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# Five Things to Consider When Negotiating Contracts for Real-World Evidence Studies

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*“Understanding the nuances of RWE studies and being able to clearly articulate them in the contract provisions is pivotal for the successful negotiation of RWE contracts.”*



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Real-World Evidence (RWE) studies are a type of research that utilizes real-world data (RWD) to evaluate the safety, effectiveness, and outcomes of medical products in real-world settings. RWD is data relating to patient health status and/or the delivery of health care routinely collected from a variety of sources, such as electronic health records, claims and billing activities, product and disease registries, or patient-generated data. The real-world evidence, which is derived from the analysis of RWD, is the clinical evidence that helps researchers understand the usage and potential risks or benefits of the medical product.

RWE studies have become increasingly important in healthcare research and decision-making due to their ability to provide insights into how treatments perform in real-world settings, outside of a controlled clinical trial environment.

RWE studies complement traditional clinical trials and contribute to a more comprehensive understanding of treatment effectiveness, safety, and economic implications. For that reason, they are pivotal in modern healthcare research. However, negotiating research agreements for RWE studies requires careful consideration of the specific characteristics of this category of clinical trials, including their design and objectives, which can be very different from the standard clinical trial agreement for randomized trials.

The following are factors to consider which will help negotiate contracts in the RWE study setting more effectively:

## **1. Understanding the Design, Scope, and Objective of the RWE Study**

The design and scope of each RWE study can vary widely based on the overall objectives of the study.

For this reason, RWE studies can take many different forms. For example, they can take the form of an observational study, a pragmatic study, a retrospective/prospective data review, a comparative effectiveness study, and many more, each having its own peculiarities. Because RWE studies can take many forms, it is essential to consider the goals and context of each study when drafting and negotiating contracts. This full understanding will play a significant role in determining what provisions from a standard clinical trial agreement will need to be included and what provisions can be left out.

## **2. Utilizing the Right Template**

Whether the sponsor of an RWE study is an organization based in the United States, Europe, or anywhere else, it will be important to tailor templates to what is customary in each country or region.



For example, it is well known that countries such as Italy, France, the UK, New Zealand, and Australia have country-level templates for randomized trials. Spain has regional or site-specific templates, as well. However, it is not common for research sites in these countries to have contract templates that are specifically tailored to RWE studies.

Adapting the study template to what the research sites are familiar with in each region will be crucial to avoid delays.

### 3. Data Access and Data Ownership

By design, RWE studies are centered around the collection and analysis of data. However, unlike standard interventional clinical trials, the data in RWE studies are collected from real-world settings, outside of traditional clinical trials or controlled research settings. Since RWD is not, in many instances, initially collected for purposes of the study, the issue of data access and ownership can become tricky.

It is important to align the data access, licenses, and ownership provisions in the contract with the needs and expectations of the protocol. Setting out requirements for who will have access to data, how it will be securely shared, and whether any data will be proprietary or open for publication will be essential.

### 4. Liability Provisions

Because RWE studies do not involve experimental interventions, the liability provisions in RWE contracts often focus more heavily on managing data-related risks rather than risks to patient safety.

As such, many liability provisions such as insurance, indemnification, and subject injury that are common in clinical trial agreements for interventional studies must be modified to align with the risks associated with RWE studies. For example, subject injury language is not often included in the RWE contract.

Indemnification obligations are also much more limited, primarily focused on breaches of data protection requirements rather than losses related to injuries.

Having a clear understanding of the specific RWE study will help avoid delays related to unnecessary additions or changes to the original contract template.

### 5. Data Protection Requirements

Data protection clauses in RWE contracts are often a heavily negotiated topic due to the wide range of data collected and shared. Data collected under a standard interventional study is typically limited to prospectively collected data from controlled environments where treatments are administered under strict protocols and supervision.

However, the data collected in RWE studies can be obtained from multiple different sources which are outside and unrelated to the study and shared with multiple different stakeholders in locations worldwide.

As such, it is of key importance that the data protection clauses in RWE contracts clearly set out the parties' obligations with respect to collection, storage, and transfer of data.

These clauses must also be drafted in a manner that ensures compliance with the applicable data protection laws of the country where data is collected, processed, and/or transferred. These may seem like key words that only relate to a well-known regulation: the EU General Data Protection Regulation; however, even research sites in the United States may need to pay attention.

Data Protection requirements are often very complex. It will be essential to have a team with the necessary expertise to ensure that all data protection requirements are clearly outlined in the contract and communicated between the parties.

### Final Note

By assessing these considerations during contract negotiations for RWE studies, stakeholders can foster productive collaborations, mitigate risk, and maximize the value of real-world evidence in advancing healthcare research and patient care. Effective contracts not only protect the interests of all parties, but also lay the groundwork for successful study execution and meaningful scientific contributions.

### About ICE Global Consulting

ICE Global offers a team of skilled lawyers and other contract professionals with industry expertise and global experience to help effectively navigate and resolve the complex issues surrounding the drafting and negotiation of contracts related to experimental, interventional and RWE studies.