



Centre of Excellence Remote and Decentralised Clinical Trials

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In association with...



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

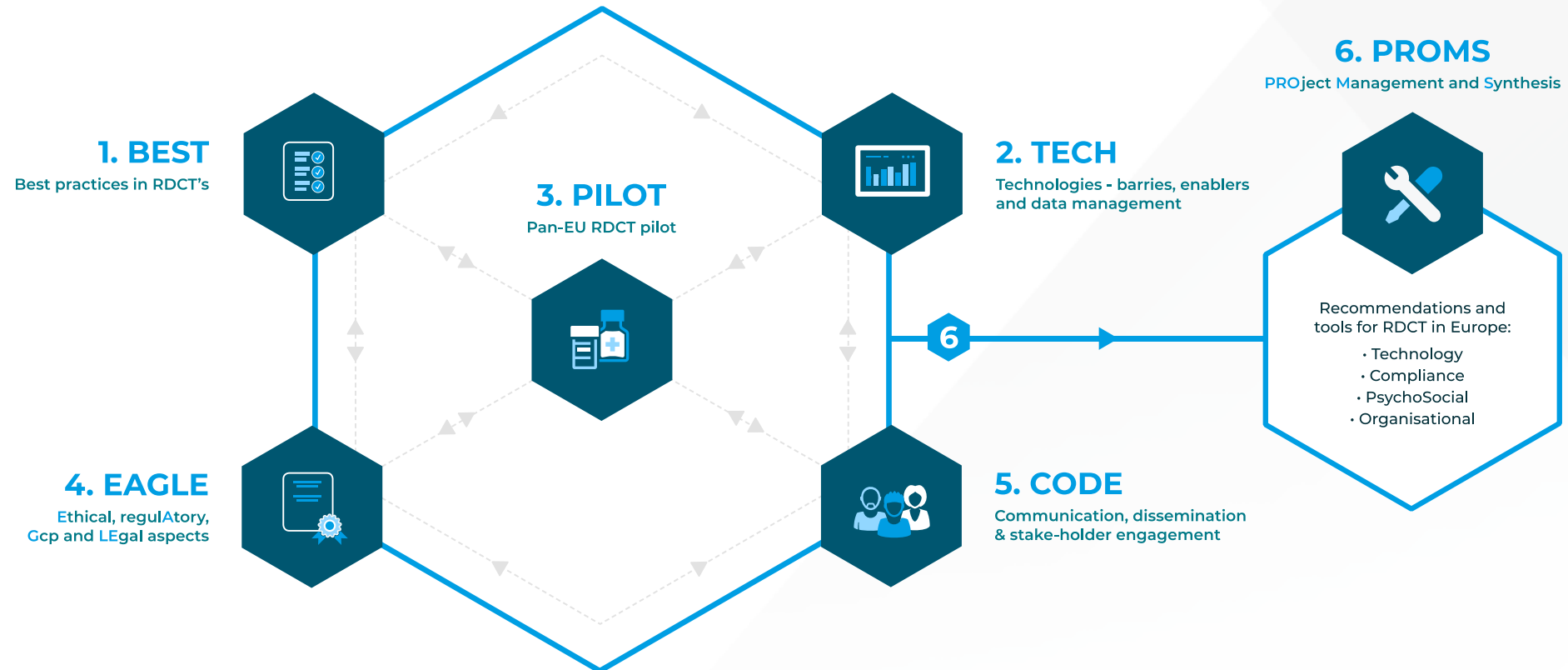
Project Aim & Objectives

To reshape clinical trial design, conduct and operations, by developing and piloting standards, recommendations and tools for the definition and operationalisation of RDCTs in Europe

- Define best practices for the conduct of RDCTs (WP BEST)
- Identify technologies and other operational innovative approaches for RDCTs and select the appropriate technology package to be used for the pan-EU pilot (WP TECH)
- Design and run a pan-EU pilot, comparing the scientific and operational quality of the RDCT with traditional trial approaches and evaluating the feasibility (WP PILOT)
- Identify, map and analyse the relevant ethical, quality, regulatory, legal and organisational barriers and enablers of RDCTs (WP EAGLE)
- Consult with stakeholders and promote the lessons from the consortium through targeted activities (WP CODE)
- Provide recommendations with supporting tools for implementing RDCTs in Europe and contribute to the update of ICH guidelines on RDCTs (ALL)

Work packages

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



WP TECH: top down approach to software composition

- Level 1, identification of distinct trial phases in “basic building blocks”

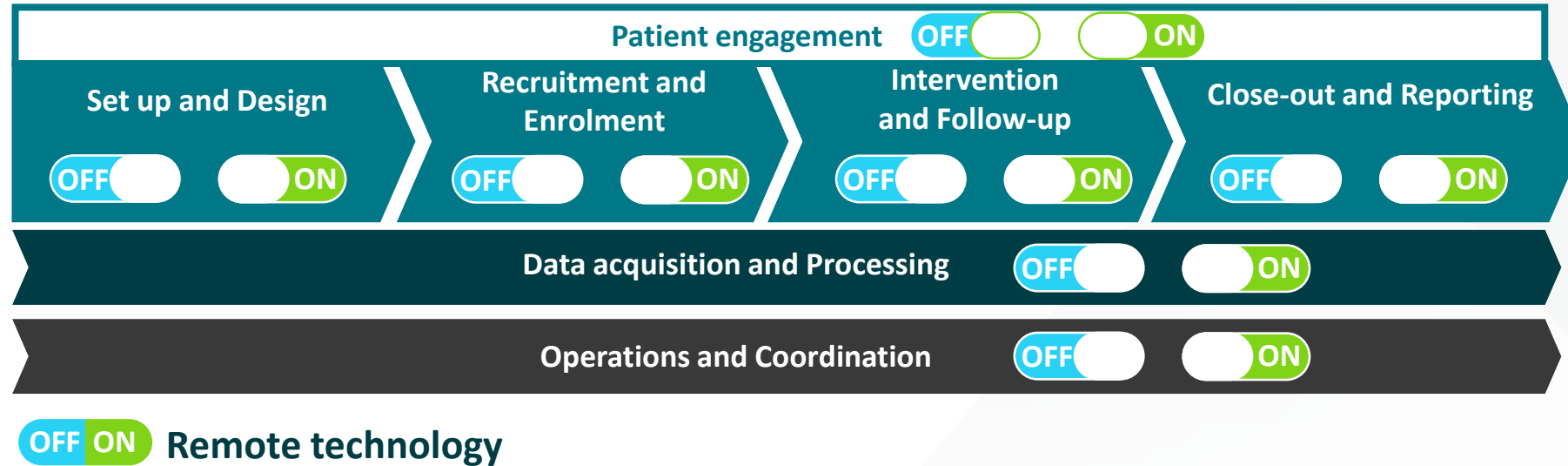
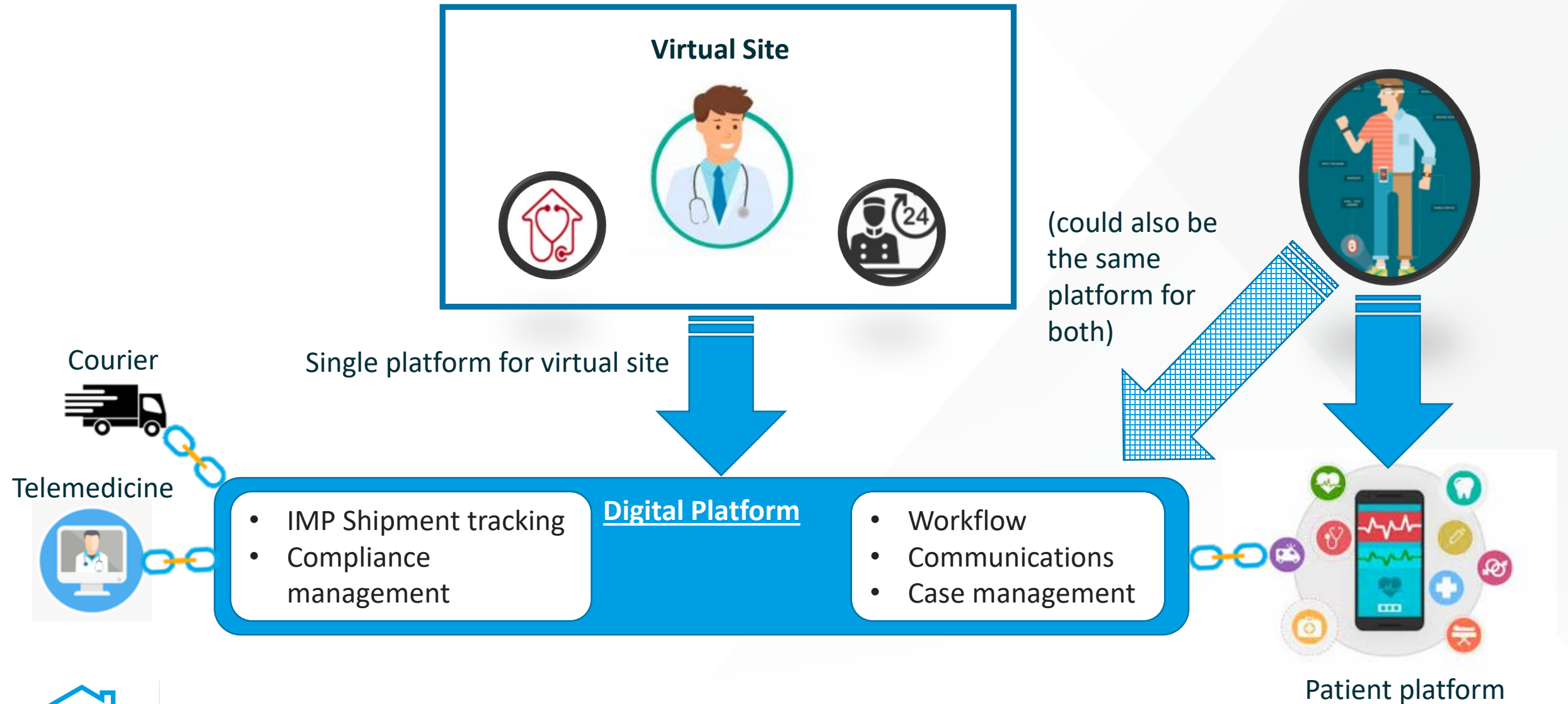


Fig.: Traditional versus hybrid and full RDCT approaches across the clinical trial building blocks

WP TECH: Trial activity model

- Level 2, example “**intervention and follow-up**”
 - **Definition:** “Activities that gather study data and/or perform interventions according to study protocol”
 - **Activities:**
 - Self-intervention and self-monitoring
 - Home Health visits
 - Telemedicine visits
 - Clinic visits
 - IMP supply & re-supply
 - IMP adherence monitoring

Example: TECH Vision for Intervention & Follow-up



T@H and the future ECSEL consortium

Mutual benefits

- Move RDCT possibilities forward together by:
 - Identification of technological gaps by T@H
 - Development of technologies for these specific gaps
- T@H to benefit from evolving tech know-how of ECSEL consortium
- ECSEL consortium to benefit from evolving clinical trial know-how of T@H consortium

Concrete interactions

1. T@H to share gap analysis on RDCT technologies with ECSEL consortium
2. Keeping each other informed on trends in the field
3. Provide concrete think tank sessions for each other on tech (ECSEL) / clinical trials (T@H)
4. T@H to incorporate ECSEL developments into the final recommendations
5. Invite each other to / joint external communications/activities

Webinar invitation: IMI Trials@Home

Wednesday 24 June 2020, 11-12 CET

- Trials@Home will host an external webinar
- The T@H group will:
 - explain the project's ambition
 - highlight our current Request for Information call, regarding RDCT technologies
- Registration is free: <https://trialsathome.com/webinars/>



Thank you!

Contact us:

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