

## Family Medicine – Clinical Trials Enhancement at the Patient’s Level

General practice and primary care are fundamental to the success of healthcare systems. There is strong evidence that primary care services achieve better healthcare outcomes at lower cost, providing comprehensive, continuous and personalised contact with the patient. So far, primary care professionals have rarely been involved in clinical research. Bringing family physicians and general practices who are close to patients both in terms of personal contact and geographical location, to clinical research, supported by innovative mobile technologies, can significantly enhance patient recruitment and retention.

The clinical research industry is in critical need of supporting patient-centricity. Patient-centricity is about engaging the patients into clinical research and bringing the trials to their homes. This is recognised as a key element in patient recruitment and retention. There are several innovative solutions supporting patient-centricity in clinical trials, like direct-to-patient studies, information and communication technologies (ePRO, social media networking), patient advocacy groups, pharmacy-directed outreach, etc.

The patient-centric approach can be facilitated by conducting study visits at patient’s homes. Many

patients prefer home care to any other options, as for some people leaving home can be disruptive and depressing, and in several medical conditions, even impossible. In many countries, home visits are claimed to be a central element of primary care provided by both nurses and physicians since the early 1900s. Over the last 20 years, home care has experienced significant changes. The home visit industry varies between countries and depends on specific local regulations and cultural aspects of societies. In the United States, home care services are delivered by thousands of nursing agencies spread all over the country. In Europe, nursing agencies are not as common, but home care visits are available through very well-developed primary care infrastructure, based mostly on family medicine and general practitioners. Home care services provided by healthcare systems include technical nursing care (blood draws and biological sampling, vital signs measurement, wound care, etc.), drug administration as well as rehabilitation, supportive care, health promotion or disease prevention, both for chronic and acute conditions.

However the use of home visits in clinical trials is limited. This is mostly due to challenges in standardisation of services across the studies, and the availability of properly trained home care service providers close to





patient location. Even though the clinical research industry recognises the value of home care, there are still challenges to face implementing these services to international, multi-centre trials. One of the biggest is the access to service providers who are close to patients' locations, experienced in clinical research and willing to participate in clinical trials. This applies especially to nurses and family physicians located outside of academic facilities, in smaller cities and rural areas. Most often they don't have access to sponsors and other clinical research institutions, facing the first entry barrier. As a result, these clinicians do not play a significant role in the research industry, while they can be a valuable source of both service providers and potential research-naïve subjects. The value of this group of healthcare professionals was highlighted in the Report on General Public and Patient Perceptions of Clinical Research published by CISCRP in 2013, which shows that for 52% of patients, the primary care physician is the preferred source of clinical research information. In contrast to the results of the survey, up-to-date engagement of family physicians and general practitioners in clinical research is very limited.

Electronic medical records, telemedicine and mobile technology have become more and more important aspects of the provision of home care services, and in many countries are commonly used by primary care physicians.

Even these tools often don't comply with clinical research expectations and regulations, and electronic infrastructure and preparedness for implementing high-tech solutions varies between places. Family physicians and their teams have very high levels of literacy in novel information and communication technologies, and can be easily trained on new sponsor and study-specific applications.

Implementing an integrated patient-centred model, connecting the clinical research industry with professionals who are closest to the patient might be a faster, cheaper and easier solution for these trials, which can be conducted outside of specialist centres. Centralised management of standardised, high quality services performed by a network of GCP-trained family physicians and their teams, supported by modern mobile technology, enables the conduct of clinical trials regardless of patients' location. The scope of services includes home visits for blood draws and biological sampling, drug administration, clinical assessments, patient and caregiver training, etc. Engaging family physicians in clinical research opens a brand new pool of clinical trial-naïve patients, as well as increasing a pool of patient-centric investigators. At the patient's level, this model offers not only access to novel treatment and medications, but is also brought to them by fully trained and well-known nurses and physicians. Being first-line medical support in everyday practice, family physicians have the best and most complex knowledge about patients' medical status. They know how to communicate trial results in lay language to study volunteers.

This approach can strengthen the relationship between sponsors, research community and patients as well as rebuilding public trust in clinical research.



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