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Centre of Excellence

Remote and Decentralised Clinical Trials

Wednesday 24
11-12 am 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 Trials@Home Presenters

Rick Grobbee
UMCU & Julius Clinical
Trials@Home Project Lead

Mira Zuidgeest
UMCU & Julius Clinical
Trials@Home Project Lead
WP PILOT Co-lead

Kim Hawkins
Sanofi
Trials@Home Project Lead
WP BEST Co-lead

Kai Langel
Janssen Clinical Innovation
WP TECH Co-lead

Jeroen De Bruin
FH JOANNEUM
Gesellschaft mbH
WP TECH Co-lead

Duane Schulthess
Vital Transformation
WP CODE Co-Lead
(Moderator)

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Welcome

Rick Grobbee

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Background

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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Kim Hawkins, Sanofi

Mira Zuidgeest, University Medical Center Utrecht

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Broad Stakeholder Involvement

- ✓ Patients
- ✓ Healthcare providers
- ✓ Regulators / HTA
- ✓ Small and medium-sized enterprises (SMEs)
- ✓ CROs
- ✓ Technology providers
- ✓ Academic researchers/PI
- ✓ Pharmaceutical industry

Regulatory acceptance of new approaches/ updating ICH guidelines process

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In association with…

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Objectives and Key deliverables

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Work packages

The six Work Packages (WPs) of Trials@Home and their interdependencies.

WP1 (BEST):
Identification of best practices in RDCTs

WP2 (TECH):
Identifying technologies and other operational innovative approaches for RDCTs; selecting the appropriate technology package for pan-EU pilot study

WP3 (PILOT):
Design, implementation and management of the pan-EU pilot; comparing the scientific and operational quality of the RDCT with traditional trial approaches

WP4 (EAGLE):
Identifying, mapping and analysing the relevant ethical, quality, regulatory, legal and organisational barriers and enablers of RDCTs

WP5 (CODE):
Communication, dissemination and stakeholder engagement activities; investigate impact of RDCT on patient-HCP interactions

WP6 (PROMS):
Develop coherent set of project recommendations; establish and maintain external stakeholder platform (ESP); project management.

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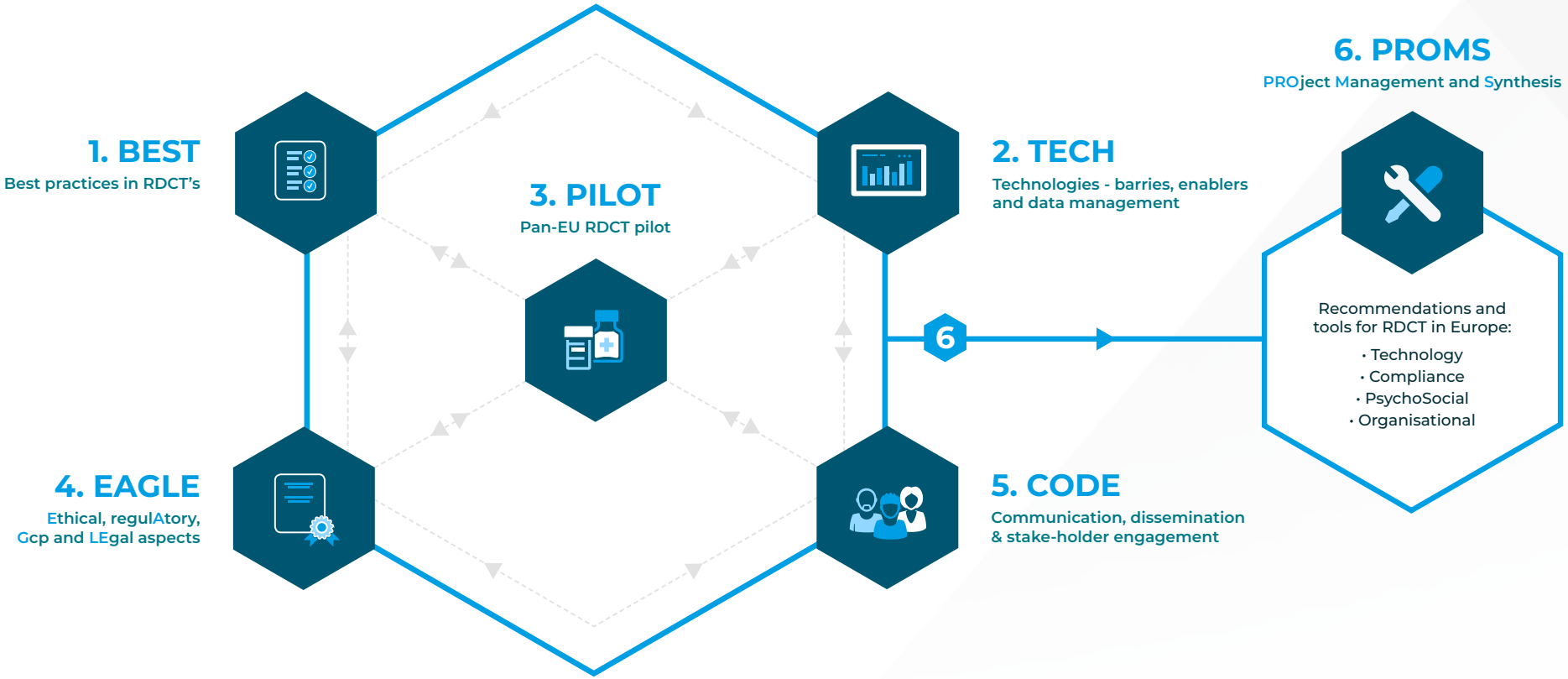

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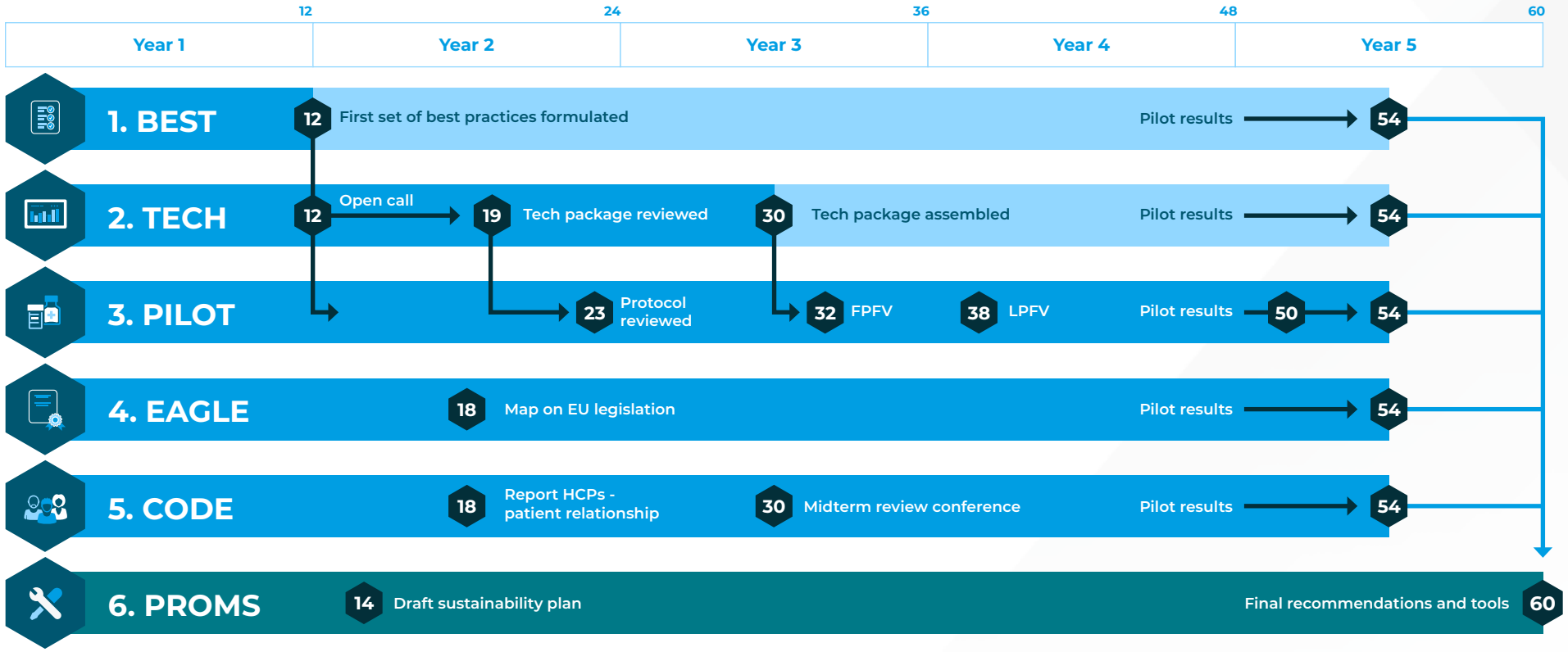
IMI DCT Topic – Overall Timing



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Diabetes as TA for the pan-EU pilot study

Rationale:

Diabetes meets all the predefined assessment criteria. Main reasons for choosing diabetes over other TA choices include:

- High disease burden & large, broad patient population
- Variety of unanswered research questions in various subpopulations
- Clear and easy to self-measure objective primary clinical outcome (e.g. bioassay);
- Variety of available technologies
- Learnings for operational approaches
- IMP can be administered at home
- IMP Cost.

Assessment criteria:

Scientific

- Benefit
- Population
- Clinical value of the study
- Generalisability

Operational

- Goodness-of-fit of TA/indication for testing RDCT approach
- Availability/suitability of IMP for the TA/indication
- Budget and time restrictions
- Practicality of deploying the IMP
- Safety

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Thank you

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The Request For Information (RFI)

Kai Langel & Jeroen De Bruin
WP TECH

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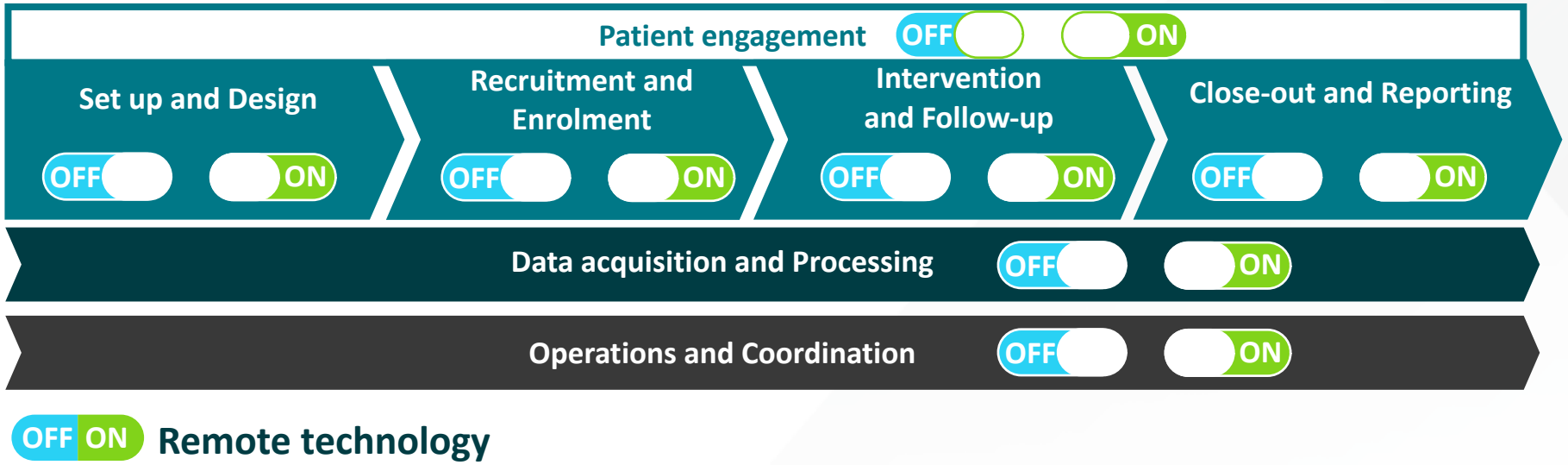
WP TECH: top down approach to software composition

- Top-level identification of distinct trial phases in “basic building blocks”
- Also acts as a reference model to synchronize and divide tasks, and identify technology gaps
  - Technology scan focusses on these blocks, missing technologies are identified along the way



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Zooming in …

Intervention and Follow-up

ACTIVITY	DESCRIPTION
Self-intervention and self-monitoring	Patients perform interventions themselves, and perform (e.g., filling out an ePRO) or allow self-monitoring by wearables, sensors and other devices installed at the home.
Home Health visits	The scheduling and conducting of study visits by home health professionals at the participant's home or other location, whereby activities such as image acquisition, sample acquisition, clinical and safety data acquisition, and IMP interventions may take place.
Telemedicine visits	The scheduling and conducting of remote study visits with the use of telemedicine solutions, whereby activities such as image acquisition, sample acquisition, clinical and safety data acquisition, and IMP interventions may take place.
Clinic visits	Conducting of physical study visits by the patients, whereby activities such as image acquisition, sample acquisition, clinical and safety data acquisition, and IMP interventions may take place.
IMP supply & re-supply	Creation of an IMP shipment from a central or local supply depot with a delivery either directly to the participant or to a local delivery report, such as a pharmacy or local GP office where the participant can collect the delivery. A system can be in place to allow the virtual site, participant and other stakeholders involved to follow the shipment progress. Re-supply can take place based on IMP consumption and / or on request by the participant or the virtual site.
IMP adherence monitoring	A smart medication system (such as a smart bottle or blister pack) can monitor IMP consumption and provide near real-time feedback for the participant themselves, as we as alert others in case of non-compliance with the prescribed IMP regimen. The adherence monitoring solution can also inform IMP re-supply needs.

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Building Block Needs

Technologies and Innovative Solutions (example)

1. **Digital platform** for communications and workflow coordination for the decentralized site team, e.g. ability to share notes about a participant, case management features, scheduling, notifications, etc.. The platform should either directly include a participant-facing interface or be able to integrate with a separate participant-facing system.
2. **Telemedicine component**, either built-in as part of the digital platform or a plug-in, allowing for video connectivity between members of the decentralized site team as well as with study participants.
3. **Courier / logistics service** for IMP: tracking shipments between central depts with local delivery location (e.g. pharmacies, etc.) and / or direct-to-participant. The shipment information should be made available to the decentralized site team within the digital platform as well as to participants.
4. **Smart medication solutions** with near real-time connectivity to be able to track IMP adherence and inventory.

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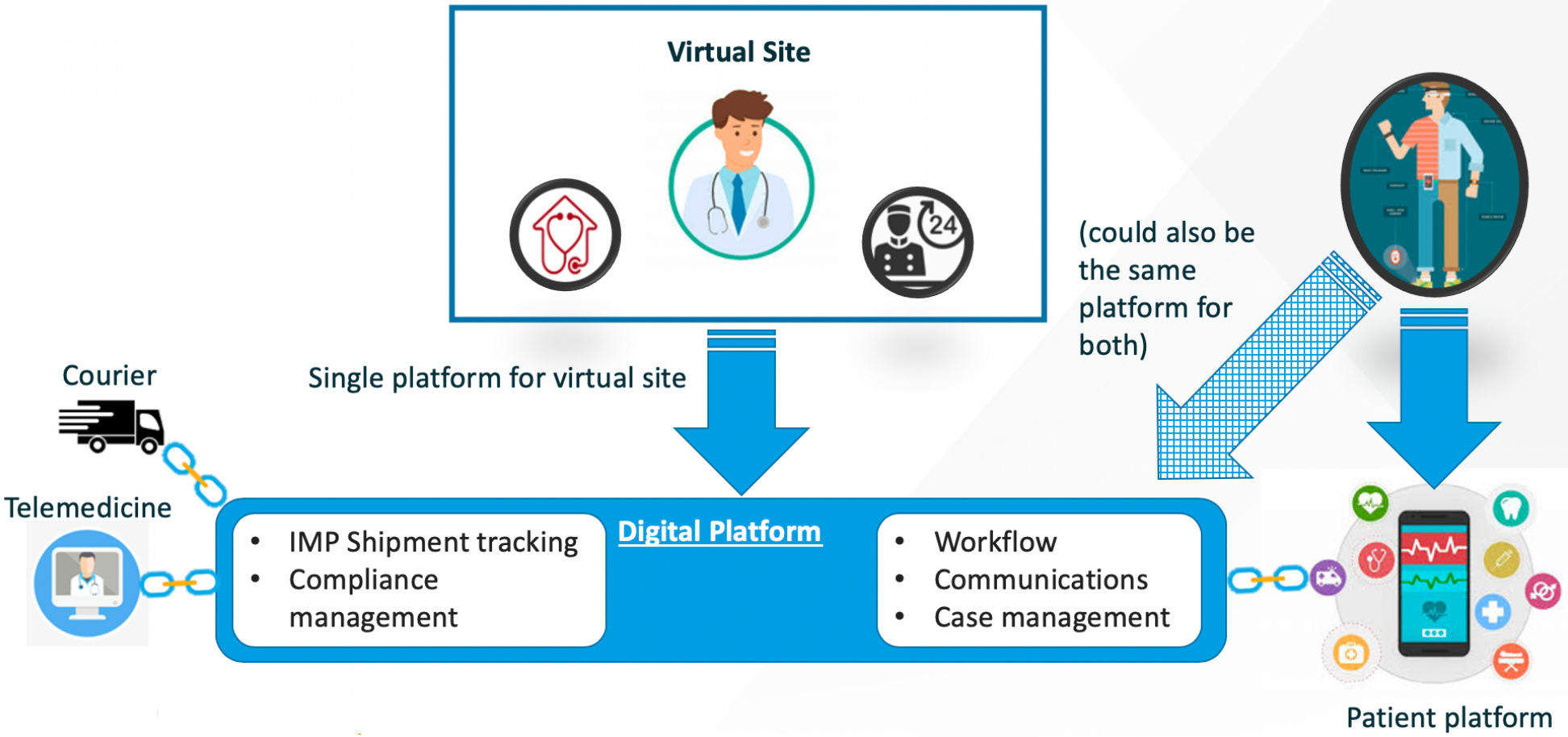
TECH Vision for Intervention & Follow-up



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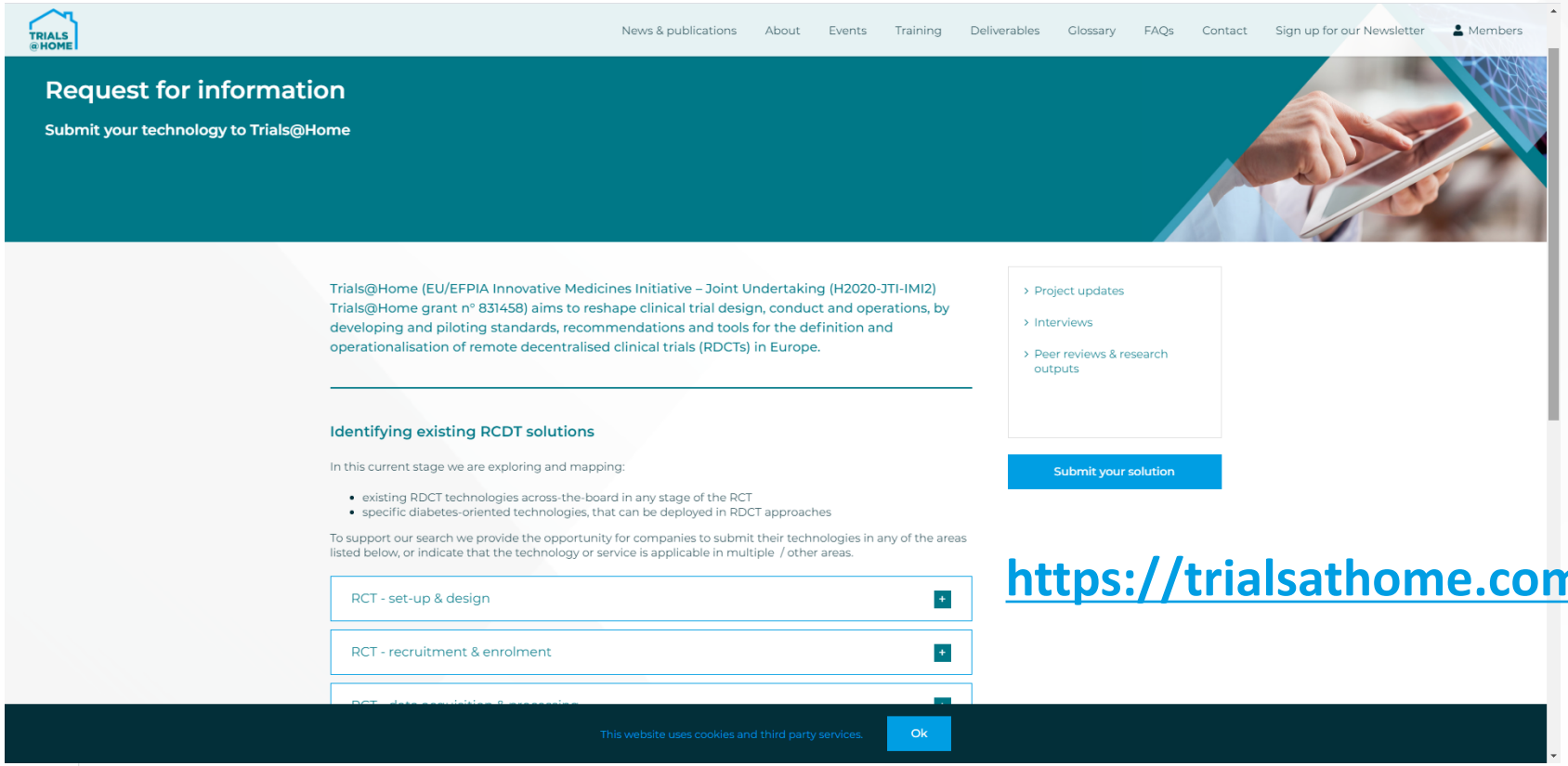
WP TECH: Request for information

- WP TECH is actively searching for technologies
- Another way to gather information on technologies is through “crowd-sourcing” using our RFI



https://trialsathome.com/request-for-information/

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QUESTIONS

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Trials@Home Project Lead

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