Topic: Centre Of Excellence – Remote Decentralised Clinical Trials

All information regarding future IMI Call topics is indicative and subject to change. Final information about future IMI Calls will be communicated after approval by the IMI Governing Board.

Specific challenges to be addressed

Developing new medicines/health solutions and improving patient health rely on the successful conduct of clinical trials to generate relevant safety and efficacy data. Recruitment and retention of patients are one of the most challenging aspects in clinical trial protocol adherence. The 2017-global CISCRP[1] survey reported the main barriers to patients' participation as "lack of patients' awareness of clinical trials" (~61%); and the "geography and the distance to the clinical site" (60%)[2]. The burden on patients, including the duration and number of clinical visits, also drives their decision. In addition, within patients who consent, an alarming 30% dropout rate across all clinical trials is observed[3]. Therefore, by the same token, improving the patients' experience through protocol optimisation to ease the perceived patient burden should improve data quality and increase the probability of success[3].

TransCelerate and IMI initiatives have already led to significant achievements in this area, For example, the first European Electronic Health Records data platform[4], which connects more than 20 European hospitals, has already resulted in reduced recruitment times. More recently, the emergence of digital technology has increased the feasibility of Decentralised Clinical Trials (DCTs), a disruptive approach consisting in setting the trial around the patient rather than a centralised trial site[5]. Positive results[6] of an acne phase 2 trial that enrolled adolescents with a reduced enrolment time of 50 percent, have recently been communicated.

Combining the adoption of digital endpoints and telemedicine as applied to trials, the DCT model could improve patient access to trials, increase the participation of more diverse populations, and enhance data collection. In addition, the DCT model can help to fill the gap between clinical development and the real world setting, providing useful real life experience while the patient is followed from home or community care. The improved clinical trial efficiency may accelerate patient access to medical breakthroughs.

Need and opportunity for public-private collaborative research

This action offers a common forum to engage key stakeholders (e.g. patients, healthcare providers (HCPs), regulators, small and medium-sized enterprises (SMEs), pharmaceutical industries) to define the European remote DCT implementation considering its environment (e.g. regulatory and ethics, International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH)[7] /Good Clinical practices (GCP)[8])[9].

Since DCTs could represent a dramatic shift both in the way clinical trials are conducted in the EU, as well as in the EU environment for clinical trials, a multidisciplinary collaborative approach among all stakeholders involved in

[1] Center for Information and Study on Clinical Research Participation
[2] Center for Information & Study on Research Participation (CISCRP). Perceptions & Insights Study. 2017
[3] Levitan, B et al. Assessing the Financial Value of Patient Engagement : A Quantitative Approach from CTTI's Patient Groups and Clinical Trial Project. Therapeutic Innovation & Regulatory Science ; 2017
[4] www.ehr4cr.eu/
[5] VERKKO trials and eClinicalHealth, e.g. Langel, K. Case Study: Remote Blood Glucose Profiling in Diabetes – Streamlining The Clinical Trial Process For Diabetes Trials. Industrial Pharmacy, Volume 50, Number 1, June 2016, pp. 11-13(3)
[6] https://www.science37.com/science-37-aobiome-complete-industry-first-virtual-clinical-trial-metasite-decentralized-operating-model/ and https://www.centerwatch.com/news-online/2016/06/22/eclinicalhealth-announces-successful-results-entirely-remote-online-clinical-trial/
[7] http://www.ich.org/home.html
[8] https://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R1_Guideline.pdf
[9] Cunningham, K., Clinical Trials Regulation (EC) No. 536/2014 Update on the EU Portal and Database. May 16, 2017

clinical research and development is essential. Federating multiple academics, clinical centres, patients' associations, regulatory bodies, SMEs, pharmaceutical and medical technology industries will ensure the concrete positioning of remote DCTs within the clinical "journey" including best practices, recommendations for the full remote DCT approach and the hybrid model. This approach should seek to build trust between all stakeholders involved in clinical trials and support efficiently the updating ICH guidelines process.

To efficiently implement the concept regarding e.g. quality process, data relevance, confidentiality, integrity, and risk assessment, a broad number of stakeholders from both the public and private sectors are needed:

- The pharmaceutical industry brings strong experience on running remote DCTs in the US and in the EU which will build upon this experience to set the scene for coordinating a pan-EU remote DCT pilot.
- Clinical centres are necessary to provide feedback on existing and future DCT initiatives and to contribute to the definition of the best practices on running full or partly remote DCTs in the EU environment. Leading clinical centres are also needed to coordinate the pan-EU remote DCT pilot and engage other centres across the EU in a different setting than the traditional one (where each site is a Principal Investigator).
- Regulators and stakeholders involved in the revision of GCP and clinical guidelines are pivotal in the approach both at national and EU level to ensure the appropriate positioning of remote DCTs in the full and the hybrid setting as well as an efficient alignment with the ICH guideline update. Regulators are obviously essential in the process of acceptance of DCT-generated data.
- SMEs are necessary to contribute at different levels, such as the evaluation of the DCT process, training tools for healthcare professionals and other relevant stakeholders, and telemedicine expertise.
- Patients and patient associations are also highly important in the definition and deployment of a patient-centric approach.
- Other organisation profiles, including (but not limited to) those with telemedicine expertise and medical technology expertise, are required to implement efficiently the remote decentralised process across the EU.
- Technology enablers and sites/site networks are critical stakeholders in defining how to reduce the burden on patients and thus increase patients' access to clinical trials.

To this end, the IMI2 JU is the most efficient programme in the EU to federate all stakeholders on a well-balanced approach and to set the relevant intermediary stage, building trust and defining recommendations for conducting full remote DCTs across the EU.

Scope

The action will focus on disaggregating the current model of running clinical trials, defining building blocks and mapping new technologies (e.g. telemedicine, mobile health…) to support the new DCT model. The objectives are: to determine whether it is feasible to run remote DCTs in Europe; to increase the access of patients to clinical research, enriching clinical trial data from more diverse and representative patient population; and to improve patient experience during the trials, with a higher speed of recruitment and better retention.

This funded action will rely on learning from historical and ongoing case studies, conducted by the members of the winning consortium (mainly pharmaceutical companies), to build on clear recommendations and define guidance for conducting remote DCTs in Europe. It will assess various options including hybrid models (combining DCTs with the traditional approach), as well as specific needs according to the disease / therapeutic area (e.g. rare disease, HIV[10]). The recommendations will consider the relevance of the model and supportive technologies for gaining approval from ethics committees, and for securing data quality, data integrity and ultimately data acceptability by regulatory agencies.

[10] Stephenson, R., Freeland, R., Sullivan, S. P., Riley, E., Johnson, B. A., Mitchell, J., McFarland, D. and Sullivan, P. S. (2017). Home-Based HIV Testing and Counseling for Male Couples (Project Nexus): A Protocol for a Randomized Controlled Trial. *JMIR Research Protocols*, *6*(5), e101. http://doi.org/10.2196/resprot.7341

The impact of remote DCTs on the relationship between patients and their treating physicians, according to the model (full remote vs. hybrid) will also be investigated. Though there could be some fears of disrupting this important relationship, the full remote DCT process may rather position the treating physicians as a pivotal local support during the study conduct. Hence the funded action will also revisit the investigating site definition, and Principal Investigator responsibilities according to ICH/GCP. Compliance with and respect of the General Data Protection Regulation (EU) 2016/679[11] and Clinical Trial Regulation (EU) 536/2014[12] (and/or Directive 2001/20/EC[13]) and any updates, and the enforcement of data security will also be addressed.

The proposed work is based on a 3-step approach and a transversal objective for ensuring the most reliable organisation at pan-EU level for conducting full remote DCTs:

- Step 1: Define the best practices for the conduct of remote DCTs using individual partner case studies (US and EU) and identify the positioning of such trials among clinical development.
- Step 2: Analyse the EU clinical environment and upgrade accordingly the best practices for remote DCTs at EU level using the outcomes of the individual partner case studies analysed in step 1. This should result in preliminary guidance to be used for the setting-up of the pan-EU pilot.
- Step 3: Design and run a pan-EU pilot remote DCT and define the positioning of full remote or hybrid model regarding clinical development. This pilot is approached through technology and clinical organisation and not as targeting a specific disease. The particular indication(s) and Investigational Medicinal Product(s) (s) for piloting the remote DCT will be selected as part of the project activities.
- Transversal objective: Contribute to the update of ICH guidelines on remote DCTs and provide recommendations with supporting tools for implementing full remote DCTs in the EU.

Expected key deliverables

- Definition of best practices using case studies (historical and ongoing) from industries and academics (indicatively by month 12):
  - Define and leverage set of criteria to analyse case studies
  - Define the operational feasibility
  - Assess data relevance, integrity and acceptability by regulators
  - Analyse and report on either the hybrid or fully decentralised model to facilitate the remote DCT approach in EU
- Technology scan for remote DCTs in an end-to-end journey assessing e.g. quality and data integrity, security, connectivity, communication interface, stakeholders' feedbacks such as patients, principal investigators, regulators, sponsors (indicatively by month 24). The scan on "remote DCT technologies" will include an assessment of a broad technology range (available or with a validated proof-of-concept) in order to enable a seamless communication, data monitoring and collection from distant locations. The "technology package" is composed of:
  - A connected central platform enabling the management of all information collected and generated in a remote DCT, e.g. central management of information and data, communication with the enrolled patients and their ecosystem (incl. webpages or generating personalised text message reminders/alerts).It should enable local connectivity with various sets of connected devices or wearables and collection of data on the fly.

[11] Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) , *OJ* L 119, 4.5.2016, p. 1–88

[12] Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC, *OJ* L 158, 27.5.2014, p. 1-76.

[13] Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use (the "Clinical Trials Directive), *OJ* L 121, 1.5.2001, p. 34.

- A "mobile technology/app with/without wearables" designed for patient enrolment and to ensure communication between patients and their ecosystem: physicians, nurses, medical laboratory staff and investigators. This mobile technology will be connected to the central platform (defined above). All data generated should be eligible for collection by this platform and open to real time data integration with more traditional existing safety and efficacy calculation systems.
- Related services: recruitment/retention strategy, recruitment networks/patient group, recruitment advertising, project management, investigator management, records retention.

All the technologies stated above should comply with GCP (Good Clinical Practices), GDPR and CTR, e-Signature process and security standards on health data.

- External review of the technology scan for remote DCT and approval of the final "technology package" to be tailored and used for running the pan-EU pilot remote DCT(before mid-term, indicatively by month 26)
- Review and analysis of the EU clinical trial ecosystem, and anticipated changes for the pan-EU "remote decentralised clinical trial centre" (indicatively by mid-term)
  - Preliminary guidance for the launch of the pan-EU DCT incl. hybrid model and to support ICH guidelines
  - Changes/adaptations to the EU environment for clinical trials
  - Definition of metrics to measure success incl. approved technology specificities
- Pan-EU pilot study designed and launched from a "central" access (by a referenced public centre) using a remote DCT approach (indicatively to be launched around month 42)
- Final recommendations on the fully remote DCT and the hybrid model (indicatively by project end)
- Final set of tools (training materials, contract templates, technology requirements…) to be used for remote DCTs in Europe (indicatively by project end)

Expected impact

Combined with the adoption of digital endpoints, the funded action should have the following **main expected impacts**:

- Increase flexibility of patient follow-up during clinical trials, reducing the burden both on patients and hospitals
- Increase the frequency and quality of data collection
- Improve patient recruitment and retention in trials.
- Accelerate clinical research and the access by the patients to more breakthrough innovative therapies.
- Support directly the update of the ICH guidelines all along the process by generating evidence.
- Reorganise the patient journey and the clinical environment
- Redefine the clinical trial framework in compliance with the EU regulations[20-22]

Other expected impacts include:

- Increase the participation of more diverse populations in clinical trials and reduce drop out,
- Adapt to specific patient populations such as in rare diseases, bringing the trial to the patient and serving the purpose of enhancing the European Reference Networks in rare disease[14],
- Support patients in managing better their disease(s) and their treatment(s) and increasing their knowledge[15]

[14] https://ec.europa.eu/health/rare_diseases/european_reference_networks_en

- Increase digital literacy among healthcare providers, facilitating later development of telehealth
- Provide evidence for supporting the European Policy on telehealth and telemedicine applied to remote patient monitoring in Europe, beyond the scope of clinical trials.

Applicants should indicate how their proposal will impact on the competitiveness and industrial leadership of Europe by, for example engaging suitable small and medium sized enterprises (SMEs).

Potential synergies with existing consortia

Applicants should take into consideration, while preparing their short proposal, relevant national, European (both research projects as well as research infrastructure initiatives), and non-European initiatives. Synergies and complementarities should be considered in order to incorporate past achievements, available data and lessons learnt where possible, thus avoiding unnecessary overlap and duplication of efforts.

The below synergies should be explored with:

- consortia utilising electronic health records for recruiting patients
- consortia developing informed consent forms to be used across the EU
- consortia involved in digital monitoring of patients, incl. endpoints, outcomes and quality of life
- consortia involved in rare disease research at international and European level
- Transcelerate[16]
- CTTI[17]
- companies offering technology solutions that would support the implementation of the platform for running the pan-EU pilot remote DCT
- consortia of European clinical trial centres
- relevant biotechnology consortia
- the consortium involved in setting up the IMI2 European Health Data Network project.
- relevant EFPIA groups (e.g. Clinical Development Expert Group…)
- central ethics Committee, central governance of country, institutional review board (IRB),
- consortia funded under ECSEL JU[18] developing the technology required in the action.

Industry consortium

The industry partners will bring the following expertise in:

- Clinical operations
- Clinical statistics
- Supply chain / IP distribution
- Telemedicine, medical technology and digital health

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[15] Example of a Danish research monitoring at home patient suffering from diabetic foot ulcers; though non statistically significant, patients who used the sensors had healed wounds and less pain after 6 months, and did not need to travel to outpatient clinic. The majority of patients using this new type of care gained more knowledge about the treatment of their wounds, were very satisfied with their home care and satisfied with the collaboration between their care providers (2015 eHealth in the WHO European region report)

[16] http://www.transceleratebiopharmainc.com/

[17] https://www.ctti-clinicaltrials.org/

[18] http://www.ecsel-ju.eu/

- Quality control and quality assessment
- Legal matters for DCT (patients' rights, data collection, data transfer, data analysis)
- Regulatory matters (incl. GDPR, CTR)
- Public affairs
- Patient advocacy
- Patient engagement

In addition, the industry partners will bring at least 5 remote DCT case studies (either as hybrid or fully remote DCTs). The organisational elements of these DCTs in terms of activity flows and quality criteria will be analysed in the funded action to establish best practices for running remote DCTs in Europe.

Indicative duration of the action

The indicative duration of the action is 60 months.

Following the delivery of the technology package, a project review will be held to review the proposed technology package (see expected deliverables) and ensure the action is on track to deliver the expected impacts within the five year period.

Future project expansion

Potential applicants must be aware that the IMI2 JU may, if exceptionally needed, publish at a later stage another Call for proposals restricted to the consortium already selected under this topic, in order to enhance their results and achievements by extending their duration and funding. The consortium will be entitled to open to other beneficiaries as they see fit. The decision for this will be based on progress of the action and decisions made in the sustainability work stream of the action. This process could be envisioned to build upon this running pan-EU pilot remote DCT with the following objectives (not all inclusive):

(i) add complementary modules that required public-private collaborations such as blockchain approach,

(ii) extend the country representativeness in the pan-EU pilot, or

(iii) even deploy the pan-EU pilot for other therapeutic areas not selected in the initial action.

These objectives are developed to generate additional evidence of the reliability of the remote DCT approach that could be required for extending the acceptance at EU level of remote DCTs.

Applicant consortium

The applicant consortium is expected to address all the topic objectives and make key contributions to the defined deliverables in synergy with the industry consortium.

The consortium shall include all relevant stakeholders involved in the clinical trial environment including SMEs to build the remote DCT Centre of Excellence:

- Regulatory agencies to contribute to the definition of guidance for remote DCTs and to ensure the alignment with the updating of the ICH guidelines
- Standards organisations on good clinical practices to implement the guidance in an ethical and legal manner
- SMEs with past and present experience on remote DCTs and deep expertise in Good Clinical Practice (GCP) using technology for recruiting and monitoring patients
- Telemedicine, medical technology companies to contribute to the new integrated mobile environment of patients incl. expertise in data validation, approved medical devices into clinical trials for data capture and continuous monitoring and their associated devices.

- Patient associations and patient groups to ensure the co-design approach of patients in the remote DCT design and execution, as members or potentially as advisors to work on guidance and the patient-specific challenges
- Academics/Clinical trial centres to co-design and implement the remote DCT, managing already trial programmes that could be adapted to DCT approach
- Academics involved in medical devices to contribute particularly in the technology scan of the remote DCT in an end-to-end journey and the subsequent deployment of the pan-EU pilot
- Health insurance organisations to support the telemedicine at patients' homes

The applicant consortium should also take into account a well-balanced representation of the EU countries to ensure the set-up of the Pan-EU remote DCT pilot and the wider acceptance of this model regarding EU regulation, e.g. GDPR, CTR.

Suggested architecture of the full proposal

The applicant consortium should submit a short proposal which includes their suggestions for creating a full proposal architecture, taking into consideration the industry contributions and expertise provided below.

The final architecture of the full proposal will be defined by the participants in compliance with the IMI2 JU rules and with a view to the achievement of the project objectives.

In the spirit of the partnership, and to reflect how IMI2 JU call topics are built on identified scientific priorities agreed together with EFPIA beneficiaries/large industrial beneficiaries, these beneficiaries intend to significantly contribute to the programme and project leadership as well as project financial management. The final architecture of the full proposal will be defined by the participants in compliance with the IMI2 JU rules and with a view to the achievement of the project objectives. The allocation of a leading role within the consortium will be discussed in the course of the drafting of the full proposal to be submitted at stage 2. To facilitate the formation of the final consortium, until the roles are formally appointed through the consortium agreement, the proposed project leader from among EFPIA beneficiaries/large industrial beneficiaries shall facilitate an efficient negotiation of project content and required agreements. All beneficiaries are encouraged to discuss the project architecture and governance and the weighting of responsibilities and priorities therein. The consortium is expected to have a strategy on the translation of the relevant project outputs into regulatory practices, clinical and healthcare practice. A plan for interactions with Regulatory Agencies/health technology assessment bodies with relevant milestones, resources allocated should be proposed to ensure the deployment and acceptance of the remote DCT concept at a Pan-EU level for clinical development.

A plan for aspects related to sustainability, facilitating continuation beyond the duration of the project should also be proposed.

The below architecture for the full proposal is a suggestion; different innovative project designs are welcome, if properly justified.

All Work package activities described below **should comply** with all EU regulations and more particularly with GDPR[20] and CTA Regulations[21].

Work package 1 – Collecting and analysing study information on previous and ongoing experiences on remote DCTs (benefits, process, patient's surveys, process data) and compilation of best practices / recommendations (liaise with WP3)

- Defining criteria for analysing the DCTs model and processes, including the set-up, recruitment, enrolment, informed consent process, and data collection, data quality and relevance
- Analysing process information from "individual partner studies" (either US or EU if any) including challenges confronted and solutions, e.g. Science37 model incl. provisions from GDPR and CTR[20-22] context
- Defining good practices and detailed SWOT on setting up "remote DCTs" using individual partner experience in regards also to GDPR[11] and CTR[21] context
- Upgrading the "individual partner studies" using the good practices developed in this funded action"

- Guidelines to set up the pan-EU pilot remote DCT incl. compliance with GDPR and CTR[20-22]
- Analysing protocol suitability for remote DCT including how to establish criteria for selecting trials for the remote DCT model

Expected key deliverables:

- Definition of criteria to analyse each case study (either hybrid/fully decentralised) and report to build up the remote DCT approach in EU
- Review of previous case studies (remote decentralised clinical trials/home monitoring) available from industries and investigation sites (public/private) to date to define and share challenges and solutions in remote DCT/home monitoring for application in an EU setting
- Definition of first best practices using individual partner case studies
- Definition of first recommendations for remote DCTs (to be implemented in the Pan-EU pilot remote DCT – cf. Work Package 2)
- Criteria defined for selection of appropriate trials

Industry contribution:

Clinical operational experts, statisticians, IT experts (telemedicine activities and digital health), quality control, pharmaceutical research scientific domain experts, legal experts, patient engagement experts. Experience from previous or on-going remote DCT case studies to build up the best practices (mainly from US), upscale the best practices in the ongoing case studies for setting-up the EU model, data validation, expertise on using approved medical devices in clinical trials for data capture (mainly for pharmaceutical sponsors and mainly continuous monitors and their associated devices).

Expected applicant consortium contribution:

Principal investigators, hospitals, clinicians, experts in the conduction of multisite clinical trials at least, preferred in the remote DCT trial incl. home monitoring, clinical statisticians, IT experts in the development of platforms for patients, supply chain / IP distribution, legal experts, previous or ongoing case studies to be used to build up the best practices regarding EU regulations[20-22] and any subsequent updates.

Work package 2 – Pan-EU "remote DCTs" pilot (liaise with WP3)

- Design a pan-EU Pilot using guidelines developed in WP1, potentially in a way that allows for comparison with a "traditional" study **–** for example run part of the same study in a remote DCT model, while the rest is traditional, or find a previously conducted study / studies that allows for some comparison **–** and integrate & tailor the "technology package" approved by the external review panel for the pan-EU pilot remote DCT
- Setting-up and run the pan-EU Pilot remote DCT
- Analysing process information from the pan-EU pilot to define the scientific and operational quality of the pilot and proposed optimisations
- Refining Key Performance Indicators to qualify and quantify the flow of activities in the pan-EU pilot, e.g. (but not limited to) recruitment rate, retention rate, patient burden/satisfaction, data quality, confidentiality and integrity compared directly during a trial (half traditional and half DCT) or retrospectively through benchmark data

Expected key deliverables:

- Setting-up of a Pan-EU pilot study or multisite study, as time and scope allows (possibly a longer term objective or even a second phase). Pilots should be private-public collaborations to the extent possible, and organised by a referenced public centre.
- Final evaluation of the Pan-EU pilot regarding the KPI defined incl. conditions of DCT use compared to traditional trial and acceptability of the model at Pan-EU level.

Industry contribution:

- Clinical operational experts, statisticians, IT experts (telemedicine activities and digital health), quality control, Pharmaceutical research scientific domain experts, supply chain / IP distribution, legal experts, patient

engagement experts, investigate and design new technologies/logistics for distant monitoring in DCT, medical technology experts, upgrading the best practices on remote DCT in their respective trials, regulatory experts.

Expected applicant consortium contribution:

- Principal investigators, hospitals, clinicians, experts to set up and run the pan-EU remote DCT pilot incl. home monitoring (if feasible), IT experts in the development of platforms for remote DCTs, regulators in agencies, patient associations, medical technology experts.

Work package 3 – Technologies – identification of barriers and enablers and data management

- Data quality and management (WP1 and 2) - activity flows
- Assessment of wide range of "technology package" (as defined in the deliverable section) either as available or as a validated proof-of-concept incl. All supporting services that are likely going to be required ("virtual site" with phone / email / chat support, logistics, home or online nurses…)
- Recommendations on technologies evaluated and data quality/data relevance incl. evaluation of some technologies available as well as in a validated proof-of-concept
- Propose refinement of Work Package 3 activities after the selection of the "technology package"
- Tailor the technology package to be used for the pan-EU pilot remote DCT

Expected key deliverables:

- Technology scan for remote DCT in an end-to-end journey assessing e.g. quality and data integrity, security, connectivity, communication interface, stakeholders' feedbacks such as patients, principal investigators, regulators, sponsors. The scan on "remote DCT technologies" will include an assessment of a broad technology range (available or with a validated proof-of-concept) in order to enable a seamless communication, data monitoring and collection from distant location (described in the specific deliverable section).
- Tailored "technology package " for running the pan-EU pilot to be deployed in the pan-EU pilot remote DCT

Industry contribution:

- Clinical operational experts, statistical experts (telemedicine activities and digital health), legal experts including data privacy experts, experts in clinical outcomes, patient engagement experts, experts in data flows and app developments for home monitoring of patients, expertise in approved medical devices into clinical trials for data capture, continuous monitors and associated devices.

Expected applicant consortium contribution:

- Principal investigators, hospitals, clinicians, IT experts on digital health, patient engagement experts, experts in data flows and app developments for home monitoring of patients, platform developers and services related to technologies used for remote DCTs, regulatory experts, regulators in agencies, expertise in approved medical devices into clinical trials for data capture, continuous monitors and associated devices.

Work package 4 – Ethics, data privacy, legal, GCP, regulatory issues and recommendations

- Continuous assessment of EU environment and the EU regulation (incl. digital policy, GDPR, CTR…) to be implemented for remote DCT approach
- Ethics organisation of remote DCTs in EU
- Defining the legal, GCP and data management for "remote DCT" approach incl. data quality and regulatory acceptability of DCT approach
- Upgrading using regulation changes
- Stakeholders' working group to align the strategy of remote DCTs with ethics, data privacy

Expected key deliverables:

- SWOT analysis of the barriers and enablers for the implementation of remote DCTs in EU for ethics, data privacy, regulation…
- Best practices on remote DCTs (first and final version) in EU and US
- Final recommendations on remote DCTs in EU incl. intermediary model (hybrid studies)

Industry contribution:

- Legal and data privacy experts, regulatory experts on the use of digital tools in clinical trials, GCP experts

Expected applicant consortium contribution:

- Regulatory experts (incl. from agencies), ethics experts, GCP experts, legal and data privacy experts

Work package 5 – Communication, dissemination and stakeholders' engagement in changing the paradigm of remote DCTs

- Interviews of stakeholders on the EU view and EU experience in remote DCTs (patients, regulatory agencies, ethics committees, principal investigators, study coordinators, hospitals, pharmaceutical companies…) to reassess the barriers and enablers
- Mapping of paradigm change on patients and HCPs between current approach and induced changes in remote DCTs
- Assess and tailor the related services of the "technology package" for the communication activities
- Check-list on best practices for setting-up a remote DCT in EU (public deliverable)
- Training kits for deploying pan-EU "remote DCTs" for Principal Investigators, HCPs, patients, inspectors, pharmaceutical companies, Clinical Research Organisation
- Company providers/developers of technologies to be deployed for remote DCTs

Expected key deliverables:

- Mapping of paradigm changes in the relationships between HCPs and patients
- Report on changing stakeholders' roles and responsibilities and proposals from stakeholders to overcome any challenges.
- Set of tools for remote DCT incl. training materials for stakeholders (e.g. Principal investigators, patients, regulatory representatives and inspectors…), and contract templates for "remote DCT"

Industry contribution:

- Representatives for stakeholder engagement at regulatory, HCP and patient engagement and data privacy levels, communication experts, clinical outcomes experts

Expected applicant consortium contribution:

- Experts in stakeholder engagement and communication for the relevant fields of this future action, IT and communication tools to support paradigm changes in remote DCTs, training to engage the relevant stakeholders

Work package 6 – Project management

This work package will establish effective governance and internal communication procedures to allow for the flow of information within the project. It will also fulfil the administrative tasks associated with management of this project. It will also take into account the particular conditions relative to the "technology package" and inclusion of new technology partners.

Industry contribution:

Project management expertise.

Expected applicant consortium contribution:

Project management expertise.