Innovative Medicines Initiative Launches ‘Trials@Home’
A major European project to bring clinical trials to the participant’s home

Brussels, October 16, 2019 –
The Trials@Home consortium will explore the opportunities of moving clinical trials from the traditional clinic setting to the participant's immediate surroundings. These so-called Remote Decentralised Clinical Trials (RDCTs) make use of new – digital – innovations and enable participants to visit a clinical trial centre less frequently, if at all. This makes it easier for larger, more diverse and remote populations to participate in clinical trials. These trials are expected to be conducted faster, more efficiently, and provide results that are more representative, because the data is collected in the daily context of the participant (Real World Evidence). The research to be conducted includes an inventory and evaluation of existing and new techniques for use in RDCTs as well as a pan-European pilot trial.

European grant for five years’ research
An international consortium of 31 members, of which IDF Europe, has received Innovative Medicines Initiative funding, to map developments in the field of RDCTs, and to test different variants to arrive at concrete and practical recommendations to promote the widespread acceptance and implementation of RDCTs across Europe. The University Medical Center Utrecht and Sanofi are coordinating this Euro40 million research project which will run for five years. Currently, clinical trials are regarded as the best way to evaluate the effectiveness of interventions. Traditionally, a participant taking part in a clinical trial has to go to a clinical trial centre regularly for face-to-face evaluation. By harnessing new technologies and transferring the trial activities to the participant's home or immediate surroundings, a trial can be less burdensome for them and produce results that can be better translated into daily practice.

The consortium will develop and test remote decentralised methods to streamline data collection, participant recruitment and retention. At the same time, it will ensure the participation of a greater number of volunteers that are more representative of the population at large. By augmenting face-to-face interaction with remote procedures, larger geographic regions will be accessible to foster the participation of unrepresented relevant populations.

A Multidisciplinary Perspective
Trials@Home is a multi-stakeholder approach where academic partners, small and medium-sized enterprises (SMEs), private foundations, and EFPIA partners will closely collaborate with practitioners, patient organisations, IT professionals, and regulators to develop concrete methods, tools, and approaches that facilitate the broad acceptance of RDCTs in Europe. The consortium will also engage with stakeholders outside of the Trials@Home consortium to incorporate the views of patients/potential trial participants, researchers, healthcare providers, regulators, payers, Health Technology Assessors, and ethics bodies to ensure that the project’s outcomes are both actionable and achievable.

Study set-up
The research includes an inventory and evaluation of studies already conducted with remote elements, research into available technologies and research into the legislation and ethical requirements in different countries in the field of enabling technologies. The project will implement a study in which one group of participants will receive an intervention using the classical site-centred trial methodology, another group will participate remotely and a third group uses a partly traditional, partly remote hybrid model. The project team hopes to determine how the approaches compare in the trial and will show which approach produces the best results in terms of participant satisfaction, inclusion rate, costs, data quality and more.
**IDF Europe**
As part of Trial@Home, IDF Europe will contribute to assessing the patient perspective on the barriers and enablers of RDCTs, in particular the required paradigm change for patients and HCPs between current approaches and changes in RDCTs, as well as developing and validating best practices for setting up a RDCT in the EU.

For more information, please contact [IDF Europe](#).

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