ABSTRACT: Implementation of International Chart Review Studies: An Assessment of Ethics and Regulatory Considerations

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Objectives

In the absence of secondary sources of healthcare data, chart review studies can result in patient level data repositories including patient characteristics, care patterns, treatment effectiveness and clinical and safety outcomes. Data can be used to populate economic evaluations, and value dossiers, and inform drug safety assessments. For successful implementation, however, knowledge of country–specific ethics and regulatory approval processes is paramount.

Methods

Operational, ethics and regulatory issues and considerations as well as strategies for study success have been summarized in the context of eleven recent multi–national chart review case studies.
Results

Two of 11 studies also collected data prospectively; two studies were categorized as post authorization safety studies and three studies were conducted in peri–approval compassionate use program populations. The majority of studies (9) were oncology focused, with two studies focused on infectious diseases and opioid–induced constipation. Sample sizes varied from 20 to 500 patients, the number of countries from 1 to 8, and the number of sites from 4 to 61. All studies included at least one European country. Across studies, key operational considerations that impacted the ethical/regulatory approval process were ambiguous/amorphous multinational regulatory requirements/guidelines; commercial availability or non–availability of the sponsor product at the time of chart abstraction; data collection method(s) (i.e., retrospective vs. hybrid chart review plus prospective data collection); country variation in informed consent requirements and definitions of personal data; and multinational contractual requirements with the participating sites.

Conclusions

International chart review studies are an effective methodology to resolve data gaps not solved by existing secondary healthcare data sources resulting in tailored, patient–level datasets. Current knowledge of the highly variable and evolving global regulatory requirements, as well as the development of a risk management plan informed by methodological and operational lessons learned at study–outset will facilitate risk mitigation and allow researchers to overcome key challenges.