

Roadmap for Clinical Research Work

To the Editor

Usually, clinical research originates based on a problem and expresses itself through question/s that reflect our curiosity about a specific and concrete topic¹. In this sense, the COVID-19 pandemic provided an opportunity, due to the coexistence of organizational care needs and enormous uncertainty related to the natural history of the disease and the efficacy and safety of treatments, to be able to give recommendations for good clinical practice².

In this context, there was a search for scientific answers in the face of social, political, and economic pressures, which led to a massive infodemic (an excessive amount of information, making it difficult for people to find reliable sources and trustworthy guidance when needed). Working in a rapidly changing world of knowledge makes the research a vital tool in professional practice, generating some evidence-based answers with methodological rigor³. However, it also represents fertile ground for new knowledge gaps, which, in turn, can become new questions¹. Undoubtedly during the health emergency, there was a boom in studies related to record-breaking vaccine production. One of the observations challenged during the campaign was the controversial occurrence

of hospitalizations due to thrombotic events close to recent vaccination. That led to the question of a recent publication of the Medical Clinic Service⁴, from which we explored the relationship between vaccinations (exposure variable) and thrombotic events (outcome variable). It is a clear example of how we are confronted daily with many doubts during our clinical work, where potential questions arise that are worth answering as long as they meet the necessary attributes: Feasible, Interesting, Novel, Ethical, and Relevant, with Biological Plausibility (acronym FINER-P)⁵. From our experience, we took the opportunity to reflect on the roadmap of every research project, understood as the ten essential steps from idea to publication (Fig. 1). Transforming this hypothesis/observation into a question, writing a protocol to be evaluated by the ethics committee, implementing the project and publishing it is usually a long and tortuous road to travel.

In addition to clearly defining the objectives and justifying the question under consideration (with bibliographic support), it is necessary to consider another important aspect: the feasibility of the project in terms of the knowledge and skills required, time availability, and resource requirements (financial, human and material)¹. An additional concern relates to timing. If the research



Figure 1. Ten key steps in all research work. Source: own elaboration.

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takes longer than expected, it may no longer be helpful when it is complete. Possibly because its results no longer apply, other studies have overtaken it, or the context is entirely changed¹. The window of opportunity renders the challenge more daunting, and for the generation of information to have a real impact during the pandemic, it needed to be remarkably quick.

All of the above led us to reflect on some lessons learned about the key factors that positively affected the journey along this path:

- **leadership:** a principal investigator who assumed his responsibility as a genuine knowledge manager ensured the completion of the project, guaranteed visibility, clarity, and transparency with all team members, and motivated different people (through positive feedback) to sustain the pace of work;
- **team:** we had the active participation of an interdisciplinary group, with sub-researchers from different sections (Internists, Pneumology, Infectious Diseases, Hematology, Epidemiology);
- **effort and perseverance,** through synchronic and periodical virtual meetings, in parallel with the assistance activities, distributing roles and tasks performed in due time and form, with strong commitment;
- **motivation and good working environment:** when the work is meaningful, it can be a fun academic experience and generates strong bonds among colleagues;
- **methodological support** from the Internal Medicine Research Area at each stage and educational opportunity, with the participation of residents.
- **educational opportunity,** with the participation of residents actively involved from the beginning.

In conclusion, we believe that this experience represented an example of a project whose question arose from the healthcare practice and was successful in terms of the unthinkable times of the process, which involved

the development of the protocol and ethical approval (CEPI#6062), implementation and dissemination of knowledge (congress/workshop** and published manuscript), which made the information generated relevant, contributing to the understanding of the field studied.

Conflict of interest: the authors declare no conflicts of interest.

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