

From PENTA to Global Health: thirty years of collaborative research in Pediatric Infectious Diseases

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Our Journey



1991

1st Penta Study

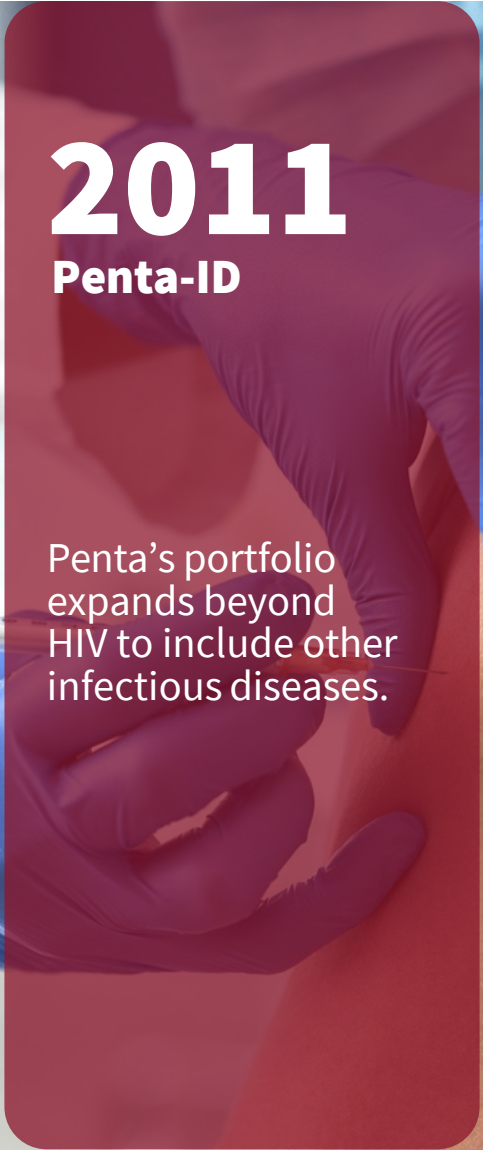
First HIV study led by PENTA – Paediatric European Network for the treatment of AIDS.



2004

Penta Foundation

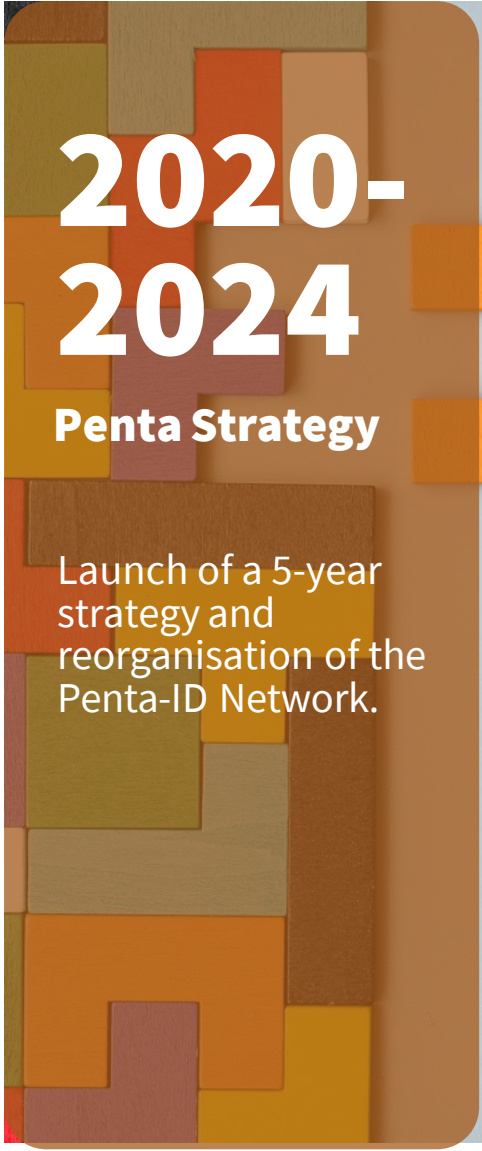
Penta Foundation is established as an Italian-based non-profit organisation.



2011

Penta-ID

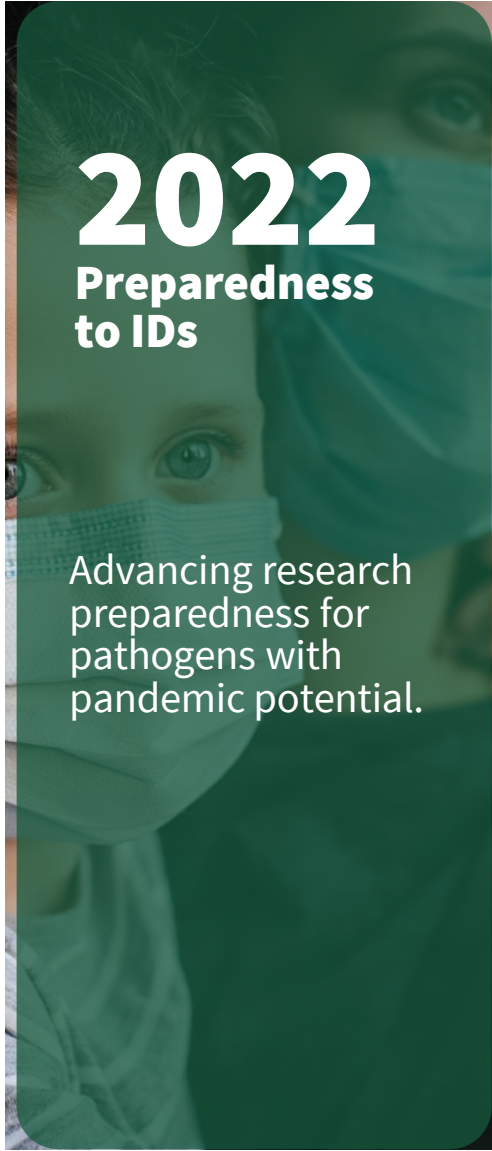
Penta's portfolio expands beyond HIV to include other infectious diseases.



2020- 2024

Penta Strategy

Launch of a 5-year strategy and reorganisation of the Penta-ID Network.



2022

Preparedness to IDs

Advancing research preparedness for pathogens with pandemic potential.



Penta's mission 2025-2029 is to be an inclusive network that delivers impactful research to improve the prevention and management of infections in **pregnancy**, infancy, childhood and adolescence globally.

Penta's vision is for a world where the health needs of **pregnant people**, infants, children and adolescents are always prioritized.

A strong and evolving
research activity over time

2025



2024



2023



2022



2021



2020

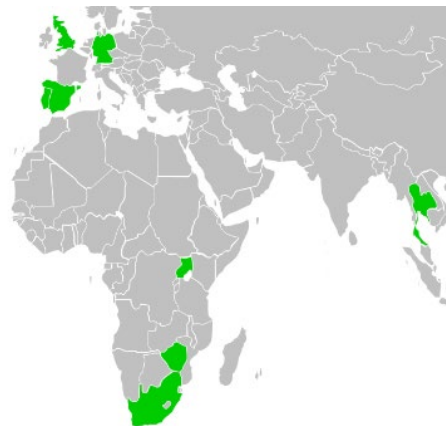


Our Network is the key to success: 2025 – 2029 objectives

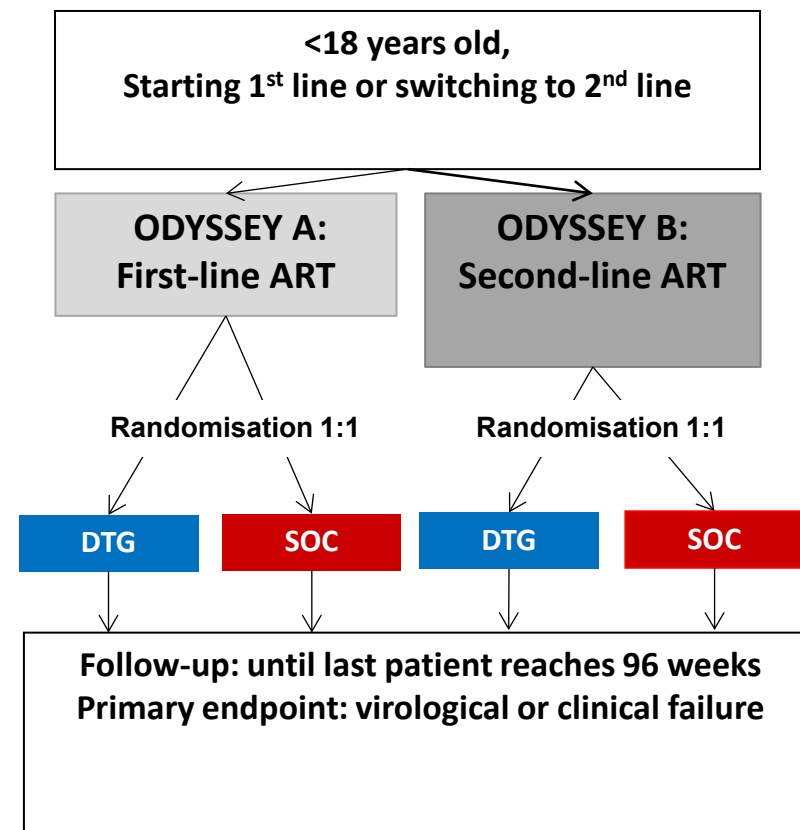


Main aim: Strengthen research capacity and expand collaborations, ensuring equitable contribution in research programmes by:

- Fostering **active participation** from target regions through Penta membership
- **Expanding training program** to underrepresented regions
- Inspiring and supporting **future leaders** in maternal and child health across regions
- Establishing and mobilising **Special Interest Groups** to incubate **new research ideas** and broadening participation of Network members



- **Open-label non-inferiority basket trial**
 - ODYSSEY A: first-line ART
 - ODYSSEY B: second-line ART
- Multi-centre: 29 sites in 8 countries
- Main trial enrolled children $\geq 14\text{kg}$ (N=707)
 - Randomised follow-up completed April 2020
- ‘Young children cohort’ enrolled children $3 < 14\text{kg}$ once the main trial completed recruitment (N=85)
 - Randomised follow-up completed September 2021
- Extended follow-up continuing in Africa & Thailand
 - To collect longer term safety data (to ~May 2023)
 - To allow continued provision of DTG where not available



The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Dolutegravir as First- or Second-Line Treatment for HIV-1 Infection in Children

Dolutegravir dosing for children with HIV weighing less than 20 kg: pharmacokinetic and safety substudies nested in the open-label, multicentre, randomised, non-inferiority ODYSSEY trial



Hylke Waalewijn, Man K Chan, Pauline D J Bollen, Hilda A Mujuru, Shafic Makumbi, Adeodata R Kekitiinwa, Elizabeth Kaudha, Tatiana Sarfati, Godfrey Musoro, Annet Nanduudu, Abbas Lugemwa, Pauline Amuge, Cecilia L Moore, Pablo Rojo, Carlo Giaquinto, Angela Colbers, Diana M Gibb, Deborah Ford*, Anna Turkova*, David M Burger*, ODYSSEY Trial Team†



Summary

Background Dolutegravir-based antiretroviral therapy is a preferred first-line treatment for adults and children living with HIV. *Lancet HIV 2022*

- **Data contributed for regulatory approvals:**

FDA (Jun 2020) and EMA (Jan 2021)

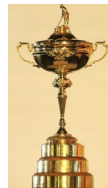
- Adult DTG 50mg for children $\geq 20\text{kg}$
- DTG dispersible 5mg for $<20\text{kg}$
- **Two DTG formulations can be used across all age and weight groups!**

SAHPRA (SA)

- ABC/3TC 120/60mg paediatric dispersible tablets in South Africa

ODYSSEY team at Radboud receives the RIHS Societal Award 2020

European Hector research award in HIV 2021 in clinical/epidemiological science



- **WHO guidelines informed on 4 accounts (2019-2021)!**

PK & safety studies:

- ✓ Optimised dosing for children $\geq 20\text{kg}$
- ✓ Dosing for children 3 to $<20\text{kg}$
- ✓ DTG dosing for children receiving rifampicin-based TB treatment

Main trial:

- ✓ **High Certainty of evidence for recommendations on DTG-based ART for first- and second-lines in children $\geq 14\text{kg}$ & $<14\text{kg}$**

ODYSSEY made it possible for DTG to become accessible for children worldwide!



The new AMR frontiers are about pathways

From:

- Which organism?
- Which antiinfective?
- Which resistance pattern?

To:

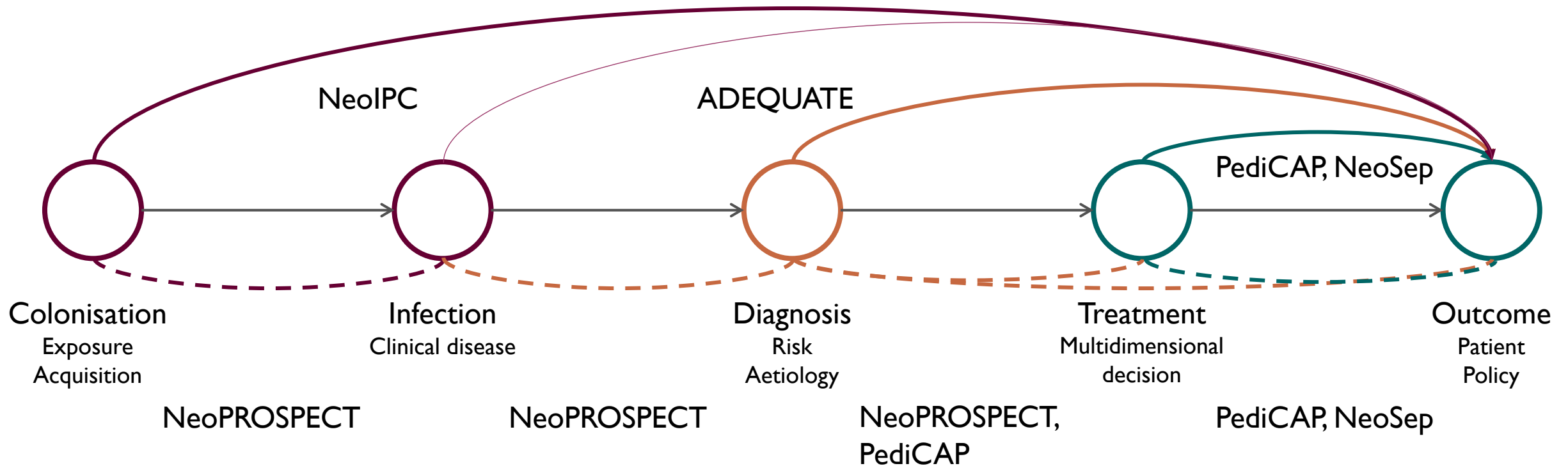
- Which treatment pathway works here?
- How do we prevent infections before treatment is needed?
- When does a diagnostic test change clinical decisions?

How do we generate evidence that changes practice?

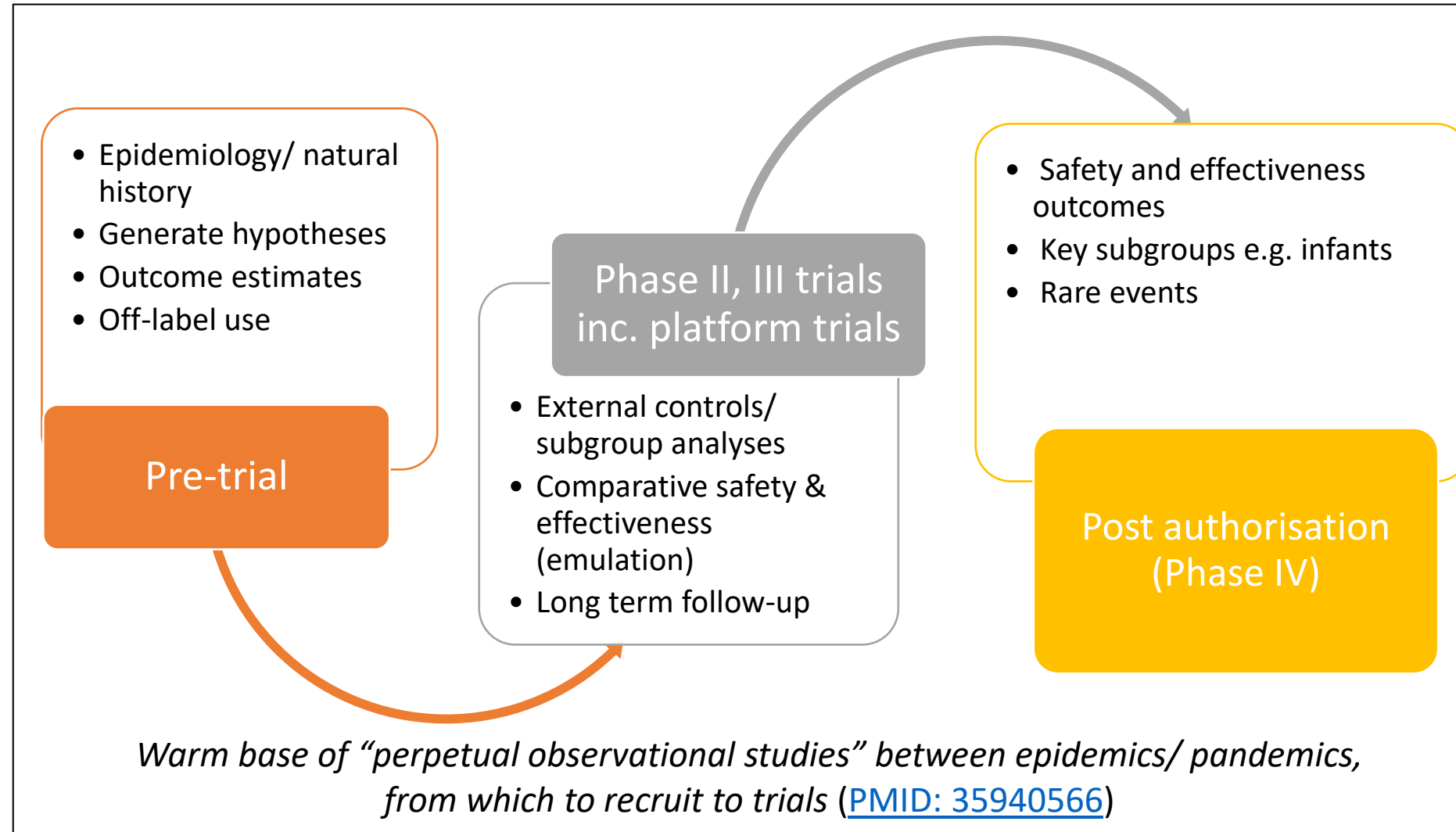
The treatment frontier:
How do we generate
evidence for real clinical
choices rather than
«just» for products?



What makes this relevant to Penta?

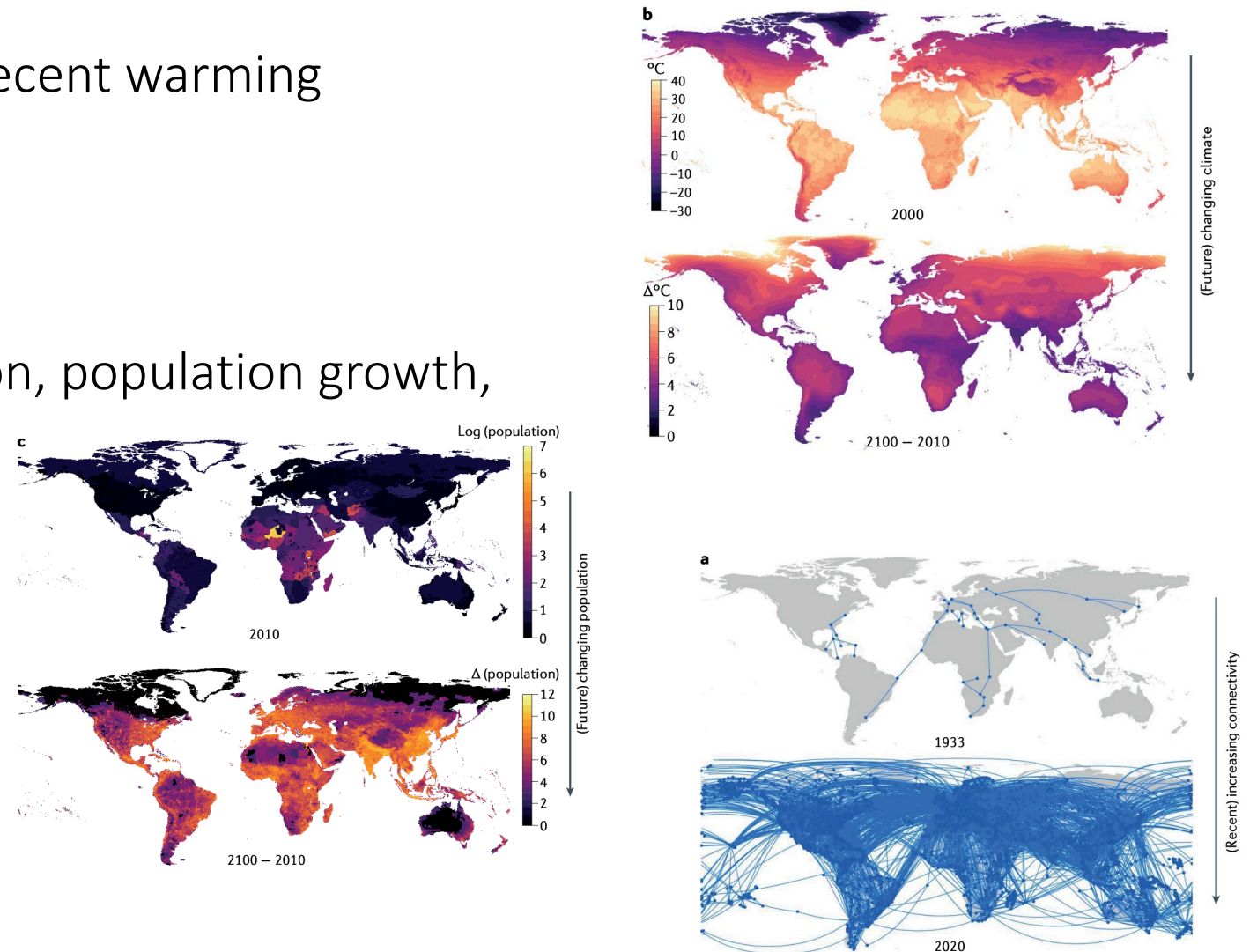


Cohorts complementing trials → clinical studies ecosystem



The landscape of infectious disease risk has changed in the past two decades: Novel interactions between species

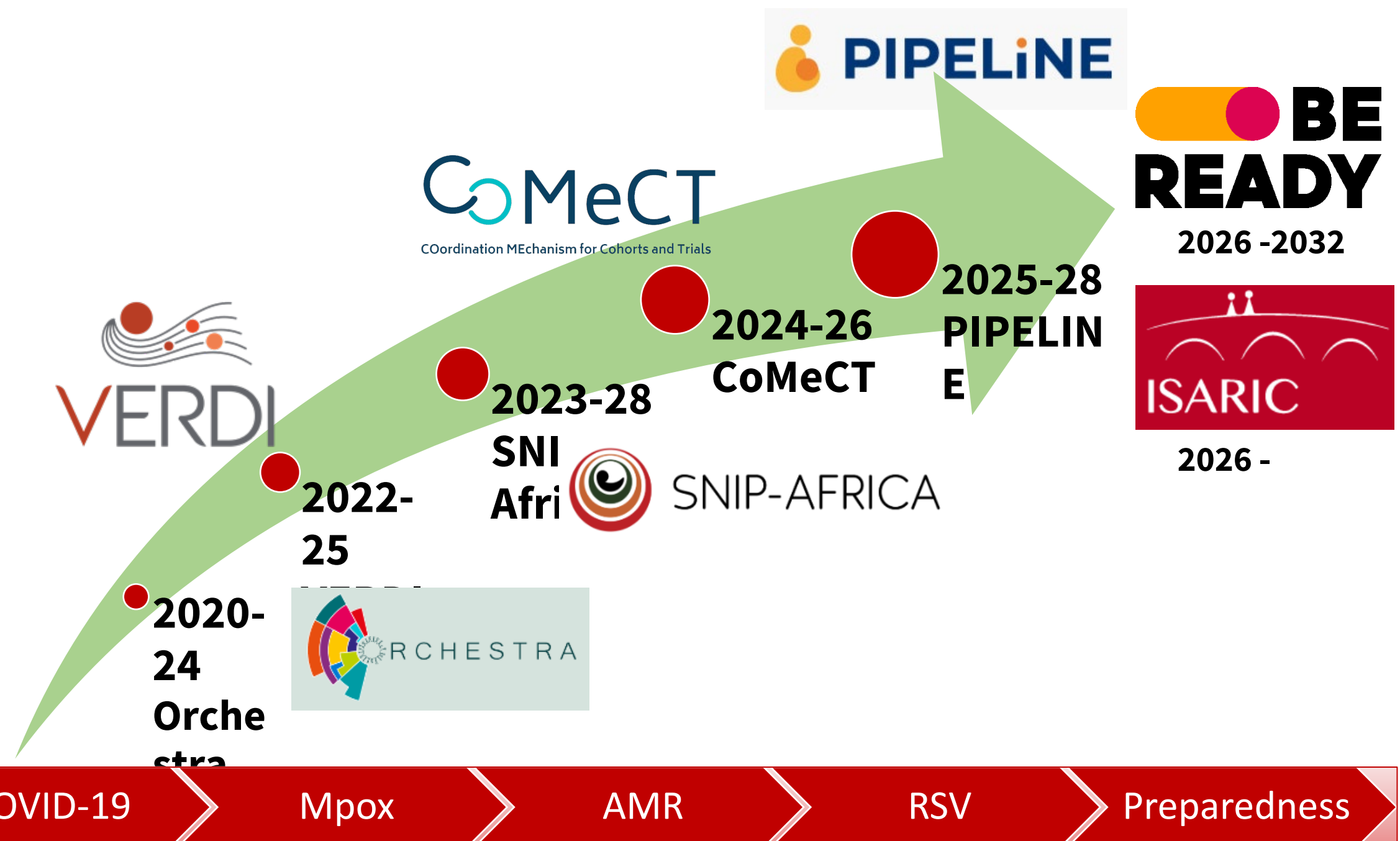
- **Anthropogenic climatic changes:** recent warming
- **Demographic changes:** urbanization, population growth, land-use change, migration, ageing and changing birth rates
- **Technological changes:** cheaper, faster global travel and trade





Preparedness specific aims:

- Maintaining a **network ready to respond** to (re)emerging infection threats
- Promoting **master protocol** approaches
- Engaging with the network to **identify important preparedness questions** relevant to the target populations
- Participating in **European and international research preparedness initiatives** to promote specific needs of the target populations
- Contributing to timely **communication of scientific evidence to the public and policy makers.**



Social & behavioural science studies for Andes

- **Aim:** To assess relationship between adherence guidance and impact of quarantine on mental health, to support quarantine experience now and in the future.
- **Current initiatives:**

RIVM + ECDC

Study design:

- Questionnaire (2x) among persons in quarantine + interviews at the end
- Interviews among professionals at regional public health center

Participants: Persons in quarantine in the Netherlands (via RIVM and GGD) and other EU countries (via ECDC). Ideally, participants are contacted by the health authorities involved in daily monitoring.

GGD (Municipal Public Health Services) Rotterdam

Study design:

- Questionnaire (weekly)

Participants: Hondius crew members quarantined in Rotterdam

UKHSA

Study design – diary study:

1. Daily short questionnaire (~5 mins)
2. Weekly longer set of questions (~30 mins)
3. Follow-up interview after end of quarantine period (~60 mins)

Participants: Contacts of hantavirus cases who are quarantining in the UK and who are fluent in English.

We try to align the content of these questionnaires

C-MATCH: Child-MATernal health under Climate cHange

- Non-communicable disease risk across the life course

Central hypothesis:

- Compound and cascading climate-driven exposures to **extreme heat and air pollution during critical windows of pregnancy, childhood and adolescence** induce serious and persistent health effects in the mother and initiate lifelong NCD trajectories in the child.
- The mediating biological mechanisms include **epigenetic reprogramming, systemic inflammation and oxidative stress**.
- The effects are expected to be non-linear and threshold-dependent, and are **amplified by social vulnerability**.

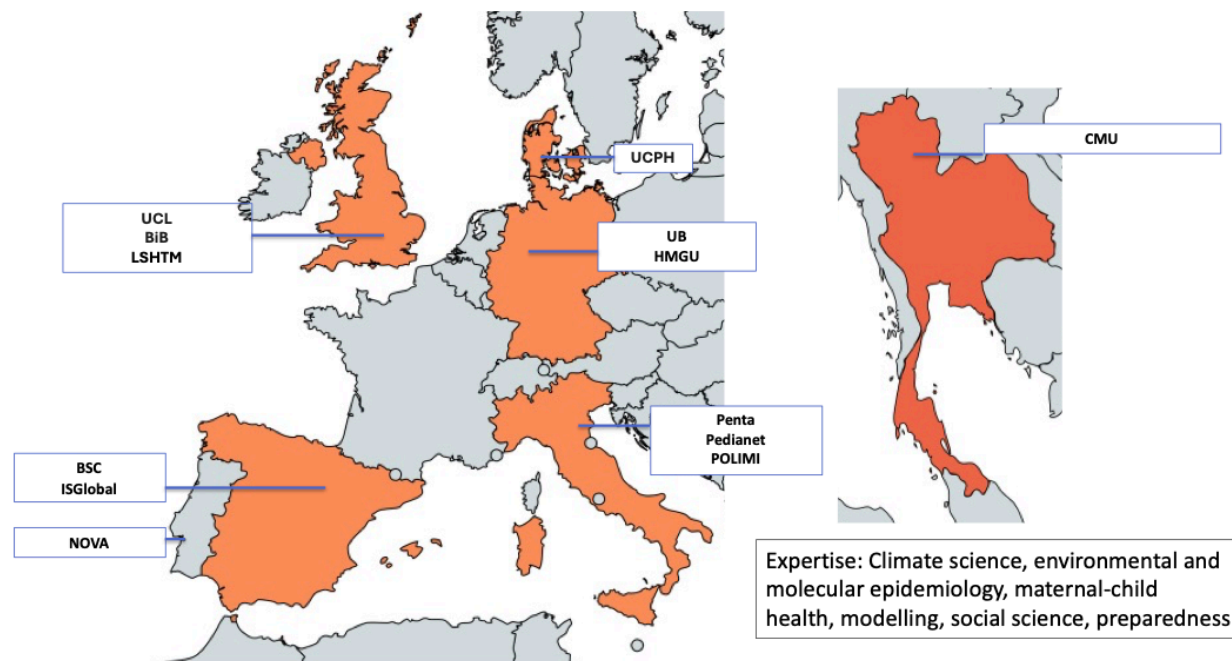
Ambition:

- By characterising these complex interactions across diverse settings and exposure intensities, **C-MATCH will provide the scientific foundations necessary to design effective prevention and climate-adaptation strategies at individual, community and policy levels**.

HORIZON-HLTH-2026-01-ENVHLTH-01

C-MATCH European & Thai Consortium

Participant organisation name	Country
Fondazione Penta ETS (Penta)	IT
University College London (UCL)	UK
Faculty of Associated Medical Sciences, Chiang Mai University (CMU)	TH
Barcelona Supercomputing Center Centro Nacional De Supercomputacion (BSC)	ES
Bradford Teaching Hospitals NHS Foundation Trust (BiB)	UK
London School Of Hygiene & Tropical Medicine (LSHTM)	UK
Helmholtz Zentrum Muenchen Deutsches Forschungszentrum Fuer Gesundheit Und Umwelt Gmbh (HMGU)	DE
University of Copenhagen (UCPH)	DK
Fundacion Privada Instituto de Salud Global Barcelona (ISGlobal)	ES
Universität Bremen (UB)	DE
Nova Id Fct - Associacao Para A Inovacao E Desenvolvimento Da Fct (Nova)	PT
Politecnico Di Milano (POLIMI)	IT
Società Servizi Telematici srl (Pedianet)	IT



Expertise: Climate science, environmental and molecular epidemiology, maternal-child health, modelling, social science, preparedness

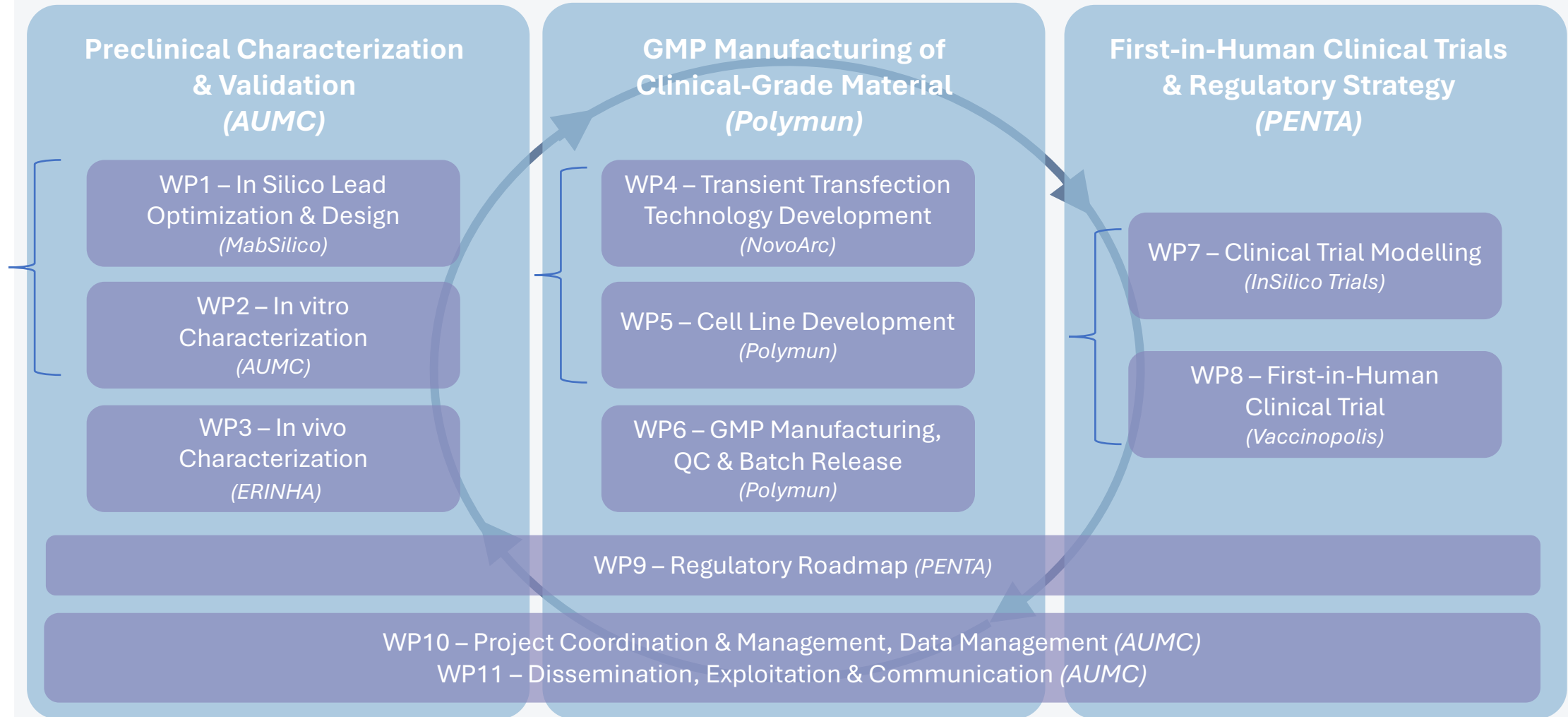
HORIZON-HLTH-2026-01-ENVHLTH-01



Development of
Monoclonals Ab against
Pathogens of Pandemic
Potential using AI.

Work in progress: Zika,
H5N1, Lassa, Chik (?)

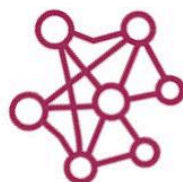
**MALASSA: A NOVEL MONOCLONAL ANTIBODY
SOLUTION FOR LASSA FEVER - TRANSFORMING
PROPHYLAXIS AND TREATMENT TO IMPROVE
HEALTH SECURITY AND PANDEMIC RESILIENCE**



MAESTRO platform

Multi-**A**gent **E**volutionary-physics **S**elf-play with **T**ensor-field **R**einforcement and **O**mnichannel feedback

1 Discovery



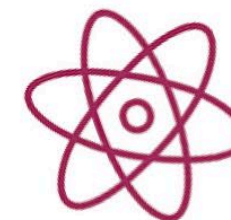
Parallel AI Stack

Generative, RL, and
structure-prediction
models



Physics-Informed Design

Atomistic, not just stats



Lab-in-the-Loop

Design → Express → Test cycle
with tight lab integration



APPRAISE (AI to improve pharmovigilance)

objectives

1. FAIR (findable, accessible, interoperable, reusable) data sources: Catalogue and FAIR-enabled PV-relevant data sources, **ensuring a cohesive network for AI-enhanced safety signal detection & risk prediction.**
2. To integrate federated and centralised analysis across different PV-relevant data sources using secure processing environments (SPE) and/or high-performance computing facilities (HCP).
3. To develop balanced, dynamic and time-stamped reference sets of medicines-outcomes associations for validating performance of safety signal detection and risk prediction using AI/ML-powered methods.
4. To evaluate, select, optimize, test, validate performance and AI/ML methods for improving signal detection with documented human oversight checkpoints, using multimodal approaches.
5. To evaluate, select, optimize, test, validate performance, and document AI/ML methods for safety risk of medicinal products risks pre-MA and for causal risk prediction in populations after validation of safety signals, with human oversight checkpoints.
6. To create an ethical, legal, regulatory-compliant framework & recommendations for human oversight of AI in PV.
7. To develop recommendations, practical tools, a shared platform, playbooks for implementation, and training materials to support the adoption of AI-powered signal detection and prediction in PV practice.

ACCESS to drugs for children is the bottleneck

> *pre studies*

> *post studies*



Prioritizing and Evaluating:

Developing a prioritized drug portfolio of the most needed formulations and assisting in the design and implementation of efficient, and high-quality clinical trials.



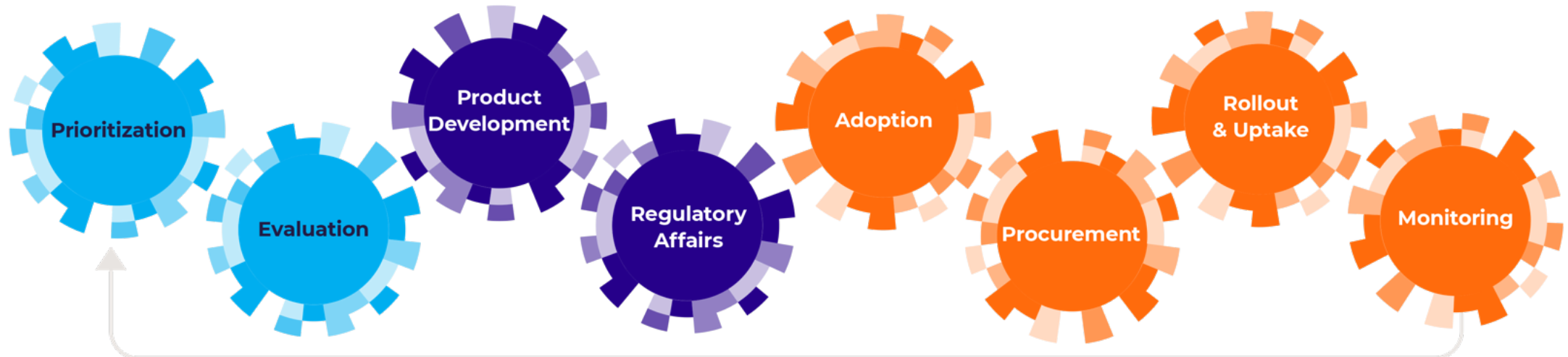
Developing:

Establishing and maintaining relationships to launch effective products and supporting regulatory submission activities to facilitate paediatric medicine approvals.



Delivering:

Supporting efforts to introduce new, adapted formulations in an equitable, accelerated, safe and coordinated manner.



Accelerating priority paediatric drug formulation development and uptake

Over 120 conflicts in 2026



COUNTRIES CURRENTLY AT WAR (MAJOR ONGOING CONFLICTS)

NT

Source: ACLED / International Crisis Group / Global Conflict Tracker

Source: ACLED / International Crisis Group / Global Conflict Tracker / Wikipedia List of ongoing armed conflicts / Recent reports (as of March 2026)



Special thanks to Ali, Costanza, Di, julia, Yazdan, Paolo,
Nicola, Francesca and all those who can recognize their
slides

Thank you!

TO ALL OF YOU !

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