SHAPING THE FUTURE OF CLINICAL TRIALS

We are transforming the future drug development

by creating a **sustainable entity**

available for industry and academia

to **conduct platform trials in any disease area**

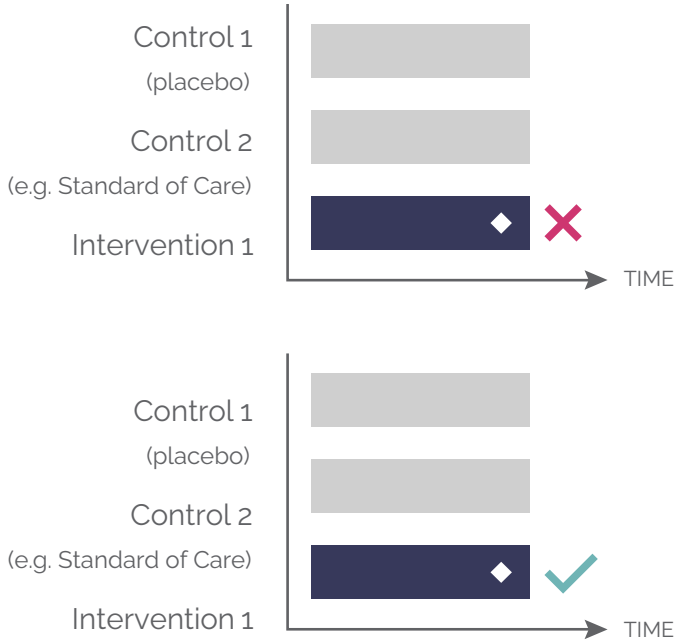
codesigned by patients

This project has received funding from the Innovative Medicines Initiative 2 Joint Undertaking (JU) under grant agreement No 853966.
The JU receives support from the European Union's Horizon 2020 research and innovation programme and EFPIA and CHILDREN'S TUMOR FOUNDATION, GLOBAL ALLIANCE FOR TB DRUG DEVELOPMENT NON PROFIT ORGANISATION, SPRINGWORKS THERAPEUTICS INC.

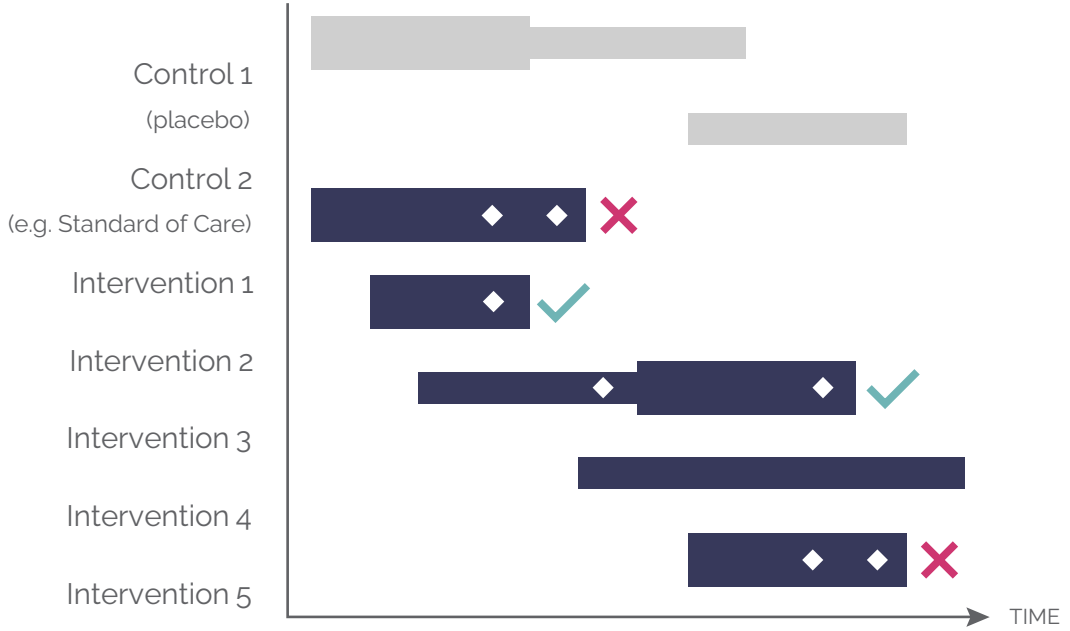
DISCLAIMER: this presentation reflects only the author's view. The JU is not responsible for any use that may be made of the information it contains.

PLATFORM TRIAL APPROACH

Traditional Clinical Trial paradigm



Perpetual open adaptive Platform Trial



(INTERIM) ANALYSIS PH 3 — STOP FOR FUTILITY — GRADUATE TO

INTEGRATED RESEARCH PLATFORMS
IRPs

An Integrated Research Platform is a novel clinical development concept which centers around a master trial protocol

It can accommodate multi-sourced interventions using the existing infrastructure of hospitals and federated patient data in design, planning and execution

An optimized regulatory pathway
for these novel treatments has been established.

WHAT IS EU-PEARL?

Strategic **alliance** between the **public** and **private** sectors to:

by developing a common framework

for platform clinical trials/Integrated Research Platforms (IRPs)

EU-PEARL hAS DELIVERED

1 A trusted sustainable entity ready to setup and coordinate the operation of Integrated Research Platforms in any disease.

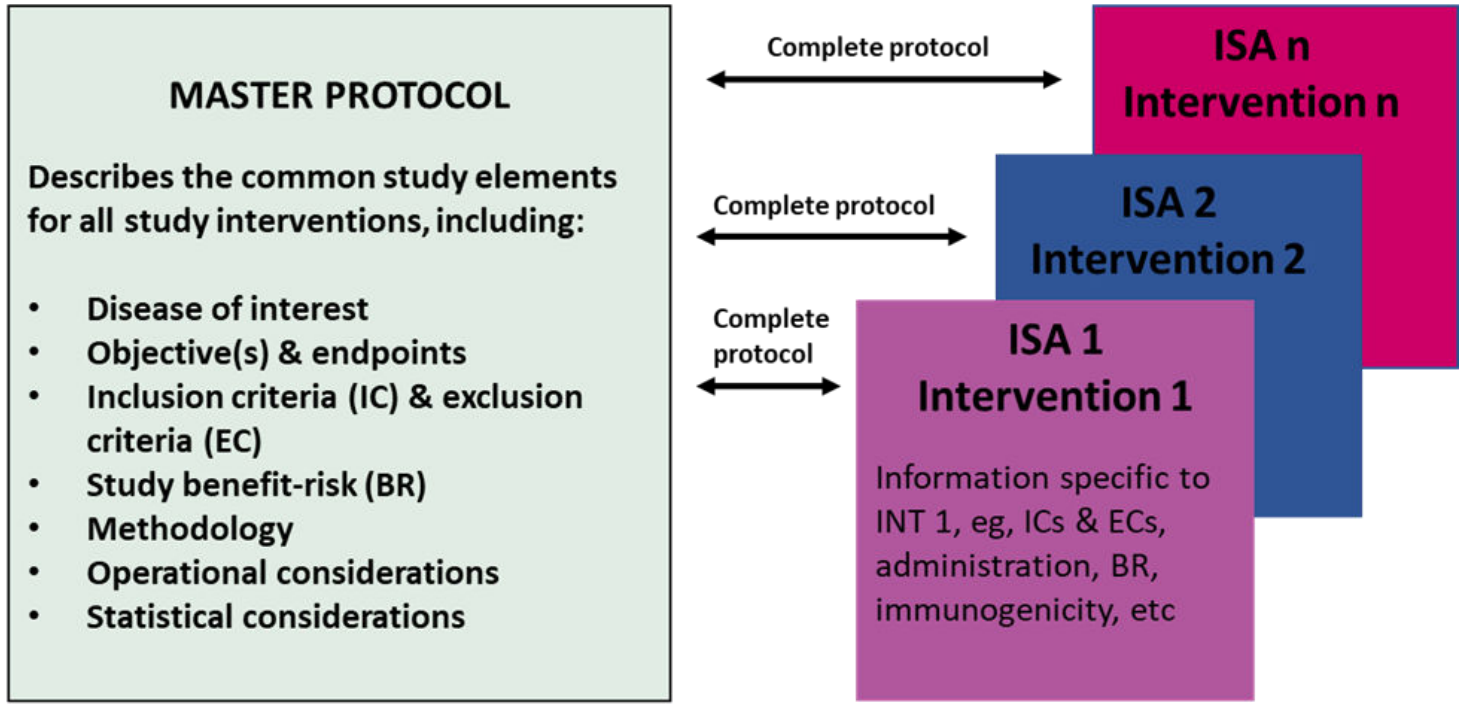
2 A Clinical Trial Platform Framework that can be used for any disease, plus four disease clinical trial platforms ready to operate at the end of the project

3 Four disease trial-ready clinical networks

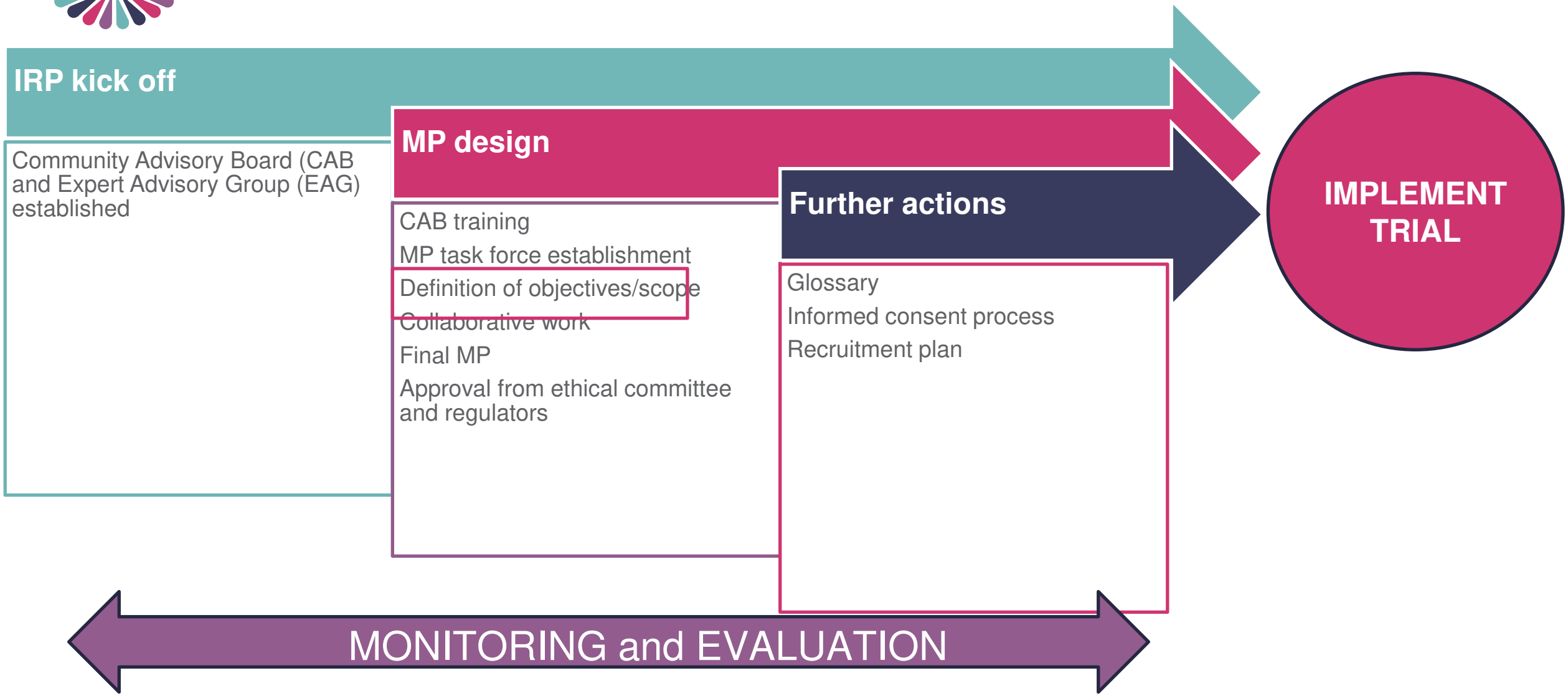
- Major Depressive Disorder
- Tuberculosis
- Non-Alcoholic Steatohepatitis (NASH)
- Neurofibromatosis

MASTER PROTOCOL AND INTERVENTION SPECIFIC APPENDICES

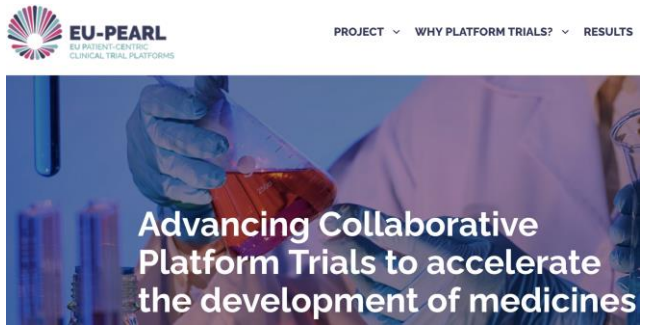
- The **Master protocol** governs the entire study and includes the **common key study design elements**
- **Intervention-specific information** is provided in **Intervention Specific Appendices (ISAs),** which are added as interventions become available and are ready to enter the platform study
- Interventions can enter the platform study **simultaneously** or **sequentially** as they become available for study
- **Both protocols** are needed to have all the information needed to conduct the study in an intervention cohort



A framework for effective Community Engagement in IRP design for TB



Next step: use of the resources



FROM Theory TO Practice

1) UNITE4TB project: outline

UNITE 4TB

Part of the **Innovative Medicines Initiative 2 (IMI-2)**

imi innovative medicines initiative

FACTS & FIGURES

Start Date	01/06/2021
End Date	31/05/2028
Call	IMI2 - Call 20
Grant agreement number	101007873

Type of Action:
RIA (Research and Innovation Action)

Contributions	**€**
IMI Funding	92 500 000
EFPIA in kind	62 364 744
Associated Partners	30 135 256
Total Cost	185 000 000

EFPIA = European Federation of Pharmaceutical Industries and Associations

DESIGN Framework

FROM Theory TO Practice

IMPLEMENT TRIAL