

Reading guide: starting a registry study

The success of creating a registry study is about careful planning and active upkeep. The time and resources required to launch, maintain and maximize benefits from a registry is often underestimated. For this reason, this reading guide is presented to provide guidance on setting up and managing registries.

First, the *cross-border PATient REGistries iNiTiative (PARENT)*¹ provides an European methodological guideline and recommendations for an efficient and rational governance of patient registries. This is the main guideline to use for creating a registry study. For additional information the *American methodological guideline*² might also be of use. Topics that are illustrated in more detail in this American guideline are, for instance, the use of patient reported outcomes (PROMs) and the monitoring of adverse events. If a more concise and practical guideline is preferred it is recommended to additionally read the Dutch study by *de Groot et al.* This is a study based on experiences in setting up oncological patient registries in the Netherlands.

Second, if a biobank is created for the purpose of the study, it is recommended to use the *ISBER recommendations*³ to facilitate the start of a biobank. It includes recommendations for repositories based on best practices and can be used as a guidance document. Besides these recommendations, a study from *Manders et al.* provides a useful tool for a stepwise procedure to obtain a data collection framework for a clinical biobank. This is aimed at acquiring sufficient data while maintaining an efficient and feasible data collection process.

At last, on the European Association of Urology research foundation (EAU-RF) website the standard operating procedures for the collection of urine samples (*without* or *with* a digital rectal exam) and *blood samples* can be found. Additionally, the *privacy policy* of the EAU-RF and the *guideline* on how to submit a pre-proposal for a EAU-RF clinical trial is found on the website.

For additional information on setting up and maintaining registries the following reading is optional:

- The study of *Somanath et al.* on 'Good Practices in the Conduct of a Patient Registry'.
- The report of *FasterCures*⁴ on 'Expanding the science of patient input: Building Smarter Patient Registries'.
- The study of *Bernhard et al.* on 'The Institution-Based Prospective Inception Cohort Study: Design, Implementation, and Quality Assurance in Pediatric Thrombosis and Stroke Research'.

¹ Cross Border PATient REGistries iNiTiative (PARENT) was a Joint Action under the EU's Health Program 2008-2013. The overall objective of this action between Member States was to support developing comparable and coherent patient registries to rationalize and harmonize their development and governance.

² The initiative is part of the Effective Health Care Program of the Agency for Healthcare Research and Quality (AHRQ). The AHRQ's mission is to produce evidence to make health care safer, of higher quality, more accessible, equitable, and affordable. They work within the U.S. Department of Health and Human Services.

³ ISBER is an International Society for Biological and Environmental Repositories. It is a global biobanking organization which creates opportunities for networking, education, and innovations and harmonizes approaches to evolving challenges in biological and environmental repositories.

⁴ FasterCures is a center of the Milken Institute. This is a nonprofit, nonpartisan, worldwide think-tank catalyzing practical solutions to global challenges. FasterCures is driven by a singular goal: to save lives by speeding up and improving the medical research system.