders

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





# Penta ID Network

The Penta ID Network is central to everything we do at 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 children, young people and pregnant women.

The Penta ID Network reaches almost every corner of the world, with members spanning from Asia, Africa and the Americas, as well as 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 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 women and children through

the generation and application of new scientific knowledge.

Throughout 2022, we carried on working towards the **key scientific priorities** set out in our Penta ID Network scientific strategy:

- HIV & viral infections
- Severe bacterial infections and antimicrobial resistance
- Infection in pregnancy and vertical transmission
- Neglected or emerging childhood infections.

Arising from our key scientific priorities, our **scientific working groups**

have been working to lead the development of new research concepts, training programmes and activities in each of these scientific areas. With five **scientific working groups** in place in 2022, we reviewed the Penta ID Network organisational structure to enable greater transparency, decision making and collaboration.

The scientific working groups focus on:

- Bloodborne viruses
- Respiratory infections
- Severe bacterial infections and antimicrobial resistance

- Infection in pregnancy and vertical transmission
- Fungal Infections.

Training and Education, Basic Science and Clinical Pharmacology are **cross-cutting themes** across the scientific working groups. Thinking ahead, we also created an Early Career Researcher working group, benefitting from mentorship from senior members of the Network.

## STORIES FROM PENTA



**David Burger,**  
Penta ID Network  
Clinical Pharmacology  
working group lead,  
The Netherlands

*“What sets Penta apart is the way it values collaboration and respect for each other’s expertise.”*

For the past 25 years, I’ve had the privilege of being a member of the Penta ID Network. Penta has been more than just a network to me – it’s been like a family. What sets Penta apart from other organisations is **the way it values collaboration and respect for each other’s expertise**. This is something I’ve experienced firsthand through the Penta working groups.

I am the Chair of the Clinical Pharmacology working group, which has been set up to drive Penta’s scientific work in this area. Our group focuses on optimal dosing of antimicrobial treatment of paediatric infectious diseases, including pregnancy. We are here to strengthen Penta’s capacity to perform pharmacometrics research and ensure that pharmacokinetic studies are nested within Penta’s clinical studies whenever possible.

Thanks to the working group, we have an opportunity to support Penta’s research studies by working closely with experts in the areas of HIV and tuberculosis, viral and fungal infections, antimicrobial resistance, as well as with other distinguished international partners.

It is inspiring to see the diversity within our group, **with pharmacologists from Europe, Africa, and Asia** coming together to work towards a common goal.

But what’s truly remarkable is **the sense of initiative and purpose we all share**. We proactively support Penta’s research agenda by bringing in our clinical pharmacology expertise. The only problem, as I often joke, is that there are only 24 hours in a day...



## Early Career Researchers

A key focus for the scientific working groups is facilitating the involvement of early career researchers to support the sustainability of the Penta ID Network. In 2021, we set up an early career researcher's (ECR) working group, where all ECRs in the Penta ID Network can come together to share ideas, learnings, 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 by:

- Developing a Penta mentoring programme, as well as channels for peer support
- Providing training opportunities and an information platform specifically tailored to ECRs
- Promoting involvement in the Penta ID Network and sharing career development opportunities.

## STORIES FROM PENTA



**Tom Jacobs,**  
member of Penta ID  
Network Early Career  
Researcher group, UK

*“If you change the beginning of the story, you change the whole story”*

Raffi Cavoukian

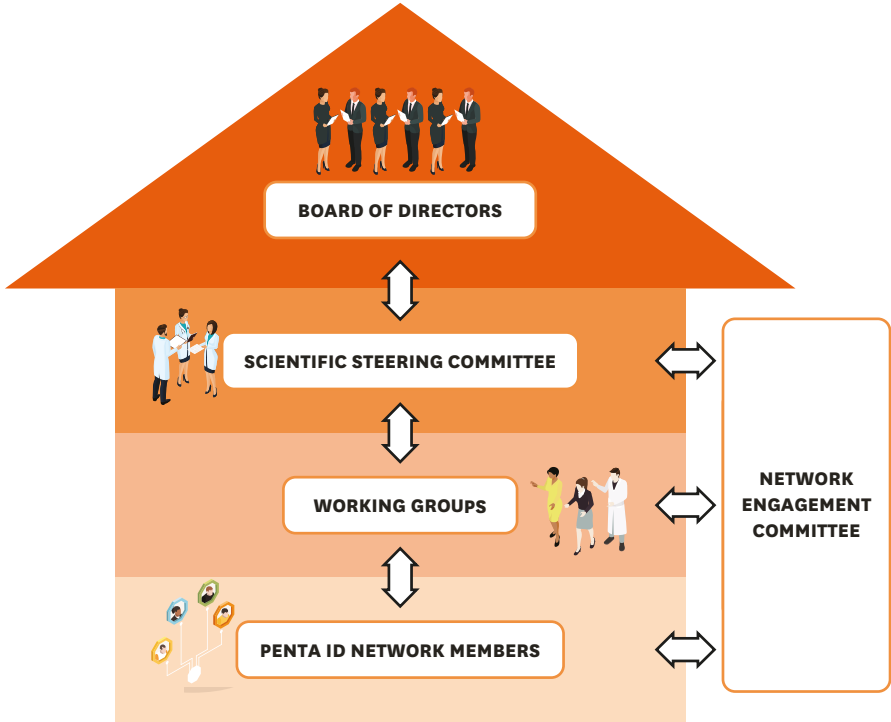
It is through my PhD research on clinical pharmacology of anti-infectives in children living with HIV that I became involved in Penta (EMPIRICAL and D3 trials). Being an early career researcher, I immediately felt very welcome in the Penta family. On top of that, **Penta provides many opportunities to develop ourselves professionally**, make friends who have a shared passion (improving child health) and collaborate with colleagues coming from different countries and cultures. Child health research is crucial as children are the most vulnerable and delicate population with the longest life ahead of them. Unfortunately, there is still a significant gap between, for example, the number of medications being available for

children compared to adults. With my future research, **I hope to contribute a little bit to closing that gap.** It is fantastic to see the important position that PK research has acquired within Penta’s strategic trials. Studies like ODYSSEY have shown that PK studies are essential to accelerate access to novel antiretroviral drugs for children. **However, none of that would have been possible without the multidisciplinary collaboration within Penta** and with partners, that resulted in rapid implementation of research, fast roll-out of new medications, and incorporation of the treatment recommendations in clinical guidelines. **Penta facilitates all that** and brings together knowledge from different disciplines to close the children-adult gap as soon as possible!





## 2. HOW WE OPERATE



### Engaging with our Network members

Our Network members are involved in everything we do at Penta. We meet regularly at online and face-to-face Scientific Meetings, recurrent information online webinars – such as Penta ‘Aperitivo’ webinars – and connect with members through our communications. All of these provide an avenue for members to share information, to network and strengthen their collaboration.

In 2022, we designed a new governance structure for the Network, to ensure more transparency and support its expansion.

There is now a more streamlined membership process and cohesive reporting line structure.

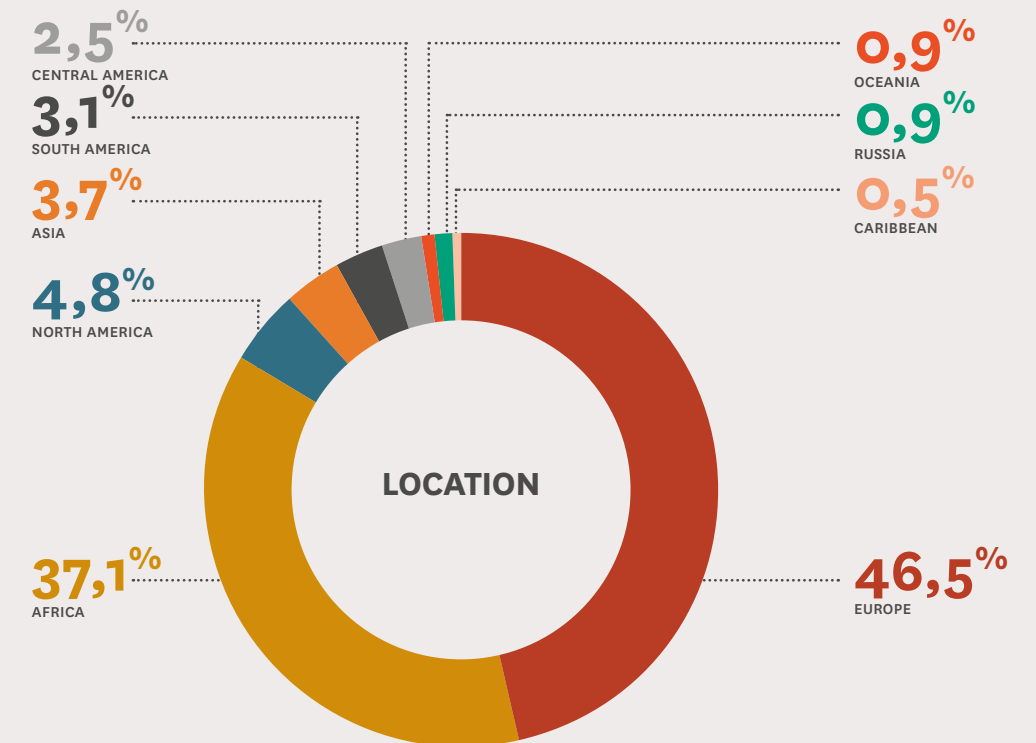
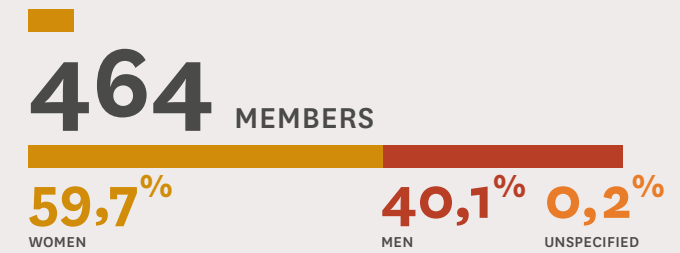
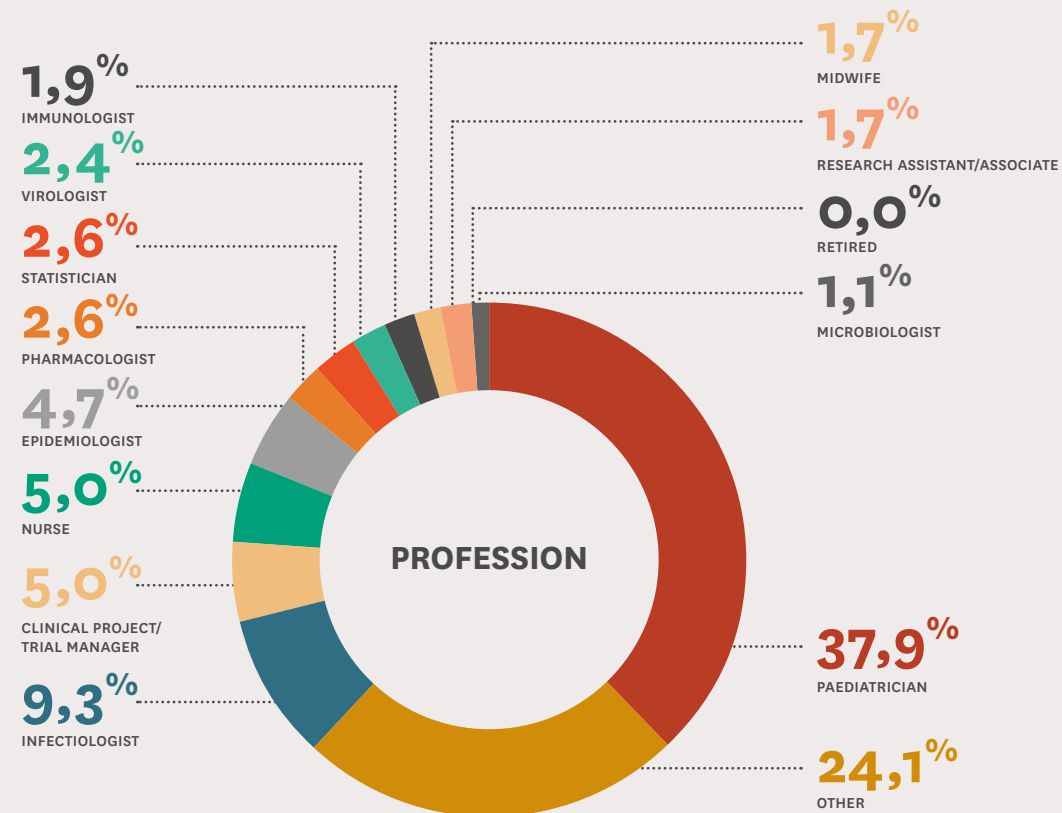
As part of this structure, we have established the **Network Engagement Committee (NEC)**, to ensure engagement of every member. The NEC is responsible for:

- designing and implementing the Network engagement plan and initiatives
- accepting/rejecting membership requests
- tracking and evaluating the expansion of the Penta ID Network.



# The Network

as of 31 December 2022





# Penta Foundation

We invest in projects that improve the lives of mothers and children with infections.

The Penta Foundation is a non-profit organisation of social utility (under Italian Legislative Decree no. 460 of 4 December 1997) set up in 2004 by "Comitato Assistenza e Ricerca AIDS Pediatrico C.A.R.A.P – ONLUS" (AIDS Paediatric Assistance and Research Committee - non-profit organisation).

The Foundation's scope is to develop, promote and support scientific research of particular social interest concerning disadvantaged people in the field of paediatric infectious (and general) diseases. In this context, the Foundation is a coordination hub of a network of scientists, researchers and healthcare professionals at an

international level, dedicated to child health. In this role, it is a promoter of clinical studies, it leads national and international research projects and delivers training programmes.

The Foundation has adopted an Organisation, Management and Control Model under the Italian Legislative Decree No. 231 of 8 June 2001, related to the "Administrative

liability of legal entities, companies and associations, including those lacking legal personality". This Model includes the appointment of a **supervisory body** and an **ethical code** that outlines the general behavioural standards to which all people working or collaborating with the Foundation must adhere.

## Penta Foundation Governance

### Penta Foundation's Board of Directors.

The current members are:

- **CHAIR**  
*Carlo Giaquinto*
- **VICE CHAIR**  
*Diana Gibb*  
*Mike Sharland*
- **BOARD OF AUDITORS**  
*Francesco Gallo* (President)  
*Francesco Grassi*  
*Elisa Mormile*
- **SECRETARY GENERAL**  
*Francesco Simone*
- **Carlo Giaquinto** (*Chair*), Paediatrician and Professor of Paediatrics at the University of Padua, Italy
- **Diana Gibb** (*Vice Chair*), Paediatrician and Professor of Epidemiology and Clinical Trials at MRC Clinical Trials Unit at University College London, UK
- **Mike Sharland** (*Vice Chair*), Paediatrician and Professor of Paediatric Infectious Diseases at Centre for Neonatal and Paediatric Infection, St George's University London, UK
- **Paolo Rossi**, Immunologist and Professor of Paediatrics at the Children's Hospital Bambino Gesù/ University of Rome Tor Vergata, Italy
- **Claire Thorne**, Epidemiologist and Professor of Infectious Disease Epidemiology in the Population, Policy and Practice Research and

Teaching Department, UCL Great Ormond Street Institute of Child Health, University College London, UK

- **Elizabeth Robinson**, Co-Founder, Vice Chairman at Indaco Venture Partners SGR.

The six members of the Board define the rules and practices by which the Foundation is directed and controlled. They review and approve the yearly financial statements. The Board delegates the day-to-day management of activities to the Senior Leadership Team, which is composed of the Chief Financial Officer, the Chief Program Officer and the Chief People, Communications & Culture Officer.

Furthermore, in the spirit of full transparency and to ensure compliance with applicable laws and regulations, Penta Foundation's Board of Directors has adopted

a supervisory structure composed of a **Statutory Supervisory Body** and a **Supervisor** for the verification of compliance with the Italian Legislative Decree 231/2001.

As a constructive mechanism for promoting continuous improvement, the Board undergoes a periodic performance self-assessment.

In accordance with EU Regulation 679/2016 General Data Protection Regulation (GDPR), Penta has appointed a **Data Protection Officer**, an external expert consultant who assists the Foundation in the implementation of the Guidelines of the European legislation on personal data protection and who constitutes the contact point between the Italian Data Protection Authority and any person interested in the way we manage personal data.





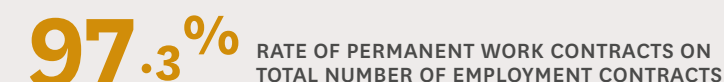
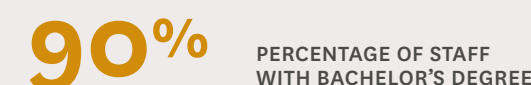
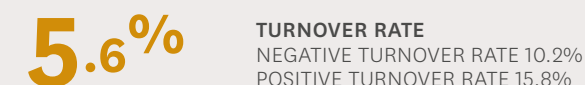
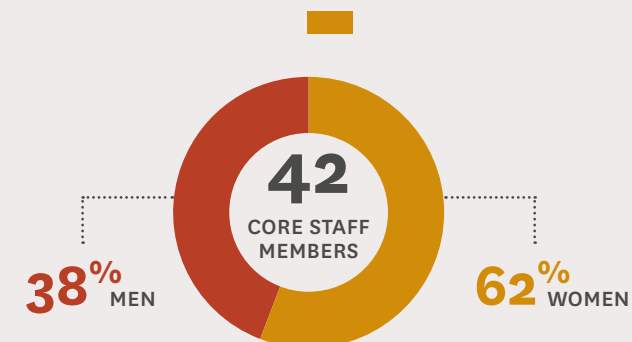
# Penta Foundation staff

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.

## 2. HOW WE OPERATE

# Our staff

AS OF 31 DECEMBER 2022





## Our responsibility towards our People

As part of our 2020-2025 strategy, we are making positive interventions to embed the ethos of **diversity, equity and inclusion** into policies, processes and everyday practice, working to eliminate barriers to participation and success. An example of this is **blind recruitment**, which is the practice of blocking out some personal information from candidate applications, in order to prevent recruiter bias, both conscious and unconscious. This is now our standard practice for selecting new employees.

In 2021, we started to analyse the gender dimension in our mode of operation, based on the Gender Equality Assessment Implementation (GEAI). The data we collected showed that Penta had achieved 54.15% of GEAI in 2021. Our goal is to achieve even greater equality rates in the coming years. The

way we will achieve this has been outlined in our Gender Equality Plan (GEP), which is our structural plan of objectives, actions and targets. As part of the Plan, we appointed an Equality Officer and set up a Gender Equality working group to implement and monitor the progress of the GEP. In 2022, the Gender Equality working group and the Equality Officer started planning and realising initiatives to engage the Penta Foundation staff in enhancing gender equality within the Foundation and, in general, promoting diversity, equity and inclusion.

Our commitment to high levels of equity does not stop with our employees. We strive to build gender equality in research and training, both on the side of researchers and trainers, and on the side of patients and trainees day by day.

In 2022, we significantly improved our **Company welfare**. Penta's paternity leave package was strengthened: we added 21 days of fully paid leave covered by the Foundation to the 10 days fathers are entitled to under Italian law. We also introduced a four-month remote working option reserved for new fathers.

As a new measure to improve employees' wellbeing at work and ensure equal opportunities, we introduced a 2-day per month **paid menstrual leave option** for women with certified dysmenorrhea. *"This initiative is the result of an internal reflection on how to guarantee a balance between work efficiency and our employees' health and wellbeing,"* said **Giuseppe Bonura**, Chief People, Communication and Culture Officer at Penta Foundation. *"We realised that women*

*with dysmenorrhea may experience challenges in achieving such balance, and that it is our responsibility to support them in any way possible. Our view is that an organisation should be able to support employees during difficult personal circumstances, whether they are temporary or permanent. An inclusive workplace environment is one where personal difficulties do not hinder career progression, and we are committed to taking further steps in promoting such an environment."* In 2022, 10% of the Foundation staff used Penta paid menstrual leave.

Regarding career progression, Penta increased the number of paid study hours available to employees for educational courses. While the national contract guarantees 150 hours of study permits over three years, Penta increased this to 400 hours, with

250 usable in a single year. In 2022, 15% of the Penta Foundation employees used study permits for a total of 423 hours.

Because we believe our success relies on highly qualified and motivated employees, in 2022, we launched the second edition of the **Penta Education call** to support their individual career plans in a transparent manner. The call was open to all our employees, with at least 50% of the funds reserved for female employees. The 2022 Education call provided €17,900 to fund job-specific training: 53.8% of our employees received financial support, with a total of 97.5% applications accepted.

The core competences Penta funded are related to project planning, proposal writing, international financial reporting standards, science writing, public health,

health economics, people management, international commercial terms.

In addition to this, all Penta Project Managers attended a Prince2 Project Management course and obtained the certification.

To support the Foundation's **digital transformation**, we invested in continuous learning for our employees to improve their IT skills. By nurturing new tech talent, we managed to move our file managing system to the cloud, and thus strengthened Penta's cybersecurity. A total of 12 staff members (sorted by area of competence based on the topics) were involved in these trainings, of whom 46% were women and 54% were men.

A total of 60 hours of training aimed at improving IT skills were issued.

## STORIES FROM PENTA



**Eleonora Brugiolo,**  
Penta Foundation HR  
Specialist and Equality  
Officer, Italy

*“I believe that promoting an inclusive work culture does not mean flattening diversity but giving everyone the same opportunities while embracing their unique qualities”.*

Penta's journey towards Diversity, Equity and Inclusion (DEI) started in 2020, but it was in 2022 that we saw a turning point with the launch of the Gender Equality Plan and the creation of the Gender Equality working group, which introduced the role of Equality Officer.

In this position, I've had the privilege of supporting my colleagues at Penta Foundation in understanding our long-term vision and objectives for DEI, which go beyond the goal of achieving gender equality. Our Plan provides us with **a clear sense of direction**; I have helped the staff realise that, for something significant for them as individuals to occur, they have to be part of this change.

In its 5-year strategy, Penta set 5 objectives to pursue through science and education:

**to nurture, to develop, to deliver,  
to collaborate and to inspire.**

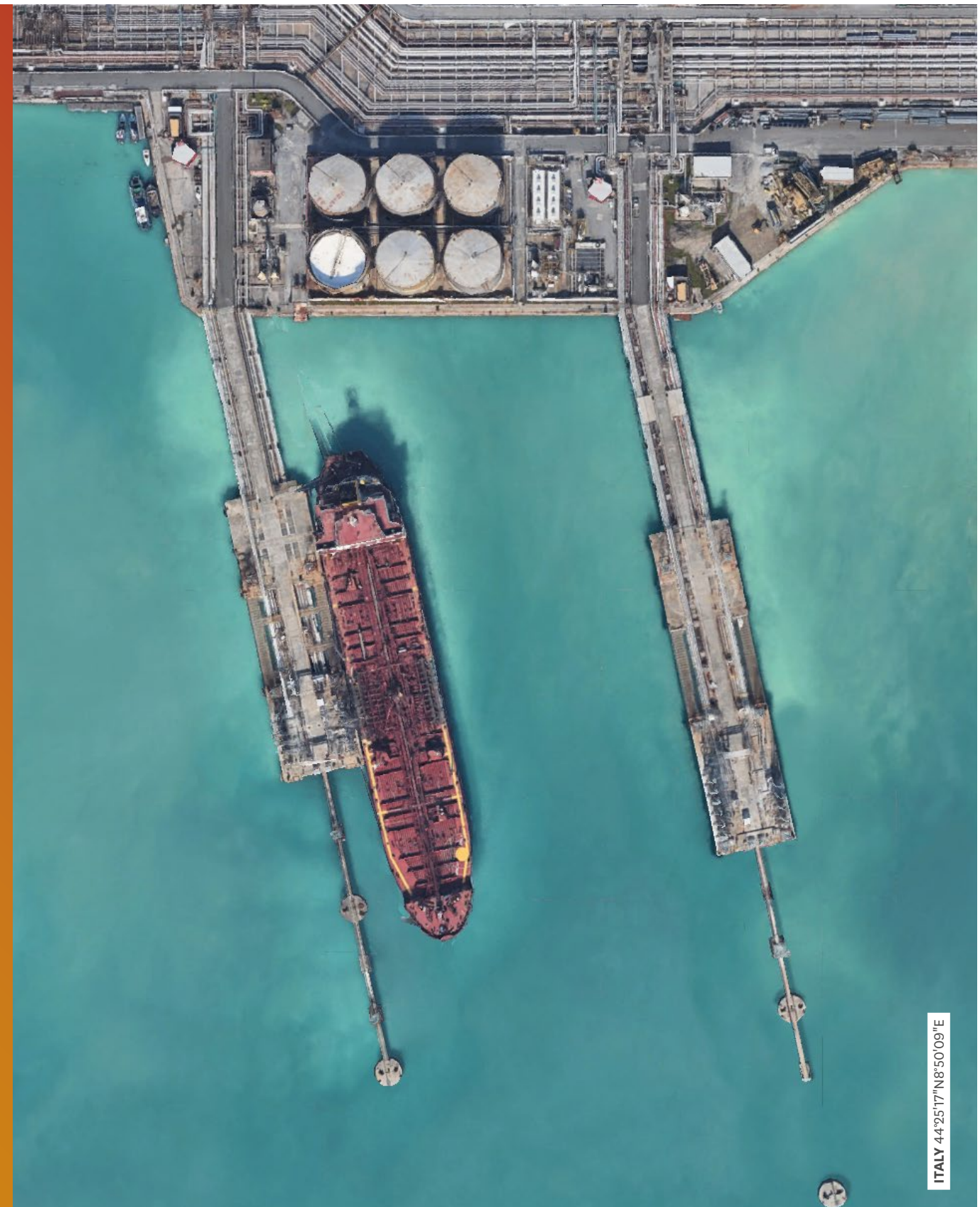
Well, I believe that these can also be used to describe our objectives from a DEI perspective. We strive to *nurture* a shared culture of real acceptance and inclusion; to *develop* the path towards DEI through concrete and engaging initiatives; to *deliver* results to the staff in terms of continuous improvement of the work environment; to *collaborate* with organisations and institutions which have the same view, in order to maximise Penta's social impact; and finally, to *inspire* other organisations and communities to work to improve their DEI practices.

All of this may sound idealistic, but we have already conducted activities that engage all Penta staff in this effort. For instance, we launched a workshop to help staff recognise and overcome biases that affect effective communication. The aim is to create a shared, inclusive culture through common definitions, language, and attention to diversity.

No matter how many policies Penta implements to improve our employees' wellbeing, nothing can **match the effect and value of a collective effort** to embrace the topics of diversity and inclusion. Inclusion, team spirit, responsibility and transparency are our guiding principles: the research that we promote is global, independent and inclusive, therefore it is imperative that these features are reflected within our organisation.

For me as a staff member, the work towards DEI has increased my sense of belonging and sharing and has given concrete shape to principles that value every worker as an individual. As Equality Officer, I believe that promoting an inclusive work culture does not mean flattening diversity but giving **everyone the same opportunities while embracing their unique qualities.**

I am honoured to be Penta Foundation's Equality Officer and hope to continue setting new standards for Diversity, Equity and Inclusion at Penta!



ITALY 44°25'17"N 8°50'09"E





## Our respect for the planet

We want our offices to be great places for our people—and for the environment.

One way we bring our purpose to life – to build a global network that conducts excellent research to help health systems achieve optimal outcomes for children – is by integrating environmental considerations into our research and operations.

As an international network, people are at the heart of everything we do. As such, face-to-face meetings are essential for us, and **travelling** has always been a distinctive feature of our approach. While it provides numerous advantages in terms of delivering global impact, such as facilitating research, exchange of ideas and improving partnerships, it also contributes to our annual carbon footprint. We are mindful of the fragility of the environment in which we live. For this reason, we have introduced a Travel Policy aimed at promoting essential, sustainable and responsible travel.

Here is what we recommend our employees and collaborators to do:



USE VIRTUAL COLLABORATION TOOLS TO REPLACE TRAVEL, WHERE IT MAKES BUSINESS SENSE



TRAVEL ONLY WHEN IT IS NECESSARY FOR BUSINESS PURPOSES



KEEP INTERCONTINENTAL FLIGHTS TO A MINIMUM



COMBINE MULTIPLE TRIPS INTO ONE. FEWER TRAVELS EQUAL LESS CARBON EMISSIONS AND INCREASED PRODUCTIVITY



AVOID PRIVATE CAR TRANSPORTATION FOR BUSINESS TRAVEL, WHENEVER POSSIBLE



CONSIDER GREENER TRANSPORTATION ALTERNATIVES, SUCH AS TRAINS OR HYBRID, ELECTRIC AND LOW CARBON VEHICLES

With the introduction of hybrid working as a permanent work mode for all Penta Foundation staff beyond the COVID-19 emergency, we saw a considerable decrease in the impact of employee commuting on our carbon footprint, which sat at 18,005 kg of CO<sub>2</sub> emissions in 2022 compared to 45,012 kg if they were to commute every day.

Additionally, we made a deliberate effort to choose training courses that could be completed online by our staff, therefore minimising the environmental impact of travel and promoting a better work-life balance for our employees.

To minimise our waste footprint, we are reducing **single-use plastic** in our offices and expanding our recycling programmes. We have dramatically reduced the amount of printed paper in our offices and have gone

completely digital with our corporate communication and dissemination activities.

We are also engaging our suppliers to help reduce their footprint. We have made this a core topic in conversations with our collaborators and vendors, and we are continuing to work with them to strengthen our environmental performance.

We are working to weave this mindset into all areas of our action — from the Foundation's operations to our studies implementation — to achieve our goals while also creating long-term value for all our stakeholders.



# Penta Foundation core competencies

In 2022, 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 brings together organisational and technical expertise to support the development of key areas of work. The team collaborates with experts from the extensive Penta ID Network to deliver **high quality and innovative data services** to healthcare research. From data management planning and data collection for observational studies to validation, transformation, long term storage, secondary use of data, dashboarding and computing infrastructure as a service.

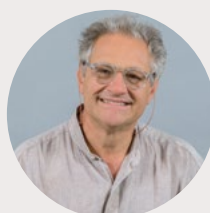
In 2020, a seed was planted by the DM&I team promoting **a technical and cultural shift toward**

**cloud technologies and information security**. A digital transformation to improve efficiency and innovation within Penta fully blossomed during 2021 and 2022. The DM&I team now handles health research data with the efficiency, security, and regulatory compliance that only modern cloud technologies can ensure. As we move onto 2023, we are working to bring machine learning and Real-World Data (RWD) approaches to the forefront of our commitment to support excellent healthcare research within the Penta ID Network.

## Program Operations

The Operations team **guides the initiation and management** of global research projects in different infectious disease areas in children and pregnant people, ranging from HIV to AMR and the most recent COVID-19 pandemic. The team brings together **Project Management, Clinical and Regulatory expertise**. Comprising professionals with **certified competencies**, they ensure sound project management through study document writing, ethics and regulator submission, site training and management, support to local project management teams, contract and budget management, writing and review of official fund reports and coordination of large international consortia.

Furthermore, our Clinical Project Managers work alongside Clinical Trial Units (CTU) and Clinical Research Organisations (CRO) in delivering global clinical trials that will **facilitate the authorisation** and use of paediatric formulations for HIV and other infections treatment. With our regulatory expertise, we continue to act as the primary point of contact for Regulatory Agencies and the European Medicines Agency for Paediatric Investigation Plan applications. Furthermore, the Operations team supports the Network working groups, ensuring new ideas arising in the Network become the basis for **new successful projects**, that contribute to achieving Penta's mission.



**PRESIDENT**  
Carlo Giaquinto



**CHIEF PROGRAM OFFICER**  
Laura Mangiarini

- NETWORK, EDUCATION AND TRAINING
- PROGRAM OPERATIONS
- DATA MANAGEMENT AND INFRASTRUCTURE



**CHIEF FINANCE AND ADMINISTRATION OFFICER**  
Luigi Comacchio

- FINANCE
- LEGAL
- ADMINISTRATION



**CHIEF PEOPLE, COMMUNICATIONS AND CULTURE OFFICER**  
Giuseppe Bonura

- HR
- COMMUNICATIONS
- IT
- QUALITY ASSURANCE

*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.*





## Quality Assurance

Penta is committed to promoting and maintaining a quality-focused culture to ensure the delivery of **high-quality, meaningful research.**

At Penta, we define quality as meeting and exceeding expectations in all critical aspects of research, including:

- Ensuring participant safety and wellbeing
- Safeguarding compliance with regulatory requirements and international standards

and guidelines

- Streamlined and efficient operations based on structured and documented processes.

Our approach to managing quality is through the Penta Quality Management System (QMS), as an instrument to achieve the intended objectives, guarantee compliance with requirements and expectations, and promote continuous improvement. We do this by holding ourselves accountable to **the highest standards** and by requesting

that the same standards are adopted by our collaborators when working with us.

In 2022, Penta successfully reviewed and implemented core policies and procedures to maintain adherence to principles and requirements as prescribed by regulatory bodies, and to the expectations of our partners. We took this as a chance to benchmark our performance and identify new opportunities for improvement to be implemented in 2023.

## Finance, Legal and Administration

Penta values transparent and sound financial management and promotes a culture of **strict compliance with national and international standards.** The Finance, Legal and Administration team works to guarantee the efficient and effective use of financial resources and provides the Penta ID Network with the legal expertise it requires to achieve success in its endeavours.

## Network, Education and Training (NET)

The NET team brings together training, education and Penta ID Network management to support the development and synergy between these key areas of work. 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 digital e-learning methods, with 'hybrid' delivery modes also becoming increasingly effective in the 'post-pandemic' era.

In 2022, we forged ahead with the update and expansion of our teaching curricula and online PentaTr@ining infrastructure, successfully delivering exciting **new programmes** in both fungal infections and viral hepatitis in paediatrics.

Moreover, we have continued to further embed the **participation of young people** in the design and delivery of our courses. This is another key area of work for the NET team more broadly, supporting and coordinating the involvement of children and young people across all of our work in Penta.

The team provides structure and management to the Penta ID Network. In 2022, we initiated the Early Career Researchers (ECR) working

group to support young researchers across the globe to develop their careers.

To enable greater collaboration between all of our members, we launched the Penta ID Network Membership and implemented some improvements to the organisational structure of our Penta ID Network, so that we can ensure we are building **a Network that is truly built to last.**

## Communications

Penta is committed to openly communicating its methods and results, as well as participating in public debates around the **role of science** and the importance of paediatric and pregnancy research in our society. Penta's Communication team, a diverse and experienced group of people, coordinates the communications activities of the Foundation and across Penta's projects. Our goal is to bring attention to the needs of mothers and children with infections and make sure they are a priority for decision

makers. Aside from supporting the dissemination of outcomes from Penta's project and studies, the Communications team strives to **raise public awareness** of Penta and its commitment to excellence. Strengthening our connection with youth and patient groups has been one of the highlights of 2022. We've continued our fruitful work with the Youth Trial Boards, our scheme of active patient participation in paediatric HIV clinical trials. We view these Boards as playing a crucial role in helping society and the general community

understand the relevance of our research, and ensuring that the ethos of "Nothing about us, without us" is central to everything we do. Additionally, we oversee and support the communication activities of the Penta Young Reporters, a team of **young influencers** who want to translate science into effective social media content and better inform their peers about HIV care. As Penta's Communication team, we are always on the lookout for ways to improve and stay up to date with the latest techniques and

trends in communications, particularly with regard to inclusive communication. In 2022, we endorsed the People First Charter and committed ourselves to using and promoting **person-first language** in the field of HIV. We will continue to expand our efforts on the use of non-discriminatory and non-stigmatising language in every disease area and pledge to promote respectful and inclusive communication practises in all aspects of our work.



# Our key partners

Our passion for collaborative research and knowledge sharing never ends. We will continue to grow our Network of researchers and build new partnerships to expand our research and training.

Penta's clinical research is only made possible through our long-standing collaboration with three leading clinical trial centres: MRC CTU at UCL (UK), INSERM (France) and PHPT (Thailand).

Our commitment to keeping the focus on children's need for better medicine is also reflected in our partnerships and collaborations. The Global Accelerator of Paediatric Formulation – **GAP-f**, which we contributed to set up, entered into its implementation phase this year. GAP-f is a WHO-led innovative collaborative model that will accelerate the availability of optimised treatment options for infectious diseases such as HIV, tuberculosis and viral hepatitis affecting children in low- and middle-income countries. Within this partnership, we are leading

the Clinical Research working group, that will facilitate all the clinical research activities in the GAP-f portfolio.

Another one of our key partners is the Global Antibiotic Research & Development Partnership – **GARDP**, which is committed to tackling serious and drug-resistant infections in children by accelerating the development of antibiotic treatments with a focus on global neonatal and paediatric strategic trials aiming to build the evidence base for public health interventions and inform treatment guidelines.

We are also engaging in strategic alliances with key players in the infectious diseases landscape. With the University of Verona, we are partnering in programmes like ORCHESTRA and VERDI to set the framework for

preparedness in the fight against future pandemics.

We have also entered into several framework collaboration agreements with other organisations that help us deliver our vision. In Italy, our key partners are Ospedale Pediatrico Bambino Gesù (**OPBG**) in Rome and the University of Padova. With the clinical team at the Paediatrics Clinic at the University of Padova (**UNIPD**), we integrate clinical expertise with regulatory and operational skills to ensure that our research produces information which can be translated into practice and accessible medicines.

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

We have strengthened our collaboration with Doctors with Africa CUAMM, a Non-Governmental Organisation based in Italy. Together, we aim to develop programmes to protect vulnerable communities in Sub-Saharan Africa.

Penta is a member of the European Network of Paediatric Research at the European Medical

*"The University of Verona and Penta have formed a dynamic working relationship, combining forces to research existing and new threats in the area of infectious diseases. Thanks to its vast network of children and cohorts of pregnant women worldwide, Penta is able to provide insight into the clinical and epidemiologic characteristics of diseases as they pertain to these specific groups. This perspective is important not only to provide valuable data for the management of infectious diseases in these vulnerable population groups but also because they provide valuable information concerning epidemiology and disease transmission that can have an impact on diseases in adults".*

**Evelina Tacconelli**, Professor of Infectious Diseases, University of Verona, Italy

Agency (**Enpr-EMA**). We are also part of the WHO's Paediatric Antiretroviral Working Group (**PAWG**) and Paediatric Antiretroviral Drug Optimization (**PADO**).

Thanks to **EPPICC** (European Pregnancy and Paediatric Infections Cohort Collaboration) and **EPIICAL** (Penta's cohorts platform focused on HIV), we have expanded our partnerships further. The **EPPICC** collaboration has taken on the legacy of EUROCOORD, an EU-funded Network of Excellence established in 2011

by the biggest HIV cohorts and collaborations within Europe: CASCADE, COHERE, EuroSIDA, and Penta. Today, EPPICC comprises 12 pregnancy cohorts in 9 countries and 24 paediatric cohorts in 18 countries in Europe and Thailand. By sharing scientific expertise and resources, the EPPICC cohorts are collecting safety data on antiretrovirals after their rollout into the market.

The EPIICAL collaboration has expanded to new world class laboratories and new cohorts from resource-limited settings.

This collaboration is becoming a unique basic research asset for infections beyond HIV.

We have started new collaborations in the area of research on COVID-19. We are bringing the expertise and capabilities of our Penta ID Network into **Vac4EU** (Vaccine monitoring Collaboration for Europe), an open community for scientific debate and study implementation around COVID-19 vaccines. Pedianet, a database of electronic medical records of children visiting general practitioners in Italy, is among them.





### 3. ACTIVITIES AND ACHIEVEMENTS

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



# Research activities

In more than 30 years of collaborative research on HIV, we are proud to have contributed to the development of key medicines, which have changed the prognosis and quality of life of children living with HIV across the world.



**Laura Mangiarini**  
Pentia Foundation  
Chief Operations  
Officer, Italy

Although our commitment to paediatric HIV has not changed (much is still to be done: we want to move from treatment to CURE!) we are applying our collaboration model, experience, best practices and lessons learned across the wide range of serious infections which threaten our children. We now have open studies targeting serious neonatal infections (viral, bacterial or fungal), antibiotic resistance, and new pathogens with pandemic potential.

We build our projects in a way that ensures **the sustainability of the expertise and outputs** deriving from these collaborations. VERDI is an example of this model:

born as a platform to study SARS-CoV-2 variants, then expanded to mpox and further, it is now developing a preparedness platform to be activated as new pathogens emerge.

Looking to the future, we will continue to build on the potential of using and re-using study data and exploit all the potential of the information deriving from the analysis of data from the real world, building processes which allow us to face all the legal challenges which come with these new approaches.

We will be targeting respiratory infections, which are becoming a new threat to our children, like the Respiratory Syncytial Virus.

We will be designing new studies testing not only traditional chemical compounds, but also **vaccines and monoclonal antibodies**.

Nothing of the above could be done without our Network of researchers across the world, which allow us to provide the right expertise where it is most needed and at the right time... and to continue to be a global network at the forefront of science.



# Ongoing research activities

Penta has a strong portfolio of studies and projects driving sustainable growth.

HIV

Antimicrobial resistance

Other viruses

Network building

COVID-19 Projects & Studies

# 2021 studies and projects

HIV

We support research that seeks to better understand both the dynamics of transmission and how to obtain optimal health outcomes for pregnant women and children.

## ODYSSEY

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

**Aim**

To assess the efficacy and toxicity of dolutegravir plus 2 NRTI versus standard of care among HIV positive children and adolescents

*from 2014 until 2024*

*Total budget*

**€ 15,764,263**

*Funder*

**ViiV Healthcare**

*Penta's Role*

**SPONSOR**



## STORIES OF IMPACT



**Eleanor Namusoke Magongo,**  
Team Lead Pediatrics and Adolescent  
HIV Care & Treatment AIDS Control  
Program, Ministry of Health Uganda

*"We need to get to that point where we begin to see more research conducted in favour of children."*

When we compare the treatment options that are available for children and adults, we know that there's a limitation for children. We need to see pharmaceutical companies manufacturing more child-friendly formulations, that will foster treatment adherence. Paediatric dolutegravir (DTG) has changed the treatment landscape in a very positive trajectory. Children now have a once-a-day treatment option, and this is great! We have started to notice upward trends in the proportions of children with HIV viral load suppression, an indicator which had stagnated for years in some countries. However, we need to remember that even with a good drug like paediatric DTG, we must maintain a holistic approach to care for the children, and also, we need to continue addressing the structural barriers that lead to the interruption of treatment. If we ignore this, we could soon find ourselves where we started before the DTG era, where children did not adhere to their treatment, which led to mutations and subsequent HIV drug resistance. It is also important for us to

ask ourselves this important question: how are we supporting the parents and caregivers to support their children better? We have invested heavily in HIV interventions at facility level; it is now time for us to do the same for community interventions if we are to achieve our goal to end AIDS by 2030. It is in the community, and at household level, that children begin to fail on treatment for various reasons like multiple, and many times, elderly caregivers, non-disclosure of HIV status, lack of transport, gender-based violence in the homes, stigma, and low treatment literacy. As we work to address the household and community challenges, we need formulations that will work around these structural barriers. We need to dream and work towards a time, when we can have child-friendly formulations and treatment delivery methods that will reduce the frequency of taking antiretroviral treatment from a daily routine to at least once a quarter, or even better, a longer duration. LET US KEEP DREAMING AND WORKING TOWARDS MAKING OUR DREAMS A REALITY.

## 3. ACTIVITIES AND ACHIEVEMENTS

### D3

*A randomised non-inferiority trial with nested 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*

#### Aim

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*

*Total budget*  
**€ 15,245,002**

*Funder*  
**ViiV Healthcare**

*Penta's Role*  
**SPONSOR**

### EMPIRICAL

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

#### Aim

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 2024*

*Penta budget*  
**€ 571,420**

*Total budget*  
**€ 7,680,619**

*Funder*  
**European Commission – EDCTP2**

*Penta's Role*  
**PARTNER**

### EPIICAL

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

#### Aim

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

*from 2020 until 2024*

*Total budget*  
**€ 8,502,850**

*Funder*  
**ViiV Healthcare**

*Penta's Role*  
**COORDINATOR AND SPONSOR**



EPPICC

<i>Cabotegravir Study</i>	<i>Dolutegravir Study</i>	<i>Tenofovir Alafenamide Fumarate (TAF) Study</i>
<i>Pregnancy and Neonatal Outcomes following Prenatal Exposure to Cabotegravir Long Acting (CAB LA): Data from EPPICC.</i>	<i>Clinical outcomes of children and adolescents with HIV taking DTG in Europe and Thailand: an EPPICC study.</i>	<i>Effectiveness and safety of tenofovir alafenamide fumarate (TAF) based therapy in children and adolescents living with HIV in Eastern and Western Europe: An EPPICC study.</i>
<b>Aim</b> 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	<b>Aim</b> 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 dolutegravir-based regimens to inform future policy and practice	<b>Aim</b> 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 TDF, and increased gain in BMI
<i>from 2021 until 2027</i>	<i>from 2022 until 2025</i>	<i>from 2022 until 2024</i>
<i>Total budget</i> <b>€ 1,030,575</b>	<i>Total budget</i> <b>€ 2,005,380</b>	<i>Total budget</i> <b>€ 802,705</b>
<i>Funder</i> <b>ViiV Healthcare</b>	<i>Funder</i> <b>ViiV Healthcare</b>	<i>Funder</i> <b>Gilead Sciences, Inc.</b>
<i>Penta's Role</i> <b>COORDINATOR</b>	<i>Penta's Role</i> <b>COORDINATOR</b>	<i>Penta's Role</i> <b>SPONSOR</b>

DOLOMITE

*Dolutegravir in pregnant women and exposed infants in Europe*

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

*from 2018 until 2023*

*Total budget*  
**€ 3,139,242**

*Funder*  
**ViiV Healthcare**

*Penta's Role*  
**COORDINATOR**

STORIES FROM PENTA



**Giorgia Dalla Valle,**  
Penta Foundation  
Clinical Project  
Manager, Italy

*“Given my midwifery background, I am particularly fascinated by the value and the power of EPPICC.”*

I have the privilege of coordinating the project management activities of the European Pregnancy and Paediatric Infections Cohort Collaboration, EPPICC.

EPPICC is a Network of national or regional cohorts, and in some cases single centres, in Europe and beyond, which collects data on pregnant people, children and adolescents living with HIV or with other infections like TB, hepatitis and COVID-19. What makes this programme of work **unique, is the model used for data collection**, consisting of regular data extractions conducted by the cohorts, based on data merger protocols. This allows the collection of a very large and geographically diverse pooled dataset. Another peculiarity is that **the cohorts' researchers play an active role** in proposing analysis to be conducted with the pooled data, which can address research questions requiring a large sample size of patients, impossible to answer by individual cohorts.

It soon became evident to me **the central role EPPICC plays in providing real world data** reflecting the actual clinical practice to

examine the long-term effects of infections and treatment, identify the regional variations, and inform public health policy. Given my midwifery background, I am particularly fascinated by the value and the power EPPICC has in investigating the safety and effectiveness of non-licensed drugs used by pregnant and breastfeeding people. These observational or active surveillance studies are **central to generating** evidence to inform the design of clinical trials which can accelerate the study of new agents in this complex population, usually excluded from clinical trials, and **provide equitable access to new and better drugs**.

Coordinating a large and evolving network may pose challenges, although what characterises EPPICC is the enthusiastic long-lasting collaboration, originating from the European Infant Collaboration in 2009, and whose roots are highly interconnected with Penta's initial HIV network history, made of people, experts in infectious diseases, working together to paint a brighter future for maternal and child health.



<div>EPPPR</div> <div>Embedding Patient Participation in Paediatric Research</div> <div><div>Aim</div><div>To develop a fully digital model of global paediatric patient participation to support the engagement of young people living with HIV in clinical trials</div><div>from 2020 until 2022</div><div><div>Total budget</div><div>€ 171,464</div></div><div><div>Funder</div><div>ViiV Healthcare</div></div><div><div>Penta’s Role</div><div>PARTNER</div></div></div>	<div>HVRRICANE</div> <div>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</div> <div><div>Aim</div><div>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</div><div>from 2018 until 2024</div><div><div>Total budget</div><div>€ 3,145,857</div></div><div><div>Funder</div><div>Henry M. Jackson Foundation and Penta</div></div><div><div>Penta’s Role</div><div>PARTNER</div></div></div>	<div>SHIELD</div> <div>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 antiretroviral therapy (cART) and have dual- or triple-class antiretroviral (ARV) resistance</div> <div><div>Aim</div><div>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 &lt; 18 years and weighing at least 20kg who are failing their current antiretroviral treatment and have dual-or-triple-class ARV resistance</div><div>from 2020 until 2027</div><div><div>Total budget</div><div>€ 9,158,955</div></div><div><div>Funder</div><div>ViiV Healthcare</div></div><div><div>Penta’s Role</div><div>SPONSOR</div></div></div>
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<div>UNIVERSAL</div> <div>Pharmacokinetic and safety studies of new antiretroviral formulations: expediting UNIVERSAL first and second line regimens for all children living with HIV in Africa</div> <div><div>Aim</div><div>To develop two complementary paediatric antiretroviral fixed dose combinations (FDCs) for infants and children newly diagnosed with HIV initiating antiretroviral therapy (ART), and for children failing first line therapy who 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</div><div>from 2021 until 2025</div><div><div>Penta budget</div><div>€ 1,619,218</div></div><div><div>Total budget</div><div>€ 3,999,819</div></div><div><div>Funder</div><div>European Commission – EDCTP2</div></div><div><div>Penta’s Role</div><div>COORDINATOR</div></div></div>
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<div>YOUNG REPORTERS</div> <div><div>Aim</div><div>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</div><div>from 2022 until 2024</div><div><div>Total budget</div><div>€ 170,000</div></div><div><div>Funder</div><div>ViiV Healthcare &amp; Gilead</div></div><div><div>Penta’s Role</div><div>COORDINATOR</div></div></div>	<div>LAAG</div> <div>Long-Acting Injectables Advisory Group</div> <div><div>Aim</div><div>To engage the voice of young people who have recent experience of paediatric HIV care in discussions on the acceptability, challenges and solutions of adopting and use of long acting injectables for them and their peers and how this could support the transition into adult care</div><div>from 2022 until 2023</div><div><div>Total budget</div><div>€ 50,000</div></div><div><div>Funder</div><div>ViiV Healthcare</div></div><div><div>Penta’s Role</div><div>COORDINATOR</div></div></div>	<div>BREATHER Plus</div> <div>A randomised open-label 3-arm, 96-week trial evaluating the efficacy, safety and acceptability of weekends off dolutegravir-based antiretroviral therapy (ART) and monthly long-acting injectable ART compared to daily dolutegravir-based ART in virologically suppressed HIV-infected children and adolescents in sub-Saharan Africa</div> <div><div>Aim</div><div>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</div><div>from 2019 until 2024</div><div><div>Penta budget</div><div>€ 88,187</div></div><div><div>Total budget</div><div>€ 7,401,327</div></div><div><div>Funder</div><div>European Commission – EDCTP2</div></div><div><div>Penta’s Role</div><div>PARTNER</div></div></div>
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# Antimicrobial resistance

Both mothers and children are at the heart of Penta: we work on the prevention of mother-to-child transmission but also on the identification of optimal treatment for babies who are infected, using old and new antibiotics and testing new combinations of antibiotics.

<b>PediCAP</b> <i>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</i>	<b>NeoIPC</b> <i>Establishing innovative approaches for optimal infection prevention of resistant bacteria in NICUs by integrating research, implementation science and surveillance in a sustainable global platform</i>
<b>Aim</b> 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	<b>Aim</b> 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
<i>from 2019 until 2024</i>	<i>from 2021 until 2026</i>
<i>Penta budget</i> <b>€ 792,756</b>	<i>Penta budget</i> <b>€ 3,185,688</b>
<i>Total budget</i> <b>€ 6,997,077</b>	<i>Total budget</i> <b>€ 9,999,817</b>
<i>Funder</i> <b>European Commission – EDCTP 2</b>	<i>Funder</i> <b>European Commission – Horizon 2020</b>
<i>Penta’s Role</i> <b>COORDINATOR AND SPONSOR</b>	<i>Penta’s Role</i> <b>PARTNER</b>

## STORIES FROM PENTA



**Martha Tholanah,**  
PediCAP Community Advisory Board member, Zimbabwe

“For our community, PediCAP is a critical study.”

PediCAP is a study looking at how community-acquired severe pneumonia can be managed by reducing the amount of intravenous medication, thereby reducing the time of hospitalisation and then managing the child at home by giving the child oral medication. This is very exciting for us as a community because it means reducing the time that the child is getting their skin punctured and **reduces pain** because a lot of time as mothers, we feel the pain when the child’s skin gets punctured. This also **reduces the costs** around frequently visiting the hospital and **it is good for the mental health of parents** to be around their children.

For our community, it is an important study as we are getting a lot of information and a lot of education. This spreads around the community, which means that **mortality is reduced** as people get to identify early that a child has pneumonia. People tend to bring their children later to the hospital when the pneumonia is already severe.



**Julia Bielicki,**  
NeoIPC Scientific Coordinator and Penta ID Network Severe bacterial infections and antimicrobial resistance working group lead, Switzerland

“Projects like NeoIPC are important, because they have a mandate to investigate interventions targeting babies.”

Newborns, when admitted to a neonatal intensive care unit (NICU), are the most vulnerable patients. They are **very susceptible to infections** and can get very sick from them. They are also cared for in an environment – the hospital – where it’s very easy for bacteria to be passed on between them.

Current infection prevention and control (IPC) interventions are often carried out by the same IPC team in all the units of a hospital, not just the neonatal unit. This means that a lot of the interventions are not adapted to the specific context of the NICU.

Projects like NeoIPC, that aims to prevent transmission of resistant bacteria in the neonatal intensive care setting, are important because they have a mandate to investigate specific IPC interventions **targeting babies**.

### Value-Dx

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

**Aim**  
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**

*Total budget*  
**€ 14,125,708**

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

*Penta’s Role*  
**PARTNER**

### COMBACTE-MAGNET

*Combatting **B**acterial Resistance in **E**urope - **M**olecules **A**gainst **G**ram **N**egative Infections*

**Aim**  
To determine more effective treatment strategies for intensive care unit (ICU) infections, particularly with Gram-negative bacteria

*from 2015 until 2022*

*Penta budget*  
**€ 397,530**

*Total budget*  
**€ 167,002,414**

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

*Penta’s Role*  
**PARTNER**

## Other viruses

We leverage our expertise in the study and prevention of mother to child transmission of HIV, we investigate the mechanisms and consequences of vertical transmission of other viruses.

### PROMISE

*Preparing for RSV Immunization and Surveillance in Europe*

**Aim**  
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**

*Total budget*  
**€ 7,024,387**

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

*Penta’s Role*  
**PARTNER**

### RESCEU

*Respiratory Syncytial virus Consortium in Europe*

**Aim**  
To gather information on the scale of **R**espiratory **S**yncytial Virus (RSV) infection in Europe and its economic impact and use this information to design best practice guidelines for monitoring of RSV and to shape future vaccination programmes

*from 2017 until 2022*

*Penta budget*  
**€ 223,306**

*Total budget*  
**€ 25,453,316**

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

*Penta’s Role*  
**PARTNER**

## SCIENCE4PANDEMICS

**Aim**  
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*  
**€ 80,000**

*Total budget*  
**€ 1,240,000**

*Funder*  
**EIT Health**

*Penta’s Role*  
**PARTNER**



# Network building

We are improving the landscape for clinical research: we facilitate the generation of information needed to ensure that the right drugs, at the right doses are developed and made available for newborns and children.

**C4C**  
*COllaborative Network for European Clinical Trials For Children*

**Aim**  
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*  
**€ 17,266,896**

*Total budget*  
**€ 154,803,199**

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

*Role*  
**COORDINATOR**

**INVOLVING PATIENTS AND FAMILIES IN THE C4C STUDIES**  
The active participation of children, young people and their caregivers is one of the key objectives of the c4c project. Their involvement is currently ongoing within c4c’s two non-industry studies, TREOCAPA and KD-CAAP. In **TREOCAPA**, a randomised European clinical trial on the use of paracetamol to close the ductus arteriosus, researchers are working with the European Foundation for the Care of Newborn Infants (EFCNI), who acts as the Patient and public involvement (PPI) partner in the study. EFCNI is helping researchers understand the impact of diseases on families and what they consider optimal outcomes, which might not necessarily be the same as for medical professionals. By working with EFCNI, the c4c project strives to advance neonatal research and put the needs of preterm and very preterm babies first, with families as key partners in their approach. Societi, the UK Foundation for Kawasaki Disease, is the PPI partner in **KD-CAAP**, a study to assess the effectiveness of adding steroids to standard treatment in children with Kawasaki Disease. The Foundation has been involved in the KD-CAAP trial from the initial concept, when Societi’s founder brought clinical experts together to focus on developing a clinical trial. Only by allowing people who are directly impacted by research to express their opinions and concerns can researchers better plan to achieve optimal outcomes, greater acceptance and the desired enrolment rates.

**GAP-f**  
*Global Accelerator for Paediatric Formulations*

**Aim**  
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 2023*

*Total budget*  
**\$ 75,000**

*Funder*  
**WHO**

*Penta’s Role*  
**PARTNER**

**ECRAID-BASE**  
*European Clinical Research Alliance on Infectious Diseases*

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

*from 2019 until 2025*

*Penta budget*  
**€ 250,000**

*Total budget*  
**€ 29,969,875**

*Funder*  
**European Commission – Horizon 2020**

*Penta’s Role*  
**PARTNER**

# COVID-19 PROJECTS & STUDIES

Working through joint collaborations to advance treatment and care of COVID-19 and building research preparedness for future emerging infections with the potential to impact maternal and child health.

VERDI

SARS-CoV-2 variants  
Evaluation in *p*Regnancy  
and *pae*DIiatrics cohorts

Aim

To improve understanding of the epidemiology, outcomes, prevention and treatment of variants of SARS-CoV-2 amongst children and pregnant women. 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 in children and pregnant people. Starting from 2023, VERDI's scope will be extended to incorporate research on mpox and pandemic preparedness

from 2021 until 2024

Penta budget

€ 954,226

Total budget

€ 9,999,998

Funder

European Commission - Horizon Europe

Penta's Role

PARTNER

ORCHESTRA

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

Aim

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

from 2020 until 2023

Penta budget

€ 1,100,000

Total budget

€ 29,799,685

Funder

European Commission – Horizon 2020

Penta's Role

PARTNER

## STORIES FROM PENTA



Gabija Morkunaite,  
Penta Foundation  
Project Manager, Lithuania

“VERDI has been a rich learning experience.”

I've been fortunate to be involved in VERDI since its birth – the proposal writing and submission – and the exciting journey has continued ever since.

VERDI was a part of the EU's COVID-19 emergency response calls and since its very start, **everything in VERDI has been very dynamic and fast tracked**: the submission, the evaluation, the grant agreement preparation and even the recent amendment on mpox and preparedness. That has definitely kept me on my toes as VERDI's project manager and has also been a rich learning experience.

One of the things I enjoy the most about VERDI is working with a very motivated and committed VERDI Project Steering Committee as well as all the partners of the Consortium. Finding the right balance between the project deliverables, cross-consortia collaboration, ongoing conversations with the EC and the ever-evolving nature of COVID-19 and other emerging and re-emerging infectious diseases has definitely been a challenge but **the team's motivation, flexibility and ability to see new opportunities** has made this rollercoaster ride very exciting and rewarding.



Ali Judd,  
VERDI co-scientific  
coordinator and Penta  
ID Network Bloodborne  
Viruses working group  
co-lead, UK

“It is rewarding to witness VERDI activity informing the policy response.”

Despite having a very short window in which to write the VERDI proposal, it was amazing that so many brilliant partners came on board, laying the foundations for **a wonderful global collaboration**, underpinned by the very experienced team at Penta. One of the defining aspects of COVID-19 is that of course it really affected everybody, and as a result there are a diverse range of studies out there which can help us answer questions related to SARS-CoV-2 and maternal and child health. VERDI includes everything: from large, population-level electronic medical record datasets, to discrete cohorts of hospitalised patients with COVID-19, testing studies in schools, transmission studies, and participatory surveillance.

A year into the 4-year grant, **we are beginning to see the fruits of the collaboration**, and it is rewarding to witness all the cross-consortium activity, sharing of ideas and know-how, and of course results, abstracts and papers, informing the policy response. These collaborations always lead to new opportunities, and some of the fun is seeing these opportunities emerge, meeting new people, discussing gaps and opportunities, and thinking about the next grant!



PFIZER-  
BIONTECH PASS  
C4591021

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

**Aim**  
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

Total budget  
€ 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

**Aim**  
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

Total budget  
€ 1,939,547

Funder  
Pfizer Inc

Penta’s Role  
COORDINATING CENTRE

PFIZER-BIONTECH  
PASS C4591052  
SYNOPSIS

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

**Aim**  
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

Total budget  
€ 41,945

Funder  
Pfizer Inc

Penta’s Role  
COORDINATING CENTRE

EPPICC COVID

EPPICC Serology Study

**Aim**  
To describe the prevalence  
and distribution of  
SARS-CoV-2 antibodies in  
children and young adults  
living with HIV in Europe  
and South Africa

from 2020 until 2022

Total budget  
€ 282,172

Funder  
ViiV Healthcare

Penta’s Role  
SPONSOR

RBDCOV

RBD Dimer recombinant  
protein vaccine against  
SARS-CoV-2

**Aim**  
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  
partners

from 2021 until 2024

Penta budget  
€ 250,000

Total budget  
€9,779,211

Funder  
European Commission -  
Horizon Europe

Penta’s Role  
PARTNER

RECoVER

Rapid European SARS-  
CoV-2 Emergency  
Research response

**Aim**  
To develop data and  
evidence-based knowledge  
on the SARS-CoV-2 epidemic  
and translate these  
into recommendations  
for improved patient  
management and/or public  
health response measures

from 2020 until 2023

Penta budget  
€ 36,250

Total budget  
€ 20,590,195

Funder  
European Commission –  
Horizon 2020

Penta’s Role  
PARTNER

VACCELERATE

European Corona Vaccine Trial Accelerator Platform

**Aim**  
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

Total budget  
€ 11,999,997

Funder  
Horizon Europe

Penta's Role  
THIRD PARTY

CORONA

Children with COVID-19

**Aim**  
Corona is a multi-centre retrospective observational study to collect clinical, epidemiological and outcome data in children in Italy with confirmed infection with SARS-CoV-2

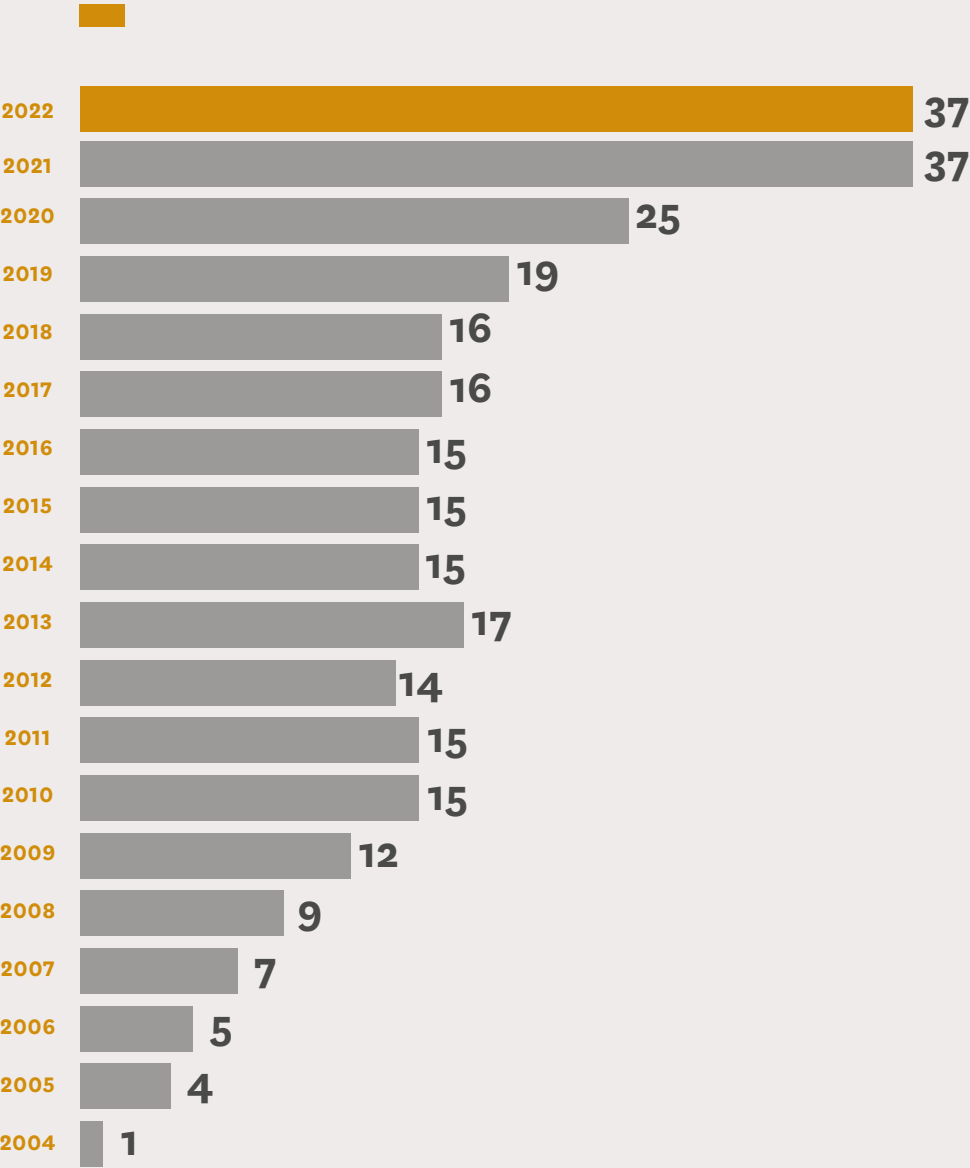
from 2021 until 2022

Total budget  
€ 90,000

Funder  
UniCredit Foundation

Penta's Role  
COORDINATOR

An ever-increasing number of research activities







LITHUANIA 56°06'17"N 23°12'47"E

## Other activities



Youth engagement & participation

PentaTr@ining

## Youth engagement & participation

Young people understand their own needs and bring a unique perspective into the planning, design and implementation of our studies. In 2022, we included their voice in more ways than ever.

Patients – including children and adolescents – must be involved in research, not as passive beneficiaries, but as leaders and influential drivers. We do research with people, so, at Penta we engage and communicate with the communities we are creating and improving medicines for, because we believe they should have a say in their health and shape the research around the medicines they take. By having conversations with the people who will be using these medicines – children, young people and their families – we get a good perspective on cultural acceptability and barriers to certain forms of medication. This is what we mean by **ethical and meaningful involvement** of the patients and community.

In recent years, we have been developing models that build the knowledge of the young people most affected by our research and create ways to ensure they have meaningful input into developing and delivering the research that impacts their lives. We are achieving this through consultation, collaboration and co-production, in key areas of our work, such as:

1. educational materials for the community
2. training and education materials for the Penta ID Network
3. policies and guidelines
4. communication campaigns
5. wider representation of young people across Penta's work.

In 2022, we continued the work in our ongoing projects and started with new initiatives:

- **Penta's Youth Trial Boards (YTB)**, running since 2017, is where we take the science from our trials to the young people involved in them and turn it into interactive, youth-friendly, activity-based training and delivery programmes, so they can shape the science that affects them. This model is the standard in Penta and operates across several countries (Uganda, Zimbabwe, South Africa and the UK) and multiple global clinical trials.
- Building on the work of the YTBs, we are improving knowledge and

understanding around clinical trials and how they work by including **youth representation in Trial Steering Committees** (TSCs) and creating an environment where young people can participate and engage. This way, they understand the science around their medicines.

- We engaged and collaborated with key stakeholders on developing the **“Quality Standards for the meaningful and ethical participation of children and young people in research”**. The Quality Standards look at how research is developed and delivered and how we can improve young people's ability to engage in

*“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

decision-making in clinical trials. The stakeholders involved include WHO, Global Network of young people living with HIV, IAS, Elizabeth Glaser Pediatric AIDS Foundation, Zvandiri, ViiV Healthcare and leads from paediatric clinical trials c4c, D3, ODYSSEY, Breather Plus and LATA. Penta is continuing to work on implementing the standards throughout the activities of the Foundation.

We also kicked off our **Young Reporters** project, where young people are trained as health reporters on various social media platforms and build skills around health messaging, so they can engage other young people globally

in conversations around science and the research for their medicines. As they are the direct beneficiaries of our research results, Penta will support them by providing access to key global scientific conferences and the opportunity to interview top scientists, doctors and researchers, with a view to democratise access to scientific knowledge and the latest research findings on medication and care for children and young people living with HIV. The young reporters are from Africa, Asia, and Latin America, selected through open global recruitment.

*“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 learned 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 learned in the conference.”*



# Our commitment to youth engagement and participation



## YOUTH ENGAGEMENT SCHEMES IN OUR STUDIES:

- YOUTH TRIAL BOARD
- YOUTH TRIAL STEERING COMMITTEE
- PENTATR@INING



75

YOUTH TRIAL  
BOARD MEMBERS



4

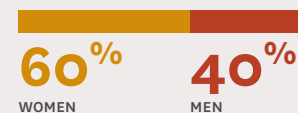
YOUTH TRIAL  
STEERING  
COMMITTEE  
MEMBERS



AGE VARIED  
BETWEEN  
15 AND 19



GENDER



GEOGRAPHICAL  
ORIGIN: ZIMBABWE,  
UGANDA, SOUTH  
AFRICA AND UK



UK 51°33'03"N 0°00'04"W





**Magda Conway, Mercy Shibemba and Lungile Jafta,**  
Penta Foundation Youth engagement & participation group, UK and South Africa

*“Health equity in paediatric research – why it matters.”*

*The World Health Organization states that “Health is a fundamental human right. **Health equity is achieved when everyone can attain their full potential for health and wellbeing.**”*

For Penta this means including pregnant people, adolescents, children and all under-represented communities in the development and testing of life-saving medication. We know that paediatric and adolescent drugs trials take too long and can be low priority or considered ‘high risk’ compared to their adult counterparts. Even where these trials are running, many communities are under-represented or simply not included. Barriers to their participation include geographic, economic, racial/ethnic bias, legal, cultural and linguistic factors. There are sub-groups of adolescents, who are already stigmatised and excluded from societies, such as LGBTQ+ communities or refugee/asylum seekers who may be **excluded from paediatric trials.**

This is something we are profoundly aware of, and we have established the Penta Youth Engagement Team where we are developing models and practice to actively engage not just children and adolescents in the research that affects their lives, but also to ensure these marginalised groups are active partners in the development and delivery of research. This is a huge task, **as health inequality and discrimination in healthcare and research are systemic.**

We have grounded our work within the ethos and framework of Community Development practice, working with and being led by the groups we support to engage in research. We uphold the principles of Youth Participation, **challenging tokenism** and working with researchers to see how to make their studies more accessible to children and adolescents, so they can be meaningful partners and have real influence in decision-making. We are learning from what has come before us, shaping this to fit the field of research and in particular, clinical trials and cohort studies.

To address Health Equity and inequality, as well as making research more accessible, we need to

be building the knowledge, understanding and confidence of these groups of adolescents, so they are equipped to enter the environment of research and have **meaningful engagements.** This must include underrepresented communities. We are actively seeking out and putting in place support packages so they can engage, which includes support that acknowledges their socio-economic situation and the time these experts are giving. A core lesson we have learnt is if you make the effort to find and engage these adolescents, they have a voice and they want this voice to be heard.

What COVID-19 showed us was that you cannot leave the public behind in discussions on science and health, particularly on infectious diseases. Research can be highly nuanced, science does not exist in a vacuum of black and white and there are many, many shades of grey. But this does not mean research and the science behind it cannot be explained simply and clearly, **engaging rather than excluding communities.** Poor communication of science leads to avoidable morbidity and mortality, and therefore must be addressed. We believe that although we still have some way to go, we are definitely on the right path to do this.



## PentaTr@ining

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.

Penta remains committed to providing expert training in paediatric HIV and other 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. 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 for clinicians and other healthcare professionals. Our current guidelines were released in October 2021 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 are due to be fully revised and updated by the writing committee in 2023.

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 people living with infectious diseases. Our pioneering training infrastructure has integrated innovative distance learning methods together with interactive face-to-face courses. Having carried out 78 training courses 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.

Amid the extraordinary circumstances of the ongoing COVID-19 pandemic, HIV services in 2022 continued to be eclipsed by the need to manage and treat COVID-19 patients. With the specific problems that can stem from reduced access to HIV care, it remained crucial to ensure that training needs of healthcare workers caring for vulnerable populations continued to be met. Following the remarkable success of our revamped flagship online course ‘HIV & other Congenital Infections’ in 2020-21, we fully revised and updated the content to deliver the second edition of the course in 2022. We also carried out our first

ever jointly hosted hybrid-mode training in Africa, for healthcare workers based in Zambia and Tanzania. While the last couple of years of global lockdowns compelled us to re-evaluate our approach and rapidly adapt to novel 100%-virtual training methods, with the gradual easing of travel restrictions in 2022 our delegates and faculty alike were thrilled to be able to get back to engaging in face-to-face/hybrid PentaTr@ining workshops.

As Penta 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 2022, we began delivering entirely new training programmes in other clinical areas of

Penta’s research activity with two fresh and timely online courses: “Fungal Infections in Paediatrics” and “Viral Hepatitis in Children”. As we look to 2023 and beyond, our ambitions remain to widen our network and teaching portfolio in other priority subject areas, such as antimicrobial resistance, research methodologies and outbreak preparedness.

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 2022, 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 building.

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 2022, Penta received endorsement and funding for training programmes from the following organisations:

- GILEAD Sciences Europe Ltd.: Independent Medical Education Grants for the hybrid course “HIV & other Congenital Infections”

and online course “Viral Hepatitis in Children”

- ViiV Healthcare: Independent Medical Education Grant for the hybrid course “PentaTr@ining Zambia-Tanzania 2022”
- KEDRION BioPharma: Unrestricted Educational Grant for the online course “Viral Hepatitis in Children”
- ESPID: Training and Education Workshop Award for the online courses “Fungal Infections in Paediatrics” and “Viral Hepatitis in Children”
- Medical Research Council Centre for Medical Mycology (MRC CMM) at the University of Exeter: for the online course “Fungal Infections in Paediatrics”.





GAMBIA 13°16'58"N 16°31'34"W

## STORIES OF IMPACT



**Isatou Sarr,**  
Researcher, Gambia

*“My PentaTr@ining Experience!”*

I first began participating in the PentaTr@ining online courses in 2022. Unlike other medical courses, PentaTr@ining is unique in that it teaches you practical skills that you can use in any area. It has provided me the opportunity to be able to critically think out clinical conundrums and scenarios for better outcomes as well as identify critical knowledge gaps for research topics that are of high public health relevance.

I believe the online trainings offer great distance learning options, while still maintaining a good measure of work-life balance. I welcomed the inter-disciplinary approach to make the right connections between ideas and concepts across different scientific disciplines and beyond. It also has given me the opportunity to reliably crowd-source answers for difficult cases that you may encounter in your work through the unflinching support of the tutors.

They are always ready and available through the learning platform and the live webinars, both of which are interactive and intuitive. Moreover, the virtual learning platform gives you the feeling that you are actually in the very same space as your peers and study guides. With this sensation of realism, it creates an engaging and immersive environment most ideal for learning.

Of all the training programmes I have taken in my professional career, PentaTr@ining has been by far the most resourceful learning initiative. I feel I'm truly part of a progressive learning community and that I am now better equipped professionally and a better team member of the DIAMONDS study at MRCG@LSHTM, which aims at improving the diagnosis and treatment of febrile children as well inflammatory conditions in the older population.

Learning with PentaTr@ining is engaging, thorough, professional and impactful!!!



## PENTATR@INING

# Since we started

## 78

TRAINING COURSES DELIVERED TO **7 000+** HEALTHCARE WORKERS FROM **37** COUNTRIES

### 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

### TYPE OF PROFESSIONALS TRAINED MAINLY PHYSICIANS

OTHERS INCLUDE:

- EPIDEMIOLOGISTS
- HEALTH PROGRAMME ADVISORS
- LAB TECHNICIANS
- MEDICAL OFFICERS
- MEDICAL STUDENTS
- NURSES
- NUTRITIONISTS
- PATIENT GROUPS
- PHARMACISTS
- PSYCHOLOGISTS
- RESEARCHERS
- SOCIAL WORKERS

### COURSES HAVE BEEN DELIVERED IN:

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

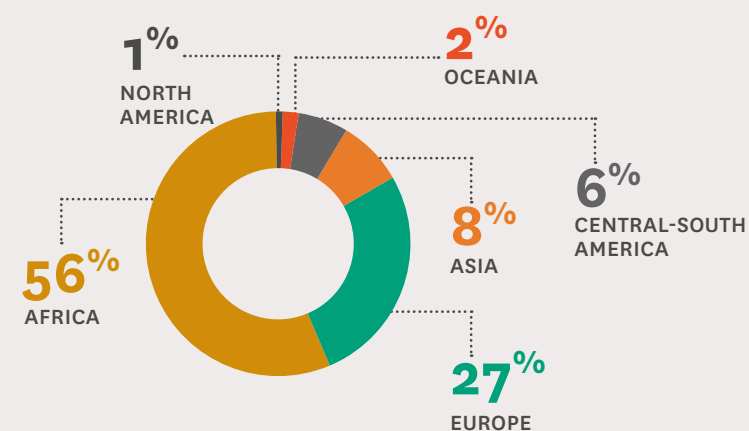
## PENTATR@INING

# PentaTr@ining in 2022

## OVER 800

DELEGATES FROM MORE THAN **60 COUNTRIES** PARTICIPATED IN OUR PENTATR@INING COURSES IN 2022

THIS GRAPH ILLUSTRATES THEIR GEOGRAPHIC REPRESENTATION BY CONTINENT

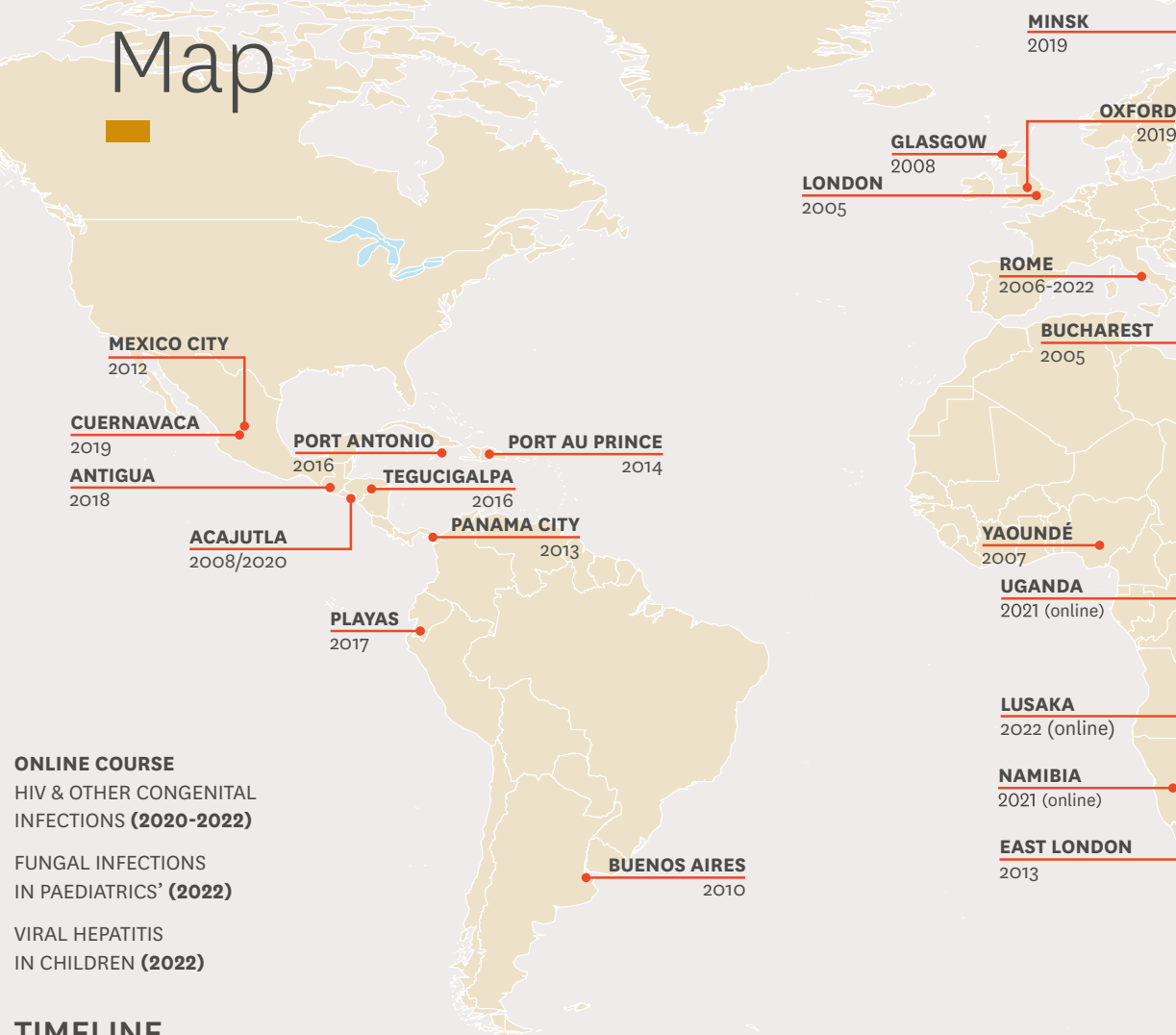


OUR PROGRAMMES IN 2022 ADDRESSED **A WIDE RANGE OF PAEDIATRIC INFECTIOUS DISEASES**, WITH OUR PARTICIPANTS BEING TRAINED ON TOPICS SUCH AS:

- HIV (INCLUDING OPPORTUNISTIC INFECTIONS)
- CONGENITAL INFECTIONS
- COVID-19
- INVASIVE FUNGAL INFECTIONS
- VIRAL HEPATITIS IN CHILDREN

## PENTATR@INING

## Map



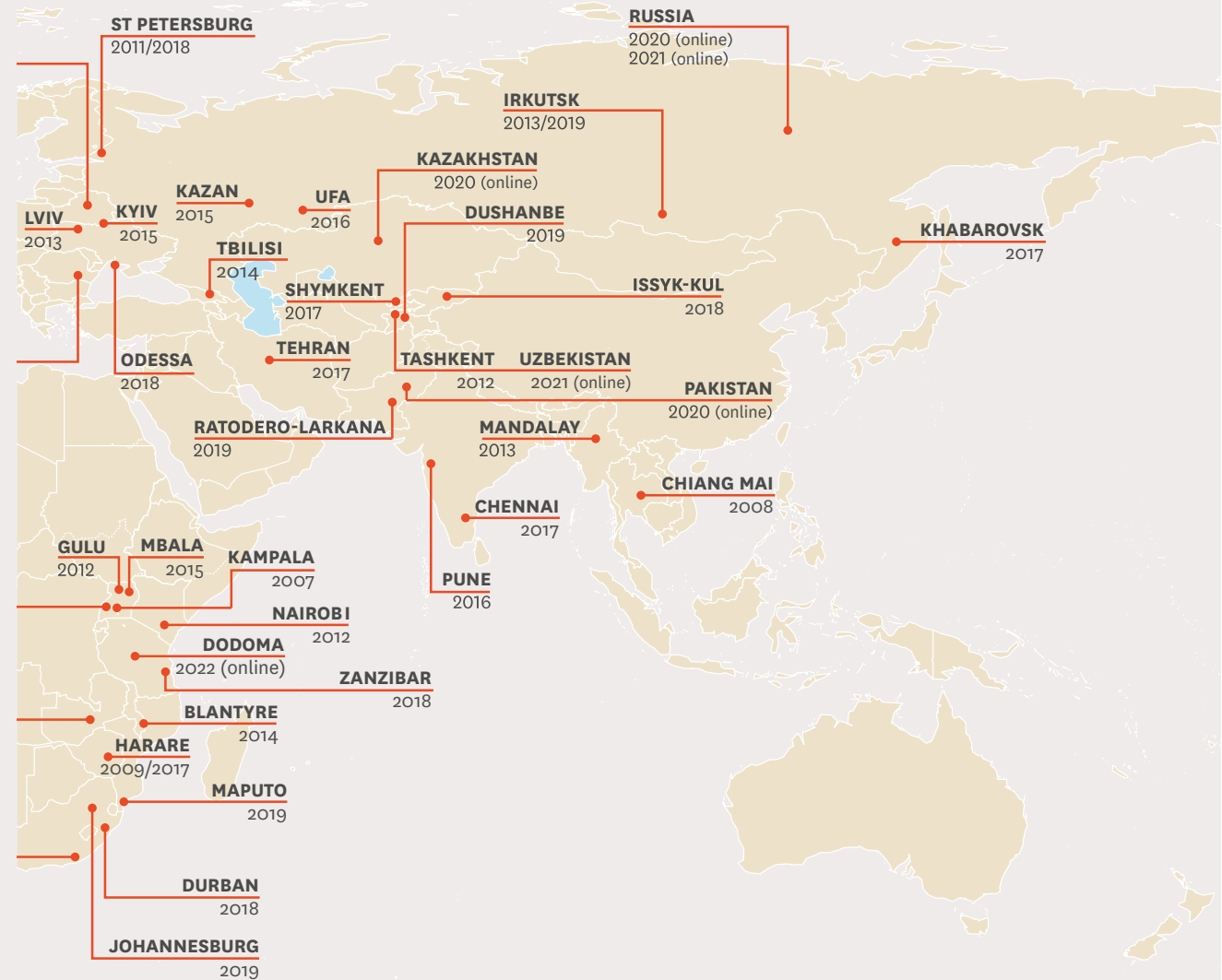
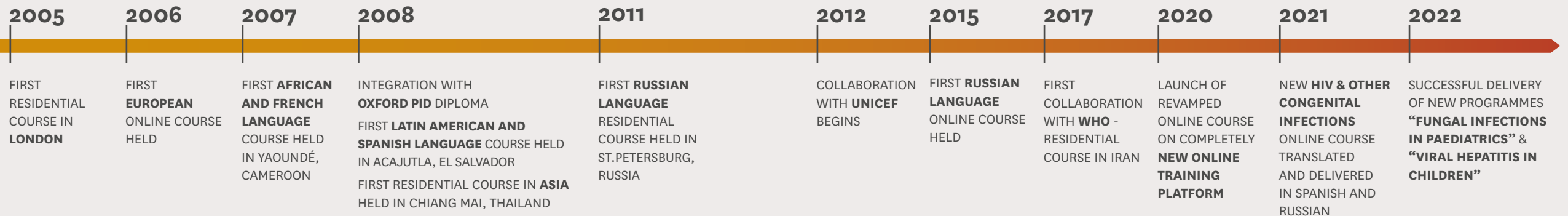
## ONLINE COURSE

HIV & OTHER CONGENITAL INFECTIONS (2020-2022)

FUNGAL INFECTIONS IN PAEDIATRICS\* (2022)

VIRAL HEPATITIS IN CHILDREN (2022)

## TIMELINE MILESTONES





PENTATR@INING

# What is our impact?

IN **2022** 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 **10** TRAINING COURSES HELD SINCE 2019: 6 ONLINE, 3 RESIDENTIAL, 1 HYBRID.

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



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



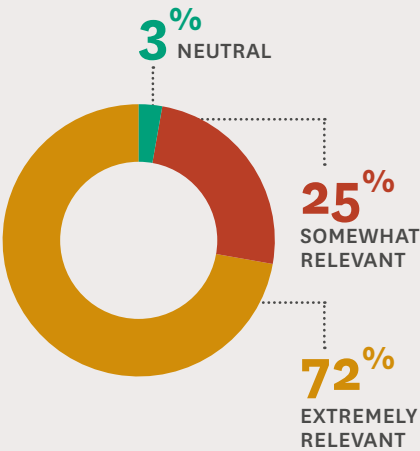
Have you had the opportunity to share acquired knowledge and help train your own colleagues?



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



How would you rate the overall relevance of the course?







ZIMBABWE 17°55'36.3"S 25°51'20.5"E



## 4. THE FUTURE: CHALLENGES AND OPPORTUNITIES



# Looking forward

As we set our sights on the years ahead, we are looking forward to:

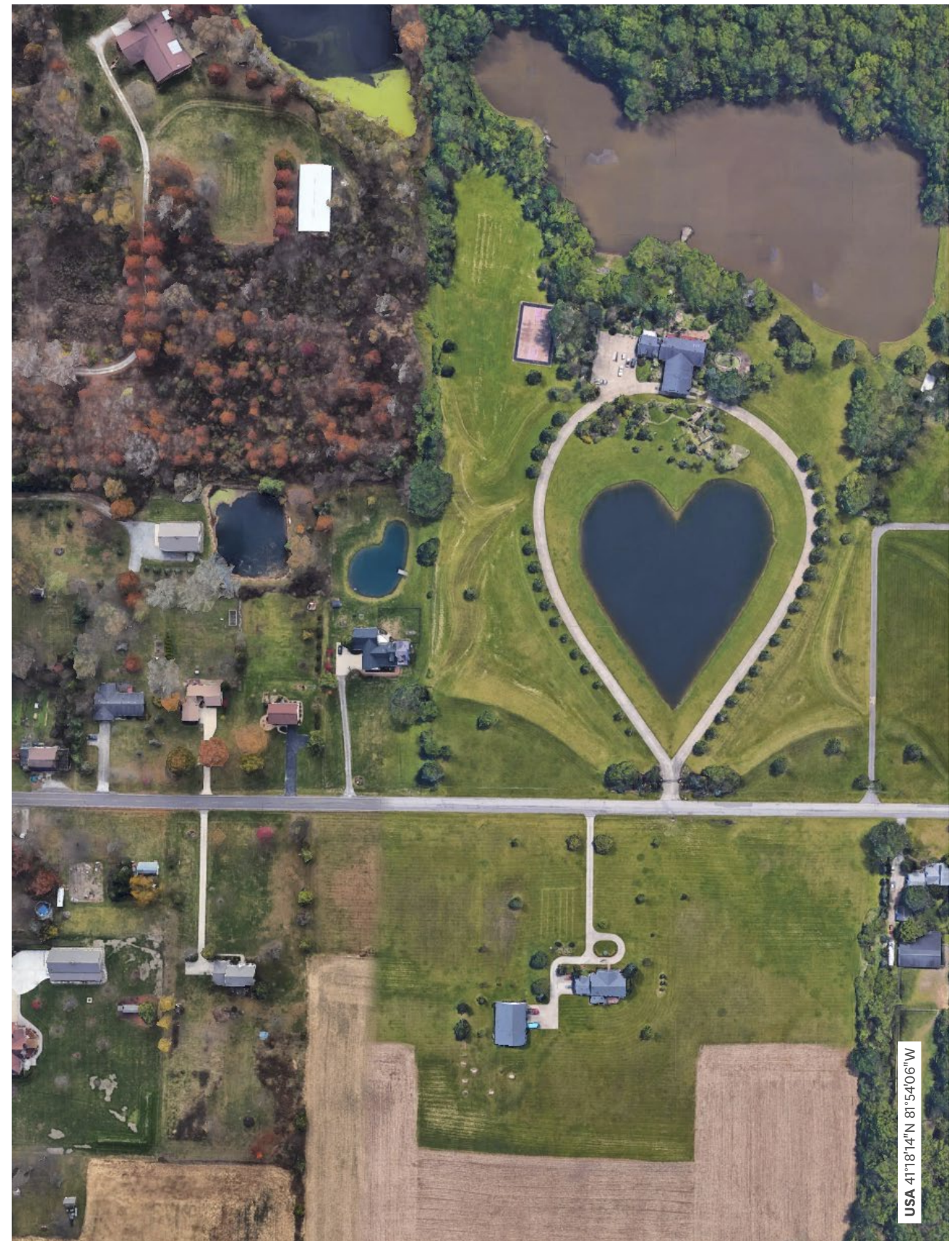
- **Adopting a public health approach to our research.** To address the needs of the most fragile populations, fighting specific diseases is not enough. In addition to epidemiological factors, in our studies we will address with even greater determination other determinants of health, including poverty, discrimination, age, nutrition and education.
- **Developing a family-centred approach to our studies.** Babies and pregnant people have acquired a central role in our research. By providing guidance and support to families, we will ensure better pregnancy outcomes and healthy newborns. Building on our expertise in engaging with older children, we will explore new avenues to engage and involve families more and better.
- Embracing patient-centred decentralised research.

There is an urgent need to identify new avenues for study participation, that are more accessible and more acceptable, for example, without asking participants to reach research facilities. Where possible, we will explore the potential of digital health to empower people who do research with us, the Patients, while safeguarding their rights and wellbeing as well as the robustness and reliability of the data collected. Decentralisation and digital health have a huge potential for more diversity and inclusion, and we are determined to explore them.

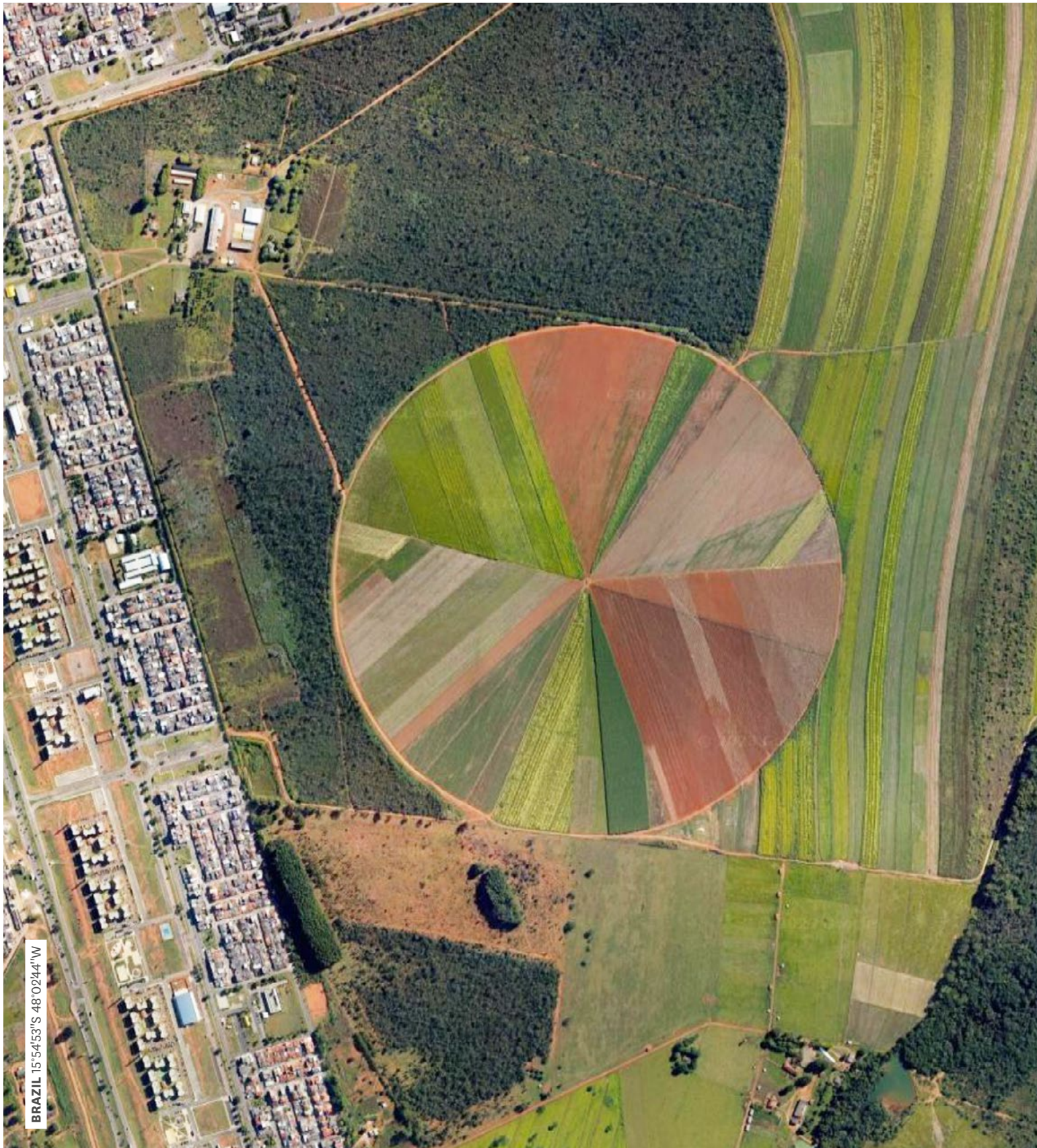
- **Citizen-led science and participatory research.** We are well aware that study participants have knowledge, expertise and lived experience; we will use their competence in combination with our researchers' expertise in every step of research, from designing a study protocol to translating the results of research for

public health action. We will leverage our partners' expertise in data science to develop research projects that use data gathered from patients directly. This is happening in our VERDI project and we will endeavor to promote it in our future project applications.

- **Strengthening our preparedness platform for emerging infectious diseases.** In an age of pandemics, research needs to be global, fast and more personalised. For us, it means relying on a ready-to-act network of research centres across the globe, that are able to apply the most advanced research methodologies and produce standardised and interoperable data. We will continue to work with our collaborating sites and research centres to strengthen their capacities for preparedness and response to any emerging infectious disease that is a threat to maternal and child health.







BRAZIL 15°54'53"S 48°02'44"W



## 5. FINANCIAL RESULTS



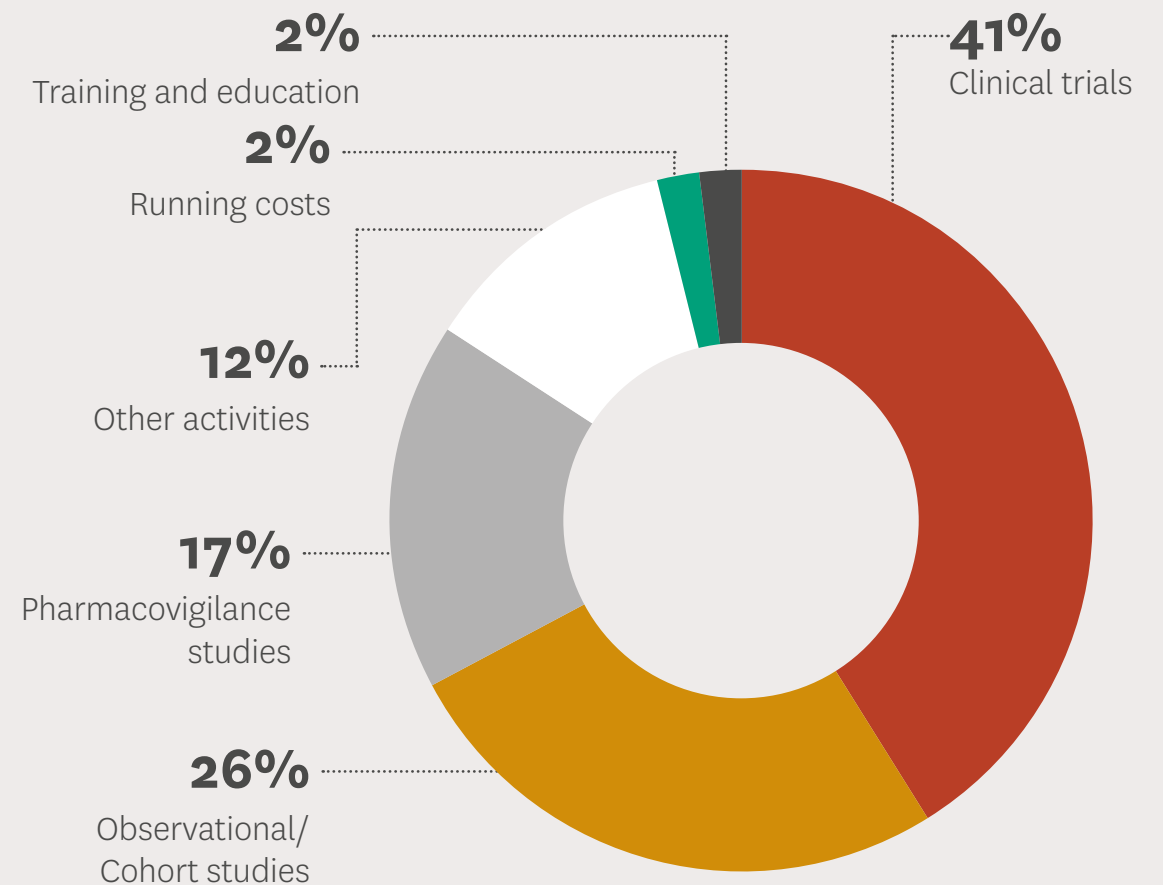
Penta is an independent organisation funded by **public and private contributions** from international organisations



Following previous trends, HIV remains a key element in the research activities of the Foundation. However, the COVID-19 pandemic led to new collaborations and projects, opening a new research area. At the same time, antimicrobials and network building still represent a considerable share of Penta's activities.

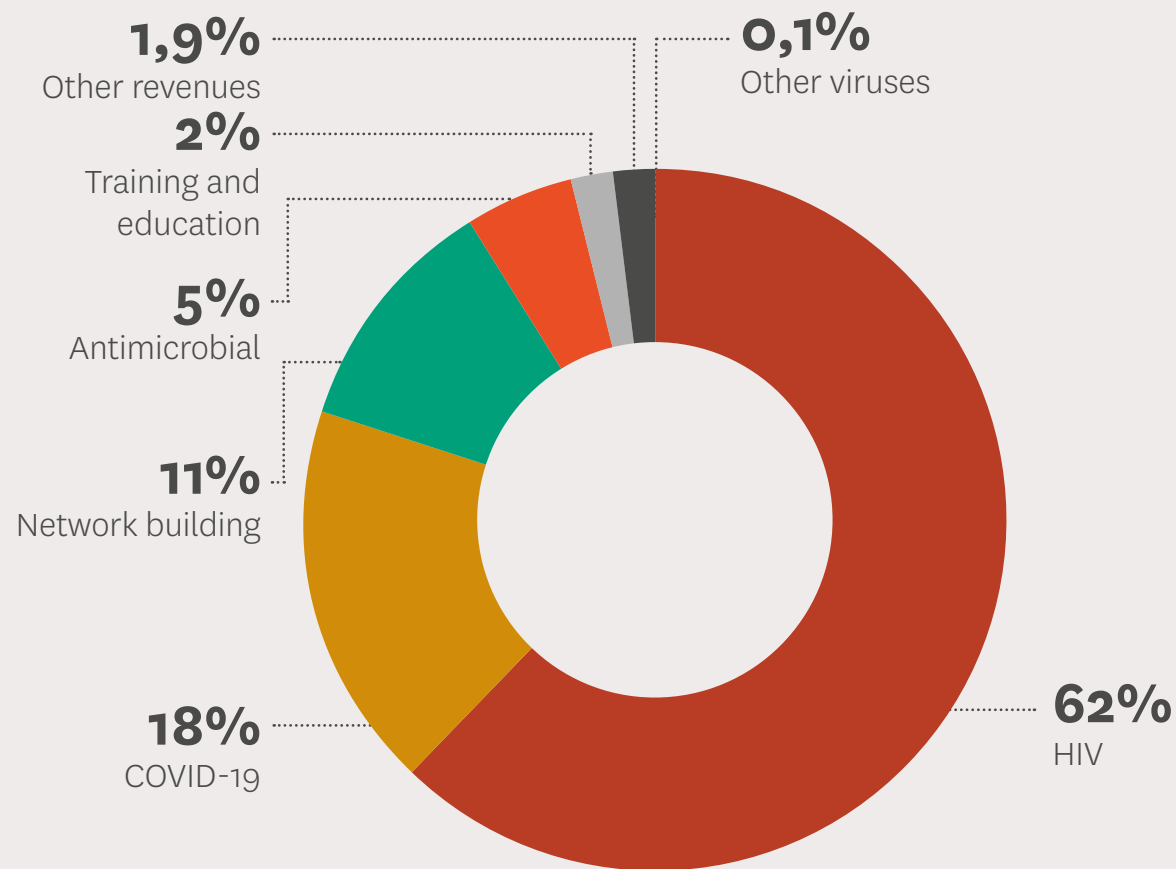
Additionally, the use of resources is mainly directed to project-related activities, especially the implementation of clinical trials and cohort studies in which the Foundation is involved. In 2022, the Foundation received funding from an array of sources, mostly from private and international institutions showing the numerous collaborations the Foundation has in place.

## Expenses by type of activity



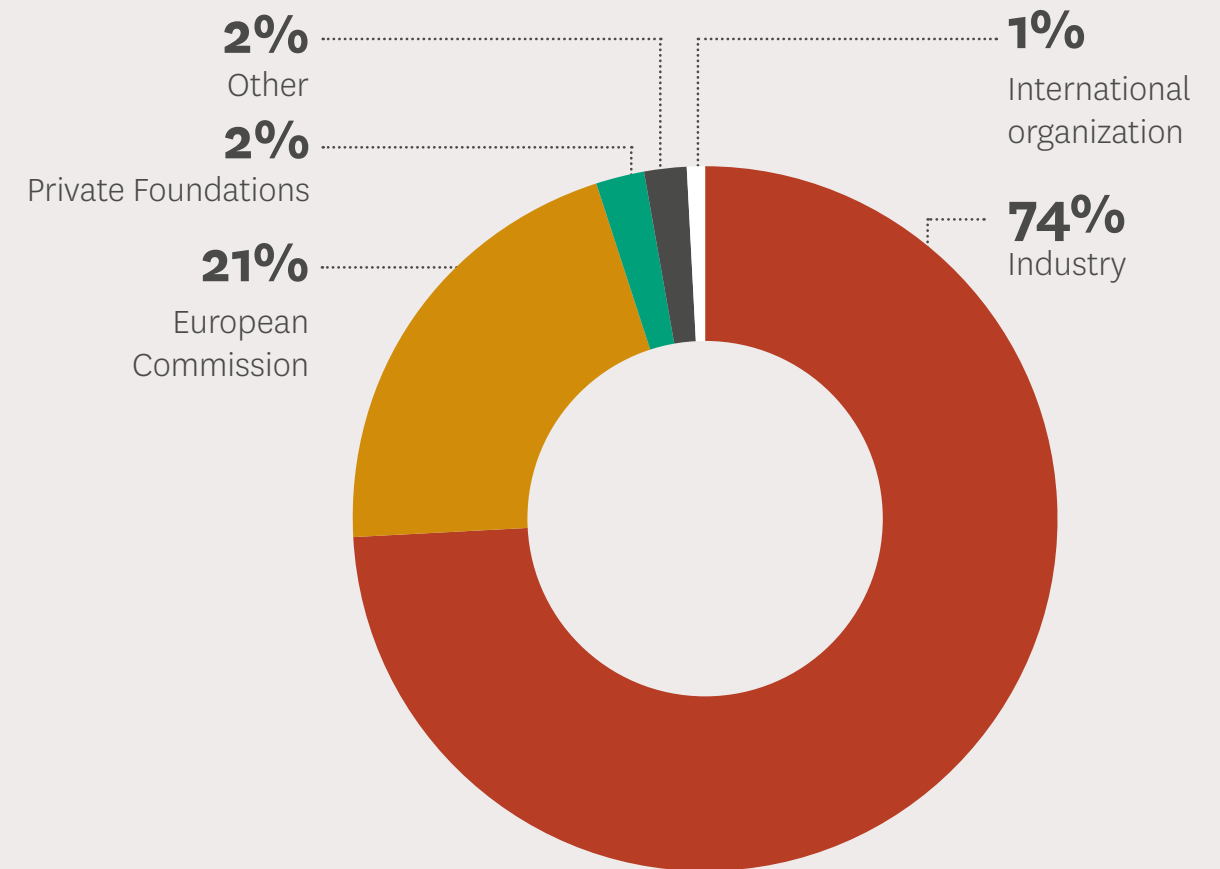
THE CHART SHOWS THE PERCENTAGE DISTRIBUTION OF THE USE OF RESOURCES BY THE FOUNDATION SEGMENTED BY TYPE OF ACTIVITY FOR 2022. AS SHOWN, THE MAJORITY OF EXPENSES WERE INCURRED IN RELATION TO THE IMPLEMENTATION OF CLINICAL TRIALS, PHARMACOVIGILANCE AND COHORT STUDIES, SHOWING THE VARIETY OF STUDIES THE FOUNDATION IS CONDUCTING.

## Revenues by research area



THE CHART SHOWS THE PERCENTAGE DISTRIBUTION OF THE USE OF RESOURCES BY THE FOUNDATION SEGMENTED BY RESEARCH AREA FOR 2022. AS INDICATED, HIV REMAINS THE FOUNDATION'S PRIMARY RESEARCH AREA FOLLOWED BY A SIGNIFICANT INCREASE IN NETWORK BUILDING ACTIVITIES COMPARED TO PREVIOUS YEARS. COVID-19 RESEARCH STILL HAS A HIGH LEVEL OF IMPORTANCE IN THE FOUNDATION'S RESEARCH EFFORTS.

## Revenues by funder



THE CHART SHOWS THE PERCENTAGE DISTRIBUTION OF REVENUES RECEIVED BY TYPE OF FUNDER IN 2022. THE HIGHEST PROPORTION CORRESPONDS TO PRIVATE SOURCES, WHICH INDICATES THE INCREASING NUMBER OF COLLABORATIONS THE FOUNDATION HAS IN PLACE. FUNDING FROM THE EUROPEAN COMMISSION CONTINUES TO BE A KEY SOURCE OF FUNDING.



# Methodological note

Social reporting is defined as measuring, disclosing and being accountable to internal and external stakeholders for organisational activities that have a social impact.

Penta Social Annual Report 2022 is written in accordance with *the Guidelines on how to write Third Sector organisations' Social Report*, as outlined in the Italian Ministry of Labour and Social Policies Decree, dated 4 July 2019.

Our Report aims to provide our stakeholders with clear and transparent information regarding our social and environmental responsibilities, the way we pursued our social goals and the results we achieved during the financial year that began on 1 January 2022 and concluded on 31 December 2022.

Where possible, the information related to this period is compared with that of the previous year.

An element of complexity in the Penta Annual Social Report is due to reporting perimeter, represented by the multiple entities that the Penta environment comprises, all united by a common vision: the Penta Foundation, a legal entity under the Italian law, and the Penta ID Network, an alliance of clinicians, researchers and healthcare professionals in 31 countries. This Report is designed to provide a unified picture, while devoting attention to the distinct features of the Foundation and those that pertain to the other entities within its environment.

The document design and content selection

were coordinated by the Communications Team at the Penta Foundation, with the involvement of the Foundation's staff.

Data provided in the Report was collated from Penta's information systems, primarily Penta's Contacts Institutions Projects Database, Penta's accounting system and our Gender Equality Plan.

The Report and the financial statements were prepared in accordance with Italian regulations and relevant accounting principles. They were approved by the Board of Directors on 28 April 2023.

The auditing company BDO S.p.A. audited the financial statements of the

Foundation, certifying that they give a true and fair view of its financial position as of 31 December 2022, and of the results of its operations and its cash flows for the year 2022.

The stories featured in this Annual Social Report were collected during the year 2022, with the intention to give a voice to the multitude of people who have contributed substantially to the achievement of our objectives. We want to reflect a positioning that is increasingly oriented towards engaging our stakeholders, enhancing our human capital and generating impact for the communities we serve.

With reference to the quality of information in this Report, we applied the principles established by the Italian Ministry of Labour and Social Policies Decree, dated 4 July 2019 (relevance, completeness, transparency, neutrality, clarity, truthfulness and verifiability of data, period competence, comparability, reliability and autonomy of third parties), as well as the guiding principles of Penta (inclusion, team spirit, responsibility, and transparency).

Penta's Social Report is published annually.

For information relating to the Annual Social Report, please contact us by writing to:

**[communication@pentafoundation.org](mailto:communication@pentafoundation.org)**

Our Annual Social Report is also available on our website:

**<https://penta-id.org/who-we-are/annual-reports/>**

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## LIST OF ACRONYMS

<b>AMR</b> Antimicrobial Resistance	<b>GDPR</b> General Data Protection Regulation	Working Group
<b>ART</b> Antiretroviral therapy	<b>GEAI</b> Gender Equality Assessment Implementation	<b>PHPT</b> Program for HIV Prevention and Treatment
<b>CTU</b> Clinical Trial Unit	<b>GEP</b> Gender Equality Plan	<b>REACT</b> Action on Antibiotic Resistance
<b>CRO</b> Clinical Research Organisation	<b>IMI1/IMI2</b> Innovative Medicines Initiative	<b>RWD</b> Real World Data
<b>DTG</b> Dolutegravir	<b>INSERM</b> Institut National de la Santé et de la Recherche Médicale	<b>TB</b> Tuberculosis
<b>ECR</b> Early Career Researcher	<b>JCRC</b> Joint Clinical Research Centre	<b>UCL</b> University College London
<b>EDCTP</b> European and Developing Countries Clinical Trials Partnership	<b>MRC CTU</b> Medical Research Council Clinical Trials Unit	<b>UNAIDS</b> Joint United Nations on
<b>ENPR-EMA</b> European Network of Paediatric Research at the European Medicines Agency	<b>MUJHU</b> Makerere University Johns Hopkins	<b>UNICEF</b> United Nations Children's Fund
<b>DEI</b> Diversity, Equity and Inclusion	<b>NGO</b> Non Governmental Organization	<b>WHO FPPL</b> World Health Organization Fungal Priority Pathogens List
<b>FDC</b> Fixed Dose Combination	<b>OPBG</b> Ospedale Pediatrico Bambino Gesù	
<b>GARDP</b> Global Antibiotic Research & Development Partnership	<b>PADO</b> Paediatric Antiretroviral Drug Optimization	
<b>GAP-F</b> Global Accelerator for Paediatric Formulations	<b>PAWG</b> Paediatric Antiretroviral	





*concept and design*

**bcvassociati.it**

*photos*

**Google Maps**

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Dati cartografici © 2023





**Penta**  
Child Health Research

**Fondazione Penta ETS**

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