An Overview of Technology Availability to Support Remote Decentralized Clinical Trials

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Abstract : Developing new medicine and health solutions and improving patient health currently rely on the successful execution of clinical trials, which generate relevant safety and efficacy data. For their success, recruitment and retention of participants are some of the most challenging aspects of protocol adherence. Main barriers include: i) lack of awareness of clinical trials; ii) long distance from the clinical site; iii) the burden on participants, including the duration and number of clinical visits and iv) high dropout rate. Most of these aspects could be addressed with a new paradigm, namely the Remote Decentralized Clinical Trials (RDCTs). Furthermore, the COVID-19 pandemic has highlighted additional advantages and challenges for RDCTs in practice, allowing participants to join trials from home and not depend on site visits, etc. Nevertheless, RDCTs should follow the process and the quality assurance of conventional clinical trials, which involve several processes. For each part of the trial, the Building Blocks, existing software and technologies were assessed through a systematic search. The technology needed to perform RDCTs is widely available and validated but is yet segmented and developed in silos, as different software solutions address different parts of the trial and at various levels. The current paper is analyzing the availability of technology to perform RDCTs, identifying gaps and providing an overview of Basic Building Blocks and functionalities that need to be covered to support the described processes.

Keywords : architectures and frameworks for health informatics systems, clinical trials, information and communications technology, remote decentralized clinical trials, technology availability

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