Research, a Call for Action

Investigação, um Apelo à Acção

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The engagement of health professionals in translational and clinical research is fundamental to evidence-based medicine, leading to better patient outcomes. However, there is not a sufficient number of health professionals undertaking research, which has implications for advancing knowledge and science and ultimately for patient health.

A survey conducted in the United States revealed four main reasons investigators no longer conduct FDA-regulated drug trials. First is the workload balance, including long work hours, finding time to devote to activities fostering academic promotion and non-clinical work activities. Second, time requirements include the amount of time required by the investigator to support trial site staff, prepare for trial start-up, and support the conduction of the trial. The amount, method and frequency of data, safety reporting, and financial issues, namely sponsor/site budget and contract negotiations, were also reported.[1] In Portugal, we struggle with the same time constraints and difficulties in finding the right work balance and with organizational and infrastructural problems.

Establishing a clinical trial infrastructure is one of the most challenging and important tasks when developing a successful research program. There are four critical categories recommended to strengthen site-based research activities: (1) developing site research infrastructure and staff, (2) optimizing trial execution and conduct, (3) improving strong connection with support structures such as Lusíadas Knowledge Centre and (4) discovering opportunities for conducting research.[2]

It is crucial to have a team with the right level and quality of experience needed to deliver the specific clinical trial or investigation requirements. For that, we need to hire and retain well-trained staff. All involved members of the team need to act collaboratively as partners, be flexible in dealing with uncertainties and unexpected events and have a high level of communication.

Time must be allowed for the conduct of clinical trials, including patient consent, treatment per protocol, toxicity management, data recording, regulatory oversight and compliance with Good Clinical Practice guidelines. The principal investigator should have time to dedicate to implementing the research programme and structure, and co-investigators and study staff should also have time dedicated to research.

Continuous training should be provided for research staff, including epidemiology, statistics and Good Clinical Practice. For example, PharmaTrain and ECRIN (European clinical research infrastructure network) have joined forces to promote and establish a European investigator training infrastructure leading to a clinical investigators certificate (CLIC).

One must establish a process of motivation to do research, identifying health professionals' whit research capacity and interest by evaluating their expectancy and competence, value, andonnection. This process identifies motivated and highly motivated people for which identified barriers can be eliminated and connection and engagement in research established.

Site research infrastructure should include a pharmacy available for mixing and storing investigational drugs, a certified lab, a radiology department capable of data sharing and RECIST classification and affiliation with a central and local Ethical Committee.

Space should be available for staff to conduct research and securely maintain research charts and regulatory documents, including long term storage.

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Each study protocol should comply clinically and ethically with usual practice and should be reviewed against patient populations, scientific merit and the capability of accruing and following patients on study.

Each medical research facility has specific patient populations, specialized expertise, and different needs. It is crucial to start a study for which a site knows he can get enrolment. For that, aggregated data assessment of patient profiles can better understand how to position the medical institution for clinical research.

Internal procedures to identify responsibilities and steps for study implementation and management should be implemented early on and regularly reviewed. This includes standard operation procedures, a map of delegations, contingency plans and risk management plans when necessary.

Participation in academic research groups and cooperative trial groups is essential to network and have access to and share investigational projects. Investigation networks and academic centers can also assist in training and infrastructure support.

Portugal clinical trials it is a website platform developed in collaboration between AICIB (Agência de Investigação Clínica e Inovação Biomédica) and APIFARMA (Associação Portuguesa da Indústria Farmacêutica) that permits access to general public to all clinical trials ecosystem in Portugal. It is one of the ways to promote knowledge of the active research projects in Portugal and increase the visibility of centers.

A comprehensive structure like Lusíadas Knowledge Center, it is crucial to integrate, connect and develop all aspects of research. It should promote the research ability of the centers, expand the research infrastructure and procedure requirements, support study coordinators, ethical committee submissions, site budget, and contract negotiations. It must also promote training and education and support analyzing data and publishing.

There is "no research without action, no action without research" (Kurt Lewin). We must embrace research as a fundamental process and reflect and act upon the behavioral and structural changes we must endure to foster development.

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