

# PIPELINE

## PIPELINE project

Pregnancy and Infant PrEparedness  
PLatform IN Europe

**Simon Drysdale and Anna Turkova**  
on behalf of the PIPELINE project team

9<sup>th</sup> ReSViNET Conference, February 19, 2026



Funded by  
the European Union

*The PIPELINE project (101155825) is funded by the European Union. Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union or the European Health and Digital Executive Agency. Neither the European Union nor the granting authority can be held responsible for them.*

# Disclosures

- SBD has previously received honoraria from MSD and Sanofi for taking part in RSV advisory boards and has provided consultancy and/or investigator roles in relation to product development for Janssen, AstraZeneca, Pfizer, Moderna, Valneva, GSK, MundiPharma, MSD, iLiAD and Sanofi with fees paid to his institution.
- SBD is a member of the UK Department of Health and Social Care's (DHSC) Joint Committee on Vaccination and Immunisation (JCVI) RSV subcommittee and member of the Medicines and Healthcare products Regulatory Agency's (MHRA) Paediatric Medicine Expert Advisory Group (PMEAG).
- AT is a member of the Global Accelerator for Paediatric Formulations Network (GAP-f), WHO-led Paediatric Drug Optimization (PADO) RSV initiative and serves on the Scientific Committee of the Penta Infectious Diseases Network.

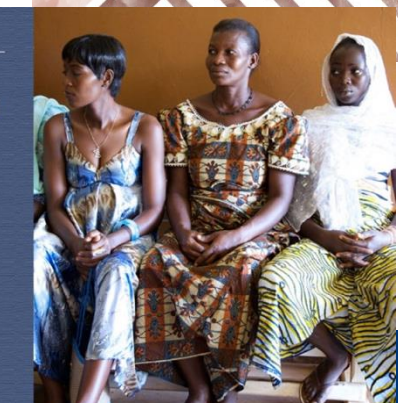
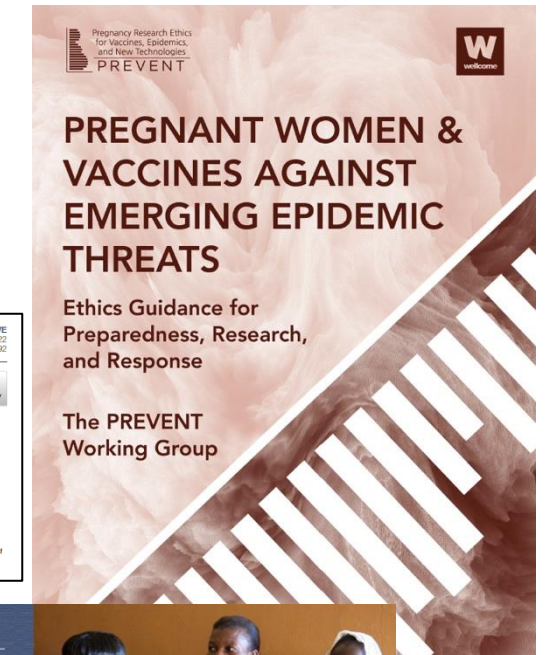
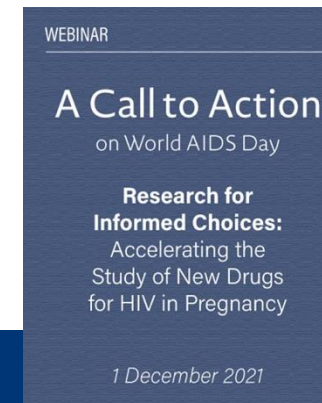
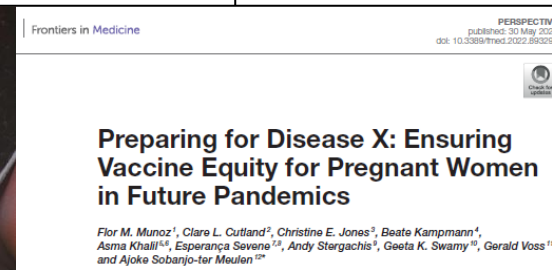
# Pregnancy, early life, and pandemics

- Infectious disease outbreaks can **severely and uniquely affect pregnant women and infants**, with important consequences (e.g. Zika, Lassa fever, Ebola, HIV, influenza A, SARS-CoV-2)
- UK COVID-19 (July–Oct 2021): **one-third of women aged 16–49 yrs on ECMO were pregnant women**, compared with 6% in March 2020
- At any time, **~3.2 million women are pregnant in the EU** and **~116 million globally**
- Despite their vulnerability, pregnant women and infants are almost invariably excluded from pandemic preparedness and response research
- This exclusion leads to delayed access to diagnostics, vaccines and therapeutics and major evidence gaps in dosing, efficacy, and safety, resulting in widespread off-label use

*Haddad NEJM 2018, Faherty AJOG 2017, Krubiner Vaccine 2021, Bonet BMJ Global Health 2024)*

# Pregnancy: paradigm shift for clinical research

- Challenging “protection” of pregnant women (and fetus) from research
- Instead, promoting inclusion in research to try to achieve earlier / faster study of new drugs and vaccines in pregnancy
- Long-standing calls to action, but slow progress



## Ambition:

To develop a dedicated pregnancy-infant preparedness platform for adaptive trials that improves pandemic readiness, enables evaluation of novel diagnostics, vaccines, and therapeutics, and delivers well-powered, policy-informing clinical evidence



# Pregnancy and Infant PrEprparedness PLatform IN Europe



**PIPELINE EU funding:** HORIZON-HLTH-2024-DISEASE-03-11-two-stage: Pandemic preparedness and response: Adaptive platform trials for pandemic preparedness

**Dates:** Jan 2025 – Dec 2028 (48 months)

**Coordinator:** Penta Foundation  
(Fondazione Penta ETS)

# PIPELINE Consortium



- University College London (UCL)
- St George's Hospital Medical School (SGUL)



- Institut National de la Santé et de la Recherche Médicale (INSERM)
- Université Paris Cité (UPCité)
- Centre Hospitalier Annecy Genevois (CHAG)
- Ecole des Hautes Etudes en Santé Publique (EHESP)



- Servicio Madrileño de Salud (SERMAS)

- Universitair Medisch Centrum Utrecht (UMCU)
- European Clinical Research Alliance on Infectious Diseases (Ecraid)
- Connect4Children Stichting (c4c-S)
- ReSViNET



- Universiteit Antwerpen (UANTWERPEN)



- Genos Glycoscience (Genos)



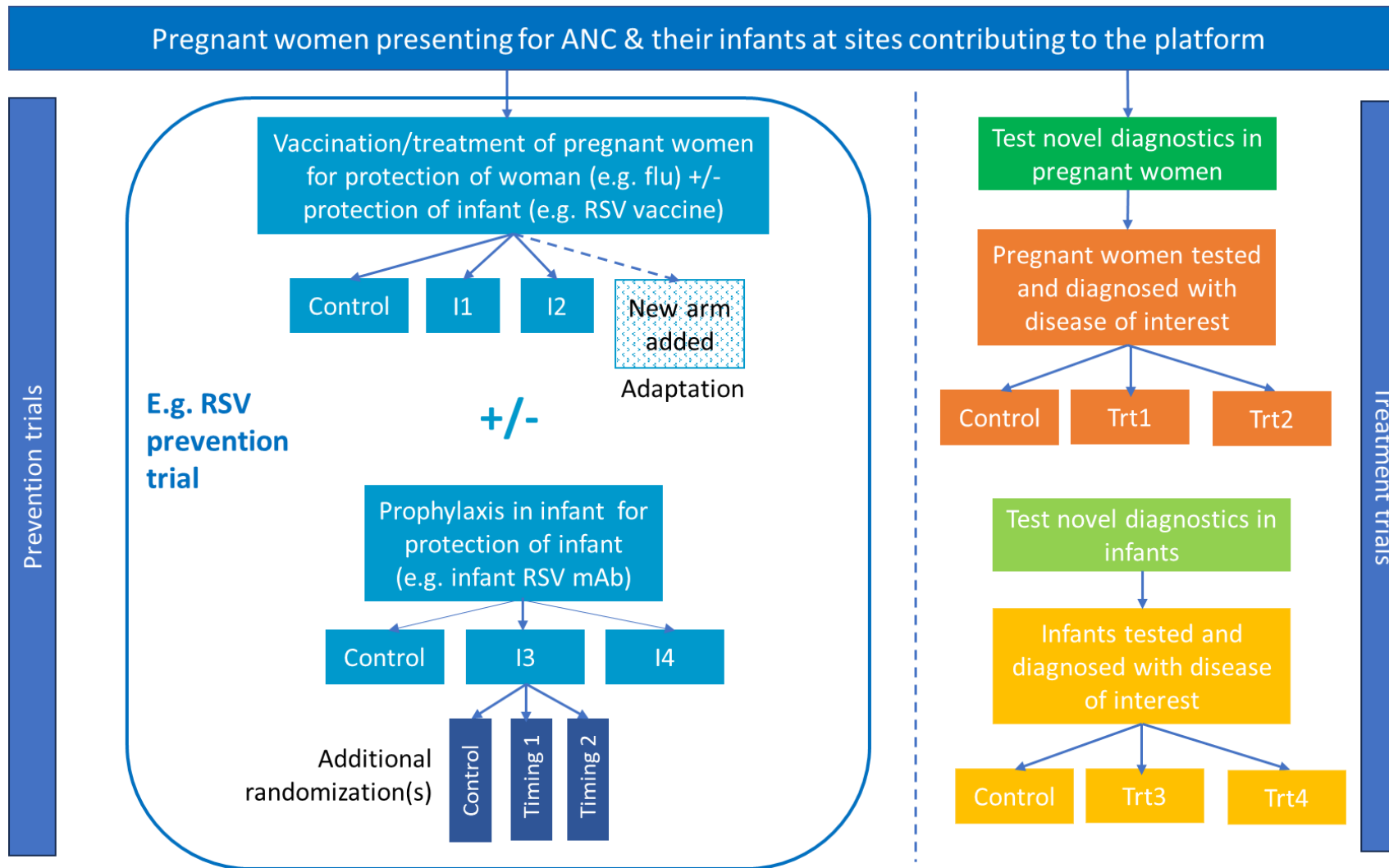
- **Fondazione Penta ETS** (Penta)
- Università Degli Studi Di Roma Tor Vergata (UNITOV)
- Istituto per l'Interscambio Scientifico (ISI)
- Università degli Studi di Verona (UNIVR)

# Objectives



- ❖ Establish a European **preparedness platform for adaptive trials** in pregnant women and infants
- ❖ Establish **and maintain** a site **network**
- ❖ Undertake an **adaptive trial** evaluating strategies for **prevention of RSV in infants**
- ❖ Evaluate **novel sampling techniques for respiratory tract infections** and RSV-associated **immunity**.
- ❖ Engage with **key stakeholders** for **pandemic preparedness** in Europe.

# Platform for trials in pregnant women and infants



# “Warm base” site network

**ecraid**

**i-reivac**  
F-CRIN Network  
Innovative clinical research network in vaccinology



**conect**  
**4children**  
COLLABORATIVE NETWORK FOR EUROPEAN  
CLINICAL TRIALS FOR CHILDREN

**ReSViNET**  
RESPIRATORY SYNCYTIAL VIRUS FOUNDATION

**Penta**  
Child Health Research

**Preg-CoV**

- **Network of maternity and infant research sites**
  - "Network of networks"
  - National Coordinators to support on country-level
  - Larger network (beyond RSV trial)
- **Research & capacity building activities to keep sites "warm"**
- **Trial-ready in case of an epidemic**

# PIPELINE National Coordinators



34 countries approached

32 country feasibility questionnaires completed



# PIPELINE-RSV trial: Background

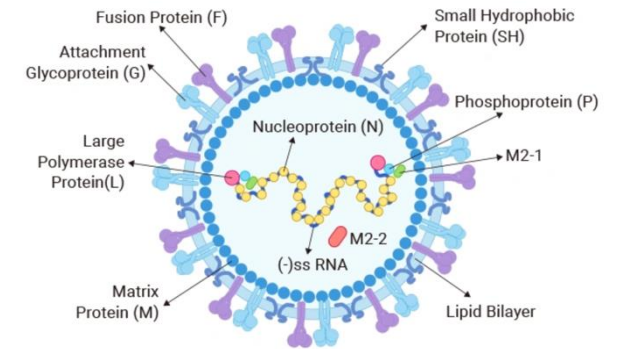
## Why choose RSV for the first trial of the platform?

- 95% of children have RSV by age 2 years
- Around 2% will require hospitalisation (in the absence of prophylaxis)
- Globally 1 in 50 deaths in those <5 years due to RSV
- Large burden on healthcare systems

## Novel, preventive strategies have recently been developed with high efficacy and good tolerance - maternal vaccine (MV) & monoclonal antibodies (mAb) to infant - but:

- Seasonal administration may be difficult in some healthcare programmes
- Uncertain efficacy beyond 6 months of age
- No studies have assessed efficacy of giving both together, or made direct comparison

+ New products round the corner



# Two parallel RSV prevention trials referred to as “PIPELINE-RSV trial”



## PIPELINE

### PIPELINE-RSV International

**PIPELINE EU funding:** HORIZON-HLTH-2024-DISEASE-03-11-two-stage: Pandemic preparedness and response: Adaptive platform trials for pandemic preparedness

**Coordinator:** Penta Foundation



### PIPELINE-RSV France

**PIPELINE-RSV-France funding:** ANRS ReCH-MIE / DGOS (French MoH)  
**Coordinator:** Centre Hospitalier Annecy Genevois



**Shared:** Safety oversight, Data management, Statistics, Economics, Trial Oversight Committees



**Aligned:** Protocols, Scientific leadership team and meetings

**Different:** Labs for RSV testing; Immunology sub-studies; Social science sub-studies

## Phase 3 open label platform trial for RSV prevention in infants

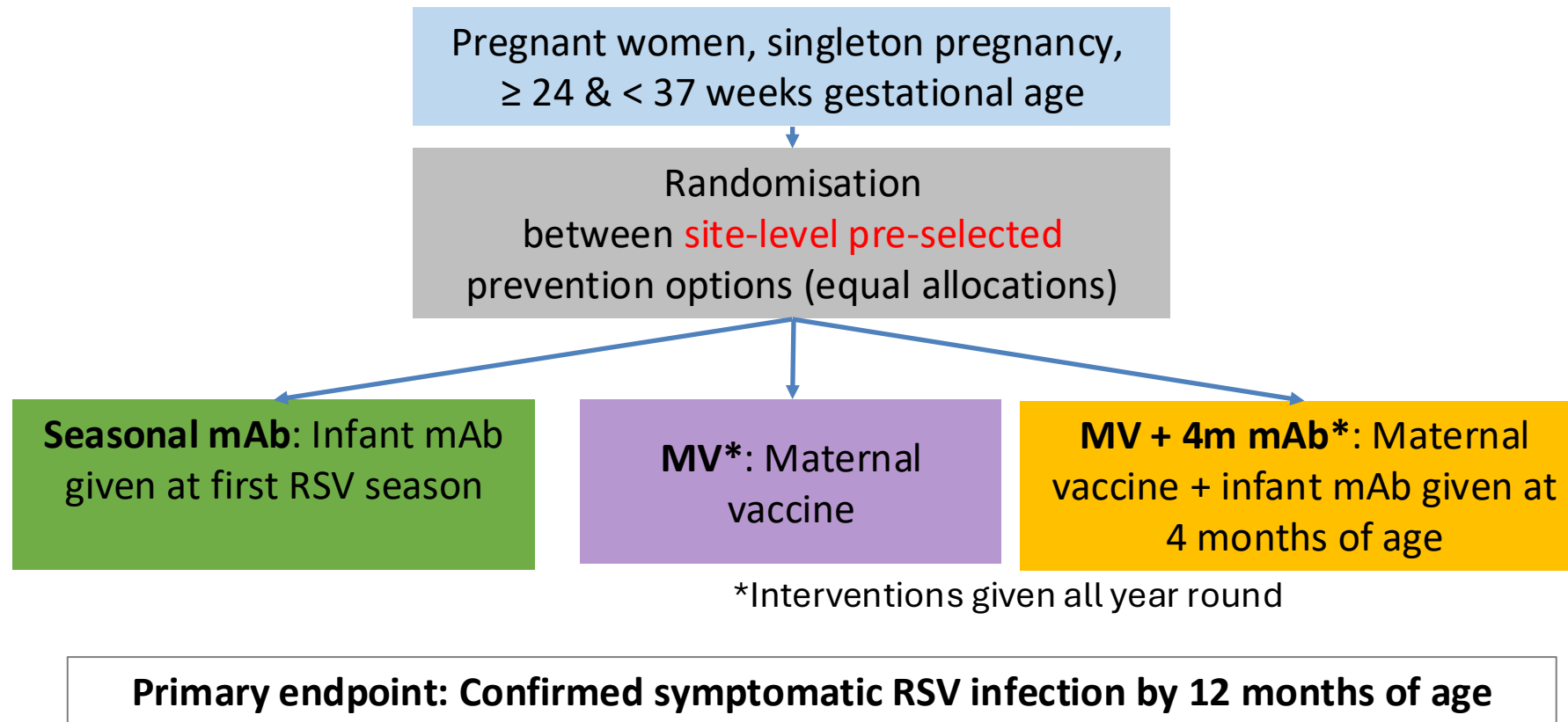
### Primary objectives

- To determine if MV + 4m mAb (all year round) provides **superior** protection against symptomatic RSV infection in infants by 12m compared to Seasonal infant mAb
- To determine if MV + 4m mAb (all year round) provides **superior** protection against symptomatic RSV infection in infants by 12m compared to MV (all year round)

### Secondary objectives

- To rank **MV all year round & Seasonal mAb** and estimate the difference between them in terms of **efficacy**
- To evaluate the interventions based on **secondary efficacy and safety outcomes**, as well as **feasibility, acceptability, cost effectiveness, virological and immunological substudies**

# PIPELINE-RSV trial schema



# PIPELINE-RSV trial: Main eligibility criteria

## Inclusion

### Pregnant women

- Provide informed consent
- Above the national legal age of consent
- Between **24+0 (or later as per national guidance) and 36+6** weeks gestation
- Able to read and complete the Participant Facing Surveys

### Infant

- Live-birth to mother enrolled in the study
- Informed consent for infant

## Exclusion

### Pregnant women

- **Major illness** of the mother or **condition of the foetus** that **would contraindicate participation**
- High **risk of prematurity** as judged by treating clinician
- **Multiple pregnancy** (i.e. twins, triplets or more)
- History of Guillain Barre Syndrome
- Receipt of any previous RSV prevention product in this pregnancy
- Any contraindication for receipt of intramuscular injection or vaccine

*Note, all live born infants to mothers in the study will be included, but infant mAb will not be given if contraindicated.*

# PIPELINE-RSV trial: **Primary endpoint**



**Symptomatic RSV respiratory tract infection (RTI) in an infant, confirmed by an approved positive RSV test, by 12 months of age**

- Mothers to **report in real time for the infants (birth-12m) on an eHealth questionnaire:**
  - All RTI **symptoms**
  - All non-routine **medical consultations**
  - **Hospital admissions**
- Mothers to take a **nasal/nasopharyngeal swab each time infant has RTI symptoms**
- Mothers to **report 2x monthly in RSV season and monthly outside season** - no relevant events have occurred
- All non-routine & hospital admissions will **trigger a call** from the clinical site
- **Routine contact at 4m & 12m** of age
  
- Trial swabs will be tested centrally for RSV
- Any RSV testing in routine care will also be captured

# PIPELINE-RSV trial: Secondary Endpoints

## Infants:

- RSV RTI by **3 & 6** months of age
- **Medically-attended** (MA)-RSV RTI by **3, 6, 12** months of age
- RSV RTI-associated **hospitalisation** by **3, 6, 12** months of age
- RSV RTI with **SpO2 <90%** and/or with **need for supplemental O2** by 3, 6, 12 months of age
- RSV RTI-associated **death** by 12 months of age
- **All-cause** RTI by 3, 6, 12 months of age
- **All-cause MA-RTI** by 3, 6, 12 months of age
- **All-cause RTI-associated hospitalisation** by 3,6,12 months
- **All-cause RTI with SpO2 <90%** and/or with **need for supplemental O2** by 3, 6 and 12 months of age
- **All-cause RTI-associated death** by 12 months of age
- **MA-wheezing** with 1 or more episodes by 12 months
- **Cycle threshold (Ct)** value overall and by RSV subtype (RSV-A or RSV-B) for RSV-infection confirmed by **PCR** by 12 months
- **Serious adverse events (SAEs), grade ≥3 AEs** by 12 months\*

## Mothers and pregnancy outcomes:

- **All-cause MA-RTI** by 12 months post-delivery
- **SAEs** by 12 months post-delivery\*
- **Pregnancy loss** (miscarriage and stillbirth)\*
- **Preterm** (<37 weeks' gestation) delivery\*
- Infant **low birth weight** (<2500g)\*

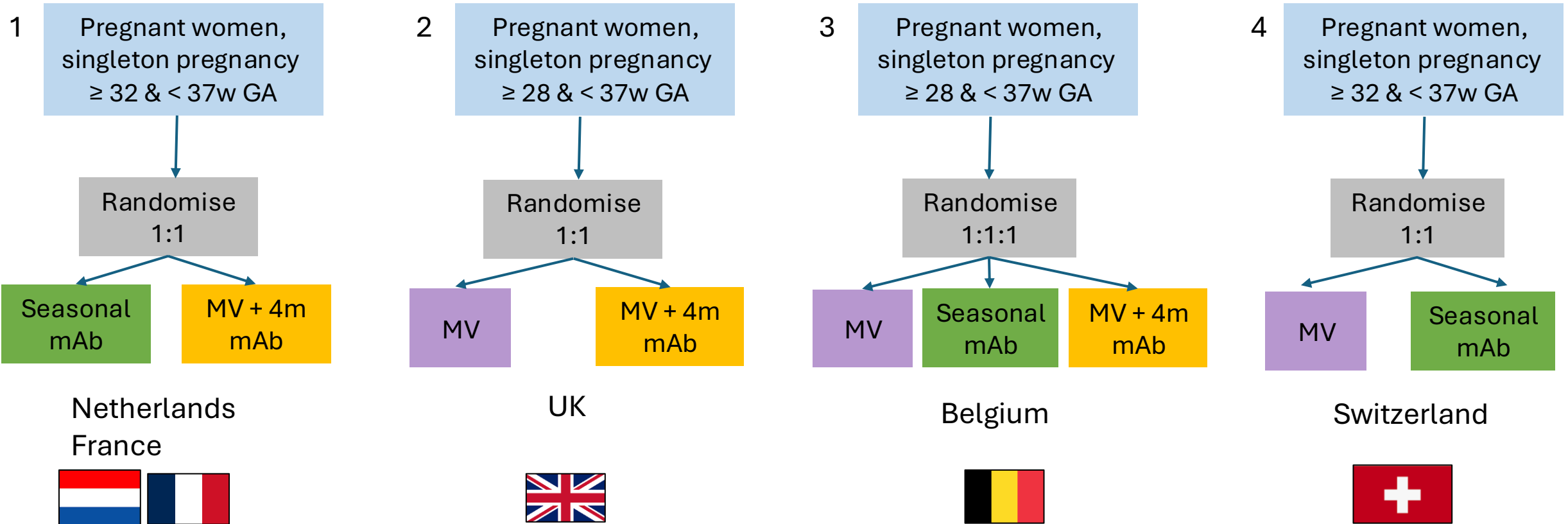
\*Safety AE – an **AE considered important for monitoring maternal or infant safety**, which is reportable in the trial.

Other safety AEs in the **mother** include medically diagnosed **GBS**, medically diagnosed **HSR** to MV and, in the **infant**, include **CVA** and medically diagnosed **HSR** to mAb and, in **mothers & infants**, symptomatic **medication error**.

Maternal information on RTIs and potential safety AEs will be collected via the eHealth questionnaire from enrolment to the end of follow-up.

GBS=Guillain-Barré Syndrome ; HSR = hypersensitivity reaction; CVA=cerebrovascular accident

# PIPELINE-RSV trial: Recruitment plans by country



# PIPELINE-RSV trial: Sample size and power



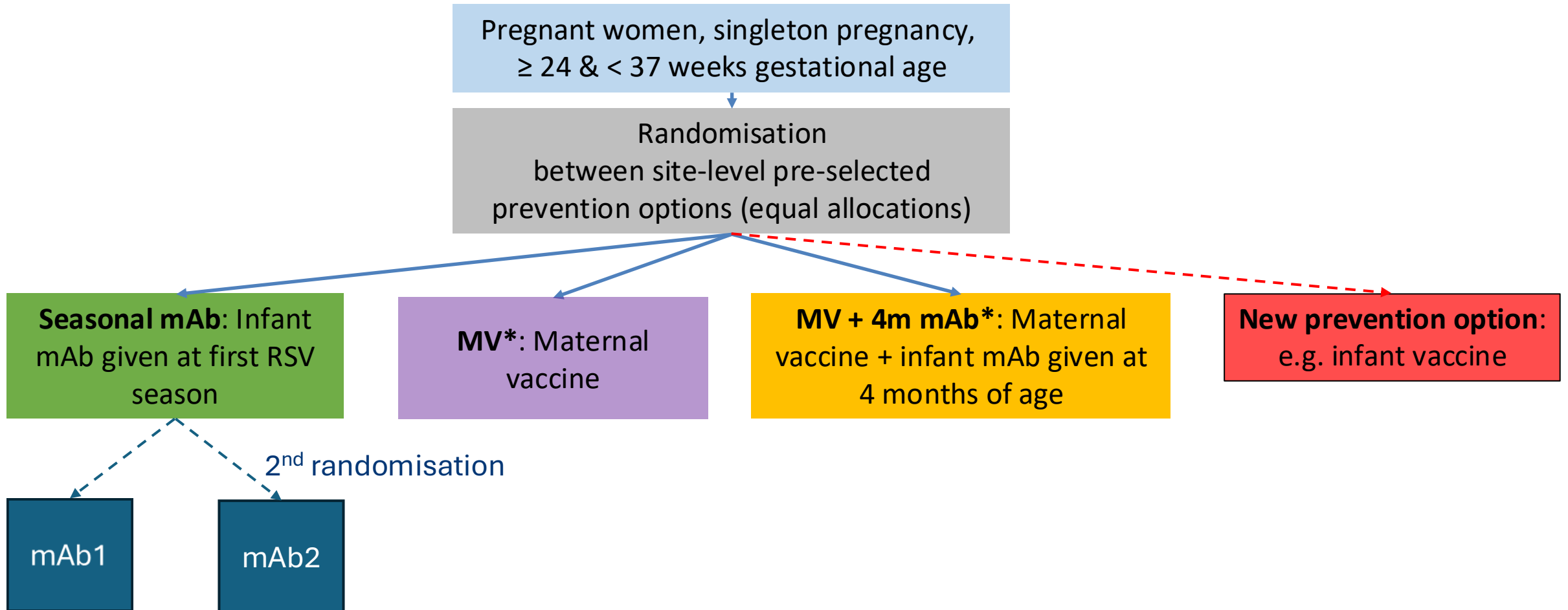
## Total 2500 mother-infant pairs

- 1500 PIPELINE-International
- 1000 PIPELINE-France

## Power

- 10% risk of symptomatic RSV infection by 12 months with a single intervention (MV or Seasonal mAb)
- 10% loss to follow-up
- $\geq 1100$  randomised between MV+4m mAb and Seasonal mAb (rx options 1 & 3) provides 80% power ( $\alpha=0.05$ ) to demonstrate a 50% reduction in risk
- $\geq 1100$  randomised between MV+4m mAb and MV (rx options 2 & 3) provides 80% power ( $\alpha=0.05$ ) to demonstrate a 50% reduction in risk

# Potential adaptations



# PIPELINE-RSV trial: **Substudies**

## **Health Economics**

- **Cost-effectiveness** of the trial interventions.

## **Immunology**

- **RSV immunity** in trial subgroups and to explore dried mucosal spots.

## **Social Science**

### **PIPELINE-RSV trial:**

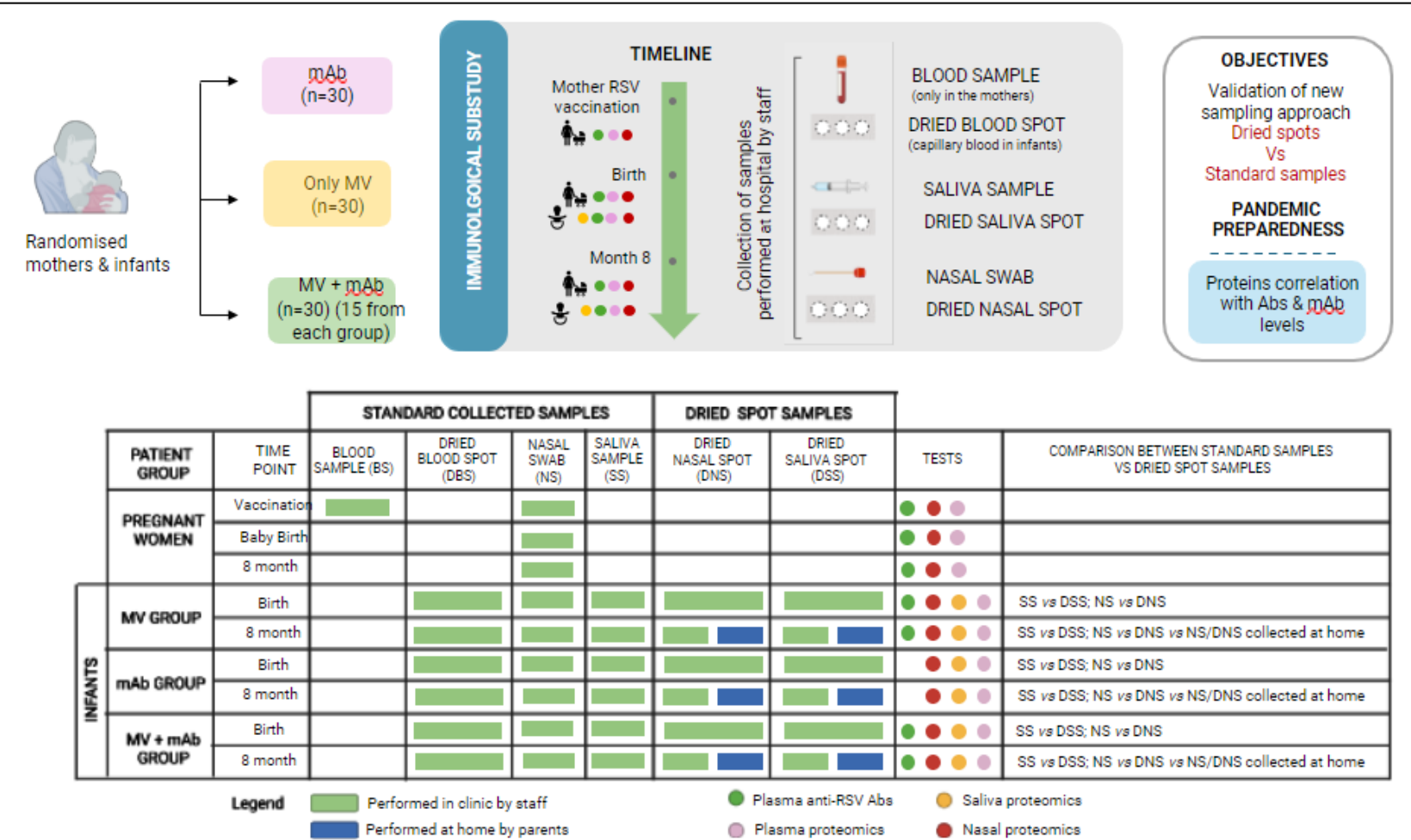
- **Facilitators** that encourage pregnant women to participate in an RSV vaccine trial and to understand preferences for different communication techniques
- **Vaccine hesitancy** and experience of side effects in the trial

### **Project-wide (outside the trial):**

- Additional **population-based** data collection among **pregnant women/recent parents and healthcare providers** to assess the **acceptability** of the infant RSV prevention strategies



# Novel sampling techniques and immunity



**To validate new sampling approaches:**  
Dried blood/nasal/saliva spots vs. standard samples for immune response

**To compare response to immunisation over time between groups**

# PIPELINE-RSV trial: expected results and potential impact

- Evidence on most effective, cost-effective and acceptable approach to preventing RSV in infants to inform policies and guidelines



Reduce RSV morbidity and mortality  
in infants in Europe



# PIPELINE EU Platform: expected results and potential impact

- First European **platform for APTs in pregnancy/ infants**
- Trained, engaged and **ready-to-act network** of clinical sites
- Better **understanding of barriers and facilitators** to participation in clinical trials and implementation of interventions in pregnancy and infants
- Resource & **support for external research consortia**



Improved European health emergency preparedness response  
More equitable access to new treatments and vaccines  
Increased capacity in Europe to conduct APTs

# Sharing resource and support externally



Collaboration with other consortia working in pandemic preparedness (e.g. PROACT EU- RESPONSE)

## Ambition

- To exploit PIPELINE **infrastructure** (e.g., processes, tools, templates) and **network** for **future research** within and beyond current consortium & beyond the life of the project
- To conduct **RSV Prevention trials in resource-limited settings** (e.g. Thailand, Africa)
- To support external collaborators wanting to recruit through PIPELINE



 **PIPELINE**

**THANK YOU!**



**Funded by  
the European Union**

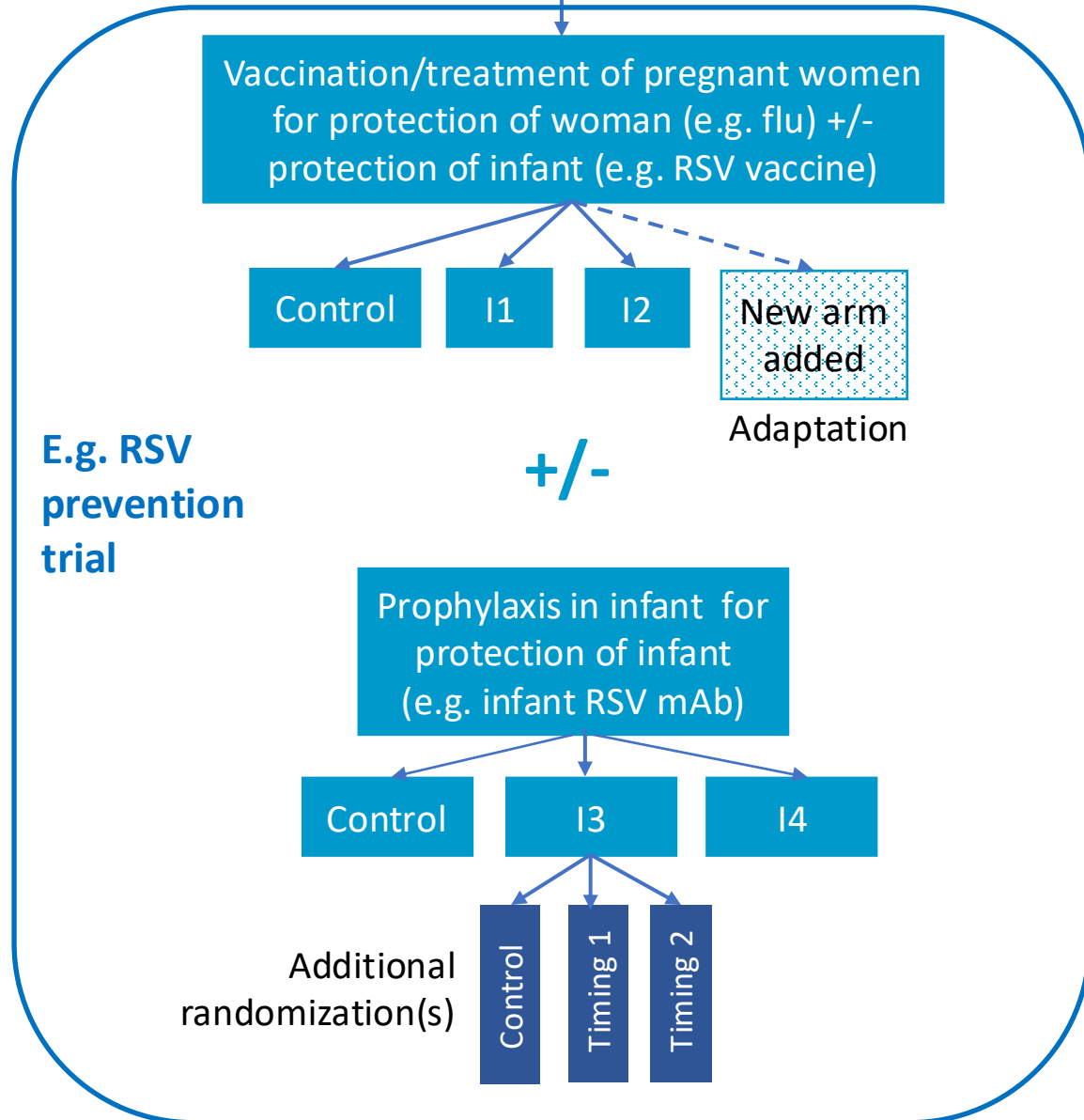
*The PIPELINE project (101155825) is funded by the European Union. Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union or the European Health and Digital Executive Agency. Neither the European Union nor the granting authority can be held responsible for them.*



*PIPELINE is sponsored by Fondazione Penta ETS.*

Pregnant women presenting for ANC & their infants at sites contributing to the platform

Prevention trials



Treatment trials

