TRIALS @HOME

Requests for Proposals

How to submit your technology to Trials@Home

Wednesday, Jan 6th
3pm CET

The research leading to these results has received support from the EU/EFPIA Innovative Medicines Initiative [2] Joint Undertaking (H2020-JTI-IMI2) Trials@Home grant n° 831458.

Meet Our Presenters

- Mira Zuidgeest – UMCU (University Medical Center Utrecht)
- Kai Langel - Director, Janssen Clinical Innovation
- Sten Hanke, FH Joanneum (University of Applied Sciences Gratz)
- Gary Friedman, Inflammation and Immunology, Pfizer
- Cinzia Molendini, R&D, UK Medical Research Network

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Project Introduction

Mira Zuidgeest, T@H Project co-lead, UMCU

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Why the Trials@Home project?

Developing new medicines/health solutions and improving patient health rely on the successful conduct of clinical trials to generate relevant safety and efficacy/effectiveness data.

Recruitment and retention of patients are one of the most challenging aspects in clinical trial protocol adherence.

Main barriers/hurdles are

- Lack of patients' awareness of clinical trials
- Distance to the clinical site
- The burden on patients, including the duration and number of clinical visits
- 30% dropout rate of patients who consented

Emerging digital technology enables **Remote Decentralised Clinical Trials (RDCTs),** a disruptive approach setting the trial around the patient rather than a centralised trial setting

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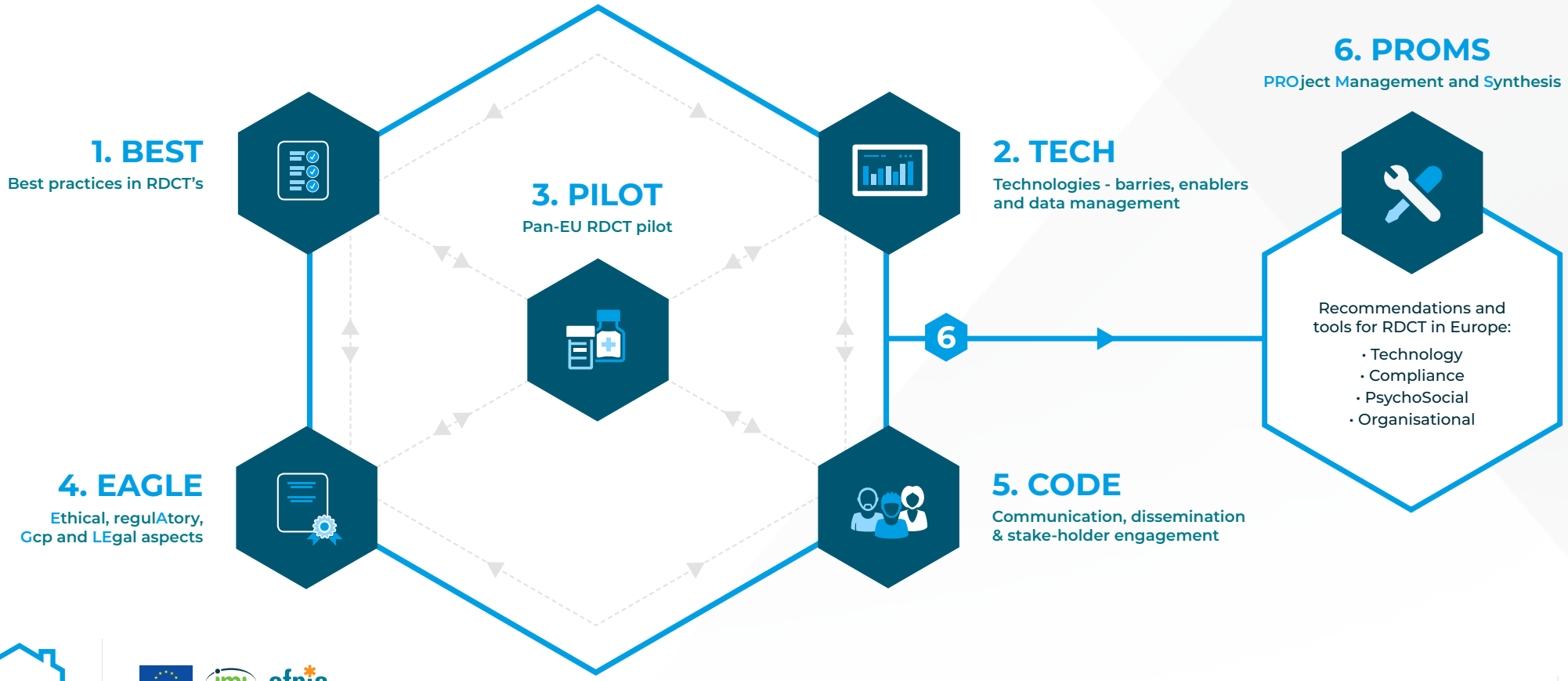
What do we do?



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Overarching aim of the T@H pan-EU pilot study

GETTY

To determine whether RDCT's can replace the existing paradigm for clinical trial conduct

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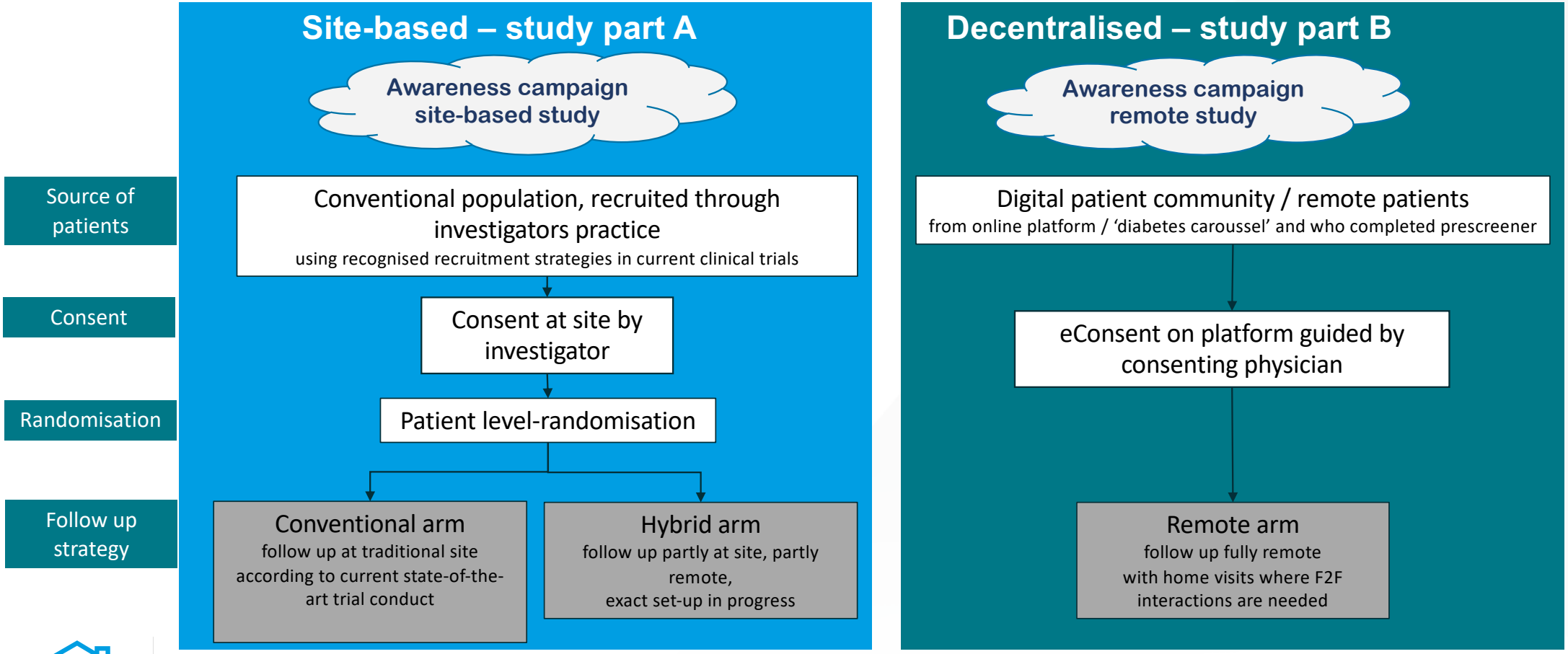
Pilot study set-up



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The RFP

Kai Langel - Director, Janssen Clinical Innovation

Sten Hanke - FH Joanneum (University of Applied Sciences Gratz)

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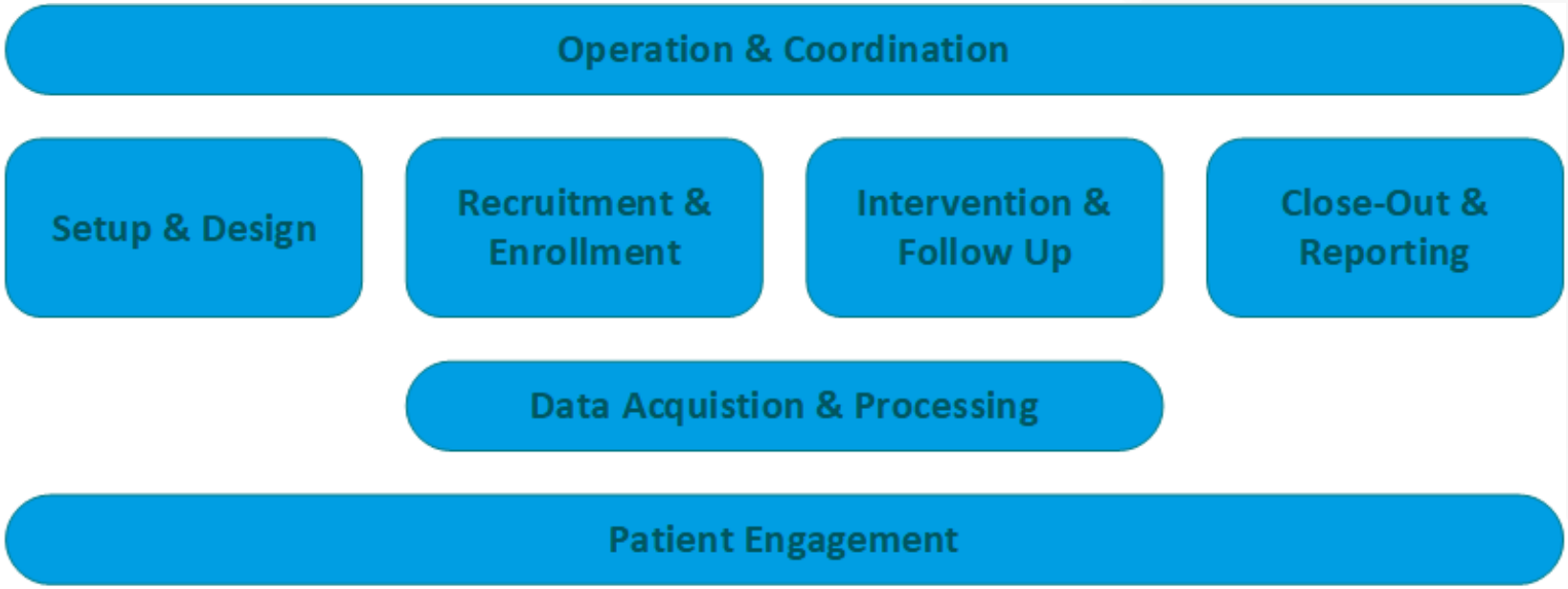
Building Block Structure

Basic Building Blocks (BBBs)



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Technology Package

CLINPAL

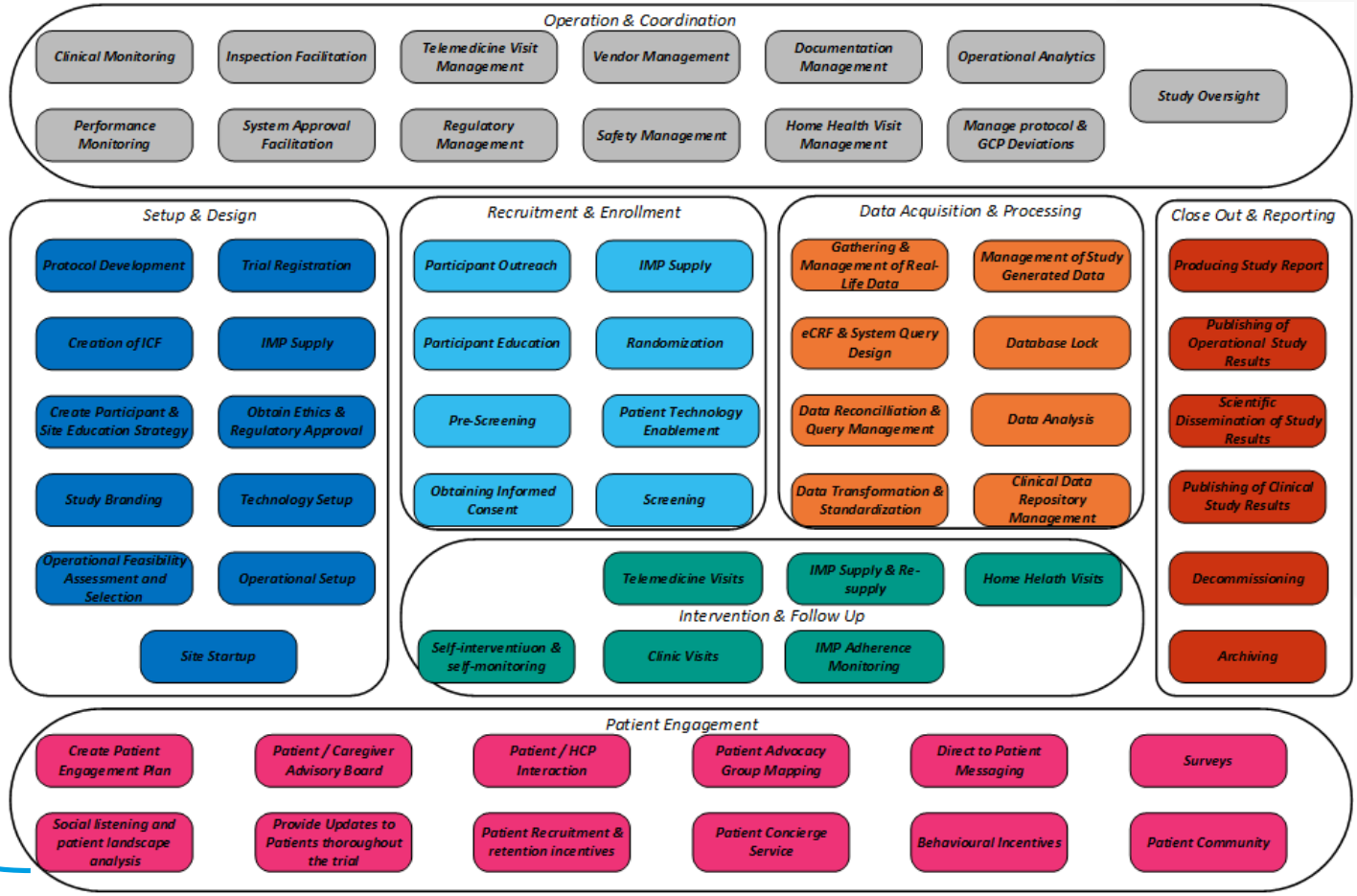
By

eClinicalHealth

(a current consortium partner)

+

Technologies sourced via the RFP



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IMP MANAGEMENT: END-TO-END

Gary Friedman, Director
Inflammation and Immunology, Pfizer

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RFP WEBINAR

IMP MANAGEMENT: END-TO-END REQUIREMENTS

06 JANUARY 2021

Gary S. Friedman, MD
Pfizer, Inflammation & Immunology
Pfizer, Representative for IMI/Trials@Home

REQUIRED DELIVERABLES

- RANDOMIZATION
- IMP ORDERING, DELIVERY, AND ACCOUNTABILITY
- IMP SUPPLY RETURN, ACCOUNTABILITY, AND DESTRUCTION
- IMP ISSUES MANAGEMENT

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RANDOMIZATION: Unique RAND# and SSID#

RANDOMIZATION

- PI/SI determines study participant eligibility and logs into IXRS
- PI/SI completes RAND assignment in IXRS for the study participant to which a unique SSID# and a unique RAND# are assigned.

SSID# & RAND#

- The unique SSID# and Rand# are connected to all subsequent IMP orders—whether initial or re-supply or replacement or returned IMP.

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IMP ORDERING, DELIVERY, & ACCOUNTABILITY

DRUG ORDERING LOGISTICS

- Electronic or paper options.
- Storage in eSource and TMF.
- Stable linkage between PI/SI, study participant SSID# and Rand#, IXRS DB, Central Courier DB, and Central Pharmacy DB to manage all intended and unintended downstream IMP issues.

CENTRAL PHARMACY SERVICES PROVIDER

- IMP Order Form (IOF), IMP Assignment Confirmation and Shipment Request (IACSR).
- IMP Payload Box from Central Courier.
- Confirmation of IMP receipt by study participant.
- Storage of IMP “paperwork” (IOF, IACSR, IMP receipt, Airbill, and IMP kit verification).
- Stable linkage between Courier DB, Central Pharmacy DB, and Study DB.

IMP TRANSIT

- IMP in GPS-tracked, temperature-controlled Payload Box.
- Intact audit trail from Central Pharmacy to Central Courier to Study Participant.

IMP DELIVERY

- Courier confirmation that IMP transit data are within range.
- Study Participant government-issued ID confirmation and handover of IMP.

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IMP SUPPLY RETURN, ACCOUNTABILITY, & DESTRUCTION

IMP RE-SUPPLY & UNPLANNED SUPPLY

- Integrated scheduler connecting Central Pharmacy, Central Courier, and Study Participant.
- IMP “pick & pack”, Payload Box RFID tagging, and IMP audit trail integrity.
- Monitoring and confirming IMP compliance.

IMP RETURN & ACCOUNTABILITY

- Study Participant informs Central Courier of need for IMP return.
- Schedule IMP return pickup by Central Courier.
- Central Pharmacy assessment of IMP compliance.
- Central Pharmacy IMP storage and destruction.

IMP ISSUE MANAGEMENT

- Central Pharmacy, PI/SI, and Central Courier awareness of IMP issues.
- IMP quality complaints and evidence of quality issue.
- Lost or stolen IMP.

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DEMANDS FOR TELEMEDICINE

Cinzia Molendini, R&D, UK Medical Research Network

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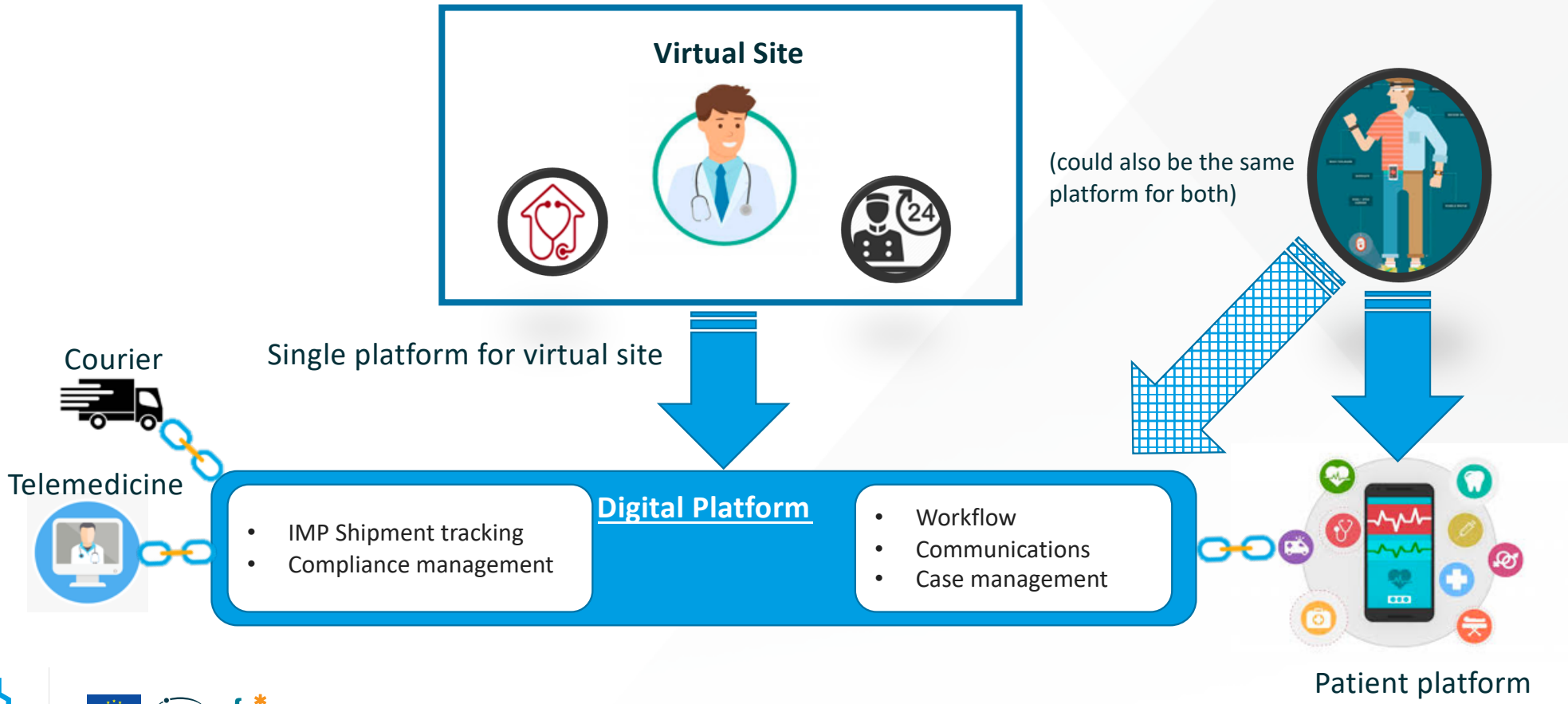
The Vision (hybrid and remote arms)



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Telemedicine requirements

- Integration with Clinpal platform
- High quality audio-visual interaction
- Multi-user (simultaneous) interaction
- Efficient scheduling solutions allowing visibility of participant, home nurse (were required) and site personnel availability:
    - Protocol-defined visits (within allowed visit window)
    - Unscheduled visits
    - Emergency visits/contacts
- User feedback after each visit and quantification of satisfactory or non-satisfactory aspects
- Ability to connect to external devices (i.e. cameras, vital sign monitoring devices, etc.)
- Recording/transcription capabilities (optional), or anyway ability to take notes for record keeping, case management and eCRF completion purposes)

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