

Evaluating Feasibility of RWD-Supported Recruitment

In evaluating whether real-world data (RWD) supported recruitment will be feasible for any given study, start with the same questions and considerations identified in [Evaluating Whether RWD Is Suitable for Planning Eligibility Criteria and Supporting Recruitment](#) to ensure available RWD are fit for purpose. Additionally, it is important to consider the following:

Questions	Factors to Consider
What is the ultimate granularity of the data?	<ul style="list-style-type: none"> ▶ For recruitment purposes, there will typically be little or no value in data that can only target the zip code level or similar. ▶ Data that allow targeting of particular practices are likely to result in challenging recruitment unless very specific directions can be given to the practice about how to search for patients; most practices will not have expertise or time for conducting their own RWD analyses.
Can potential participants be re-identified?	<ul style="list-style-type: none"> ▶ To be useable for recruitment purposes, data sources must provide an appropriate pathway to re-identify patients while protecting PHI (Protected Health Information). Early conversations with Institutional Review Boards or documentation of previous approved trials that used similar recruitment approaches are strongly advised. ▶ Often, researchers will work with anonymized or de-identified data to build a cohort of patients meeting trial entry criteria. Re-identification and contacting individual patients would then be completed by a point of contact appropriate to the data source (e.g., providers might contact patients identified through EHRs, and payers might contact patients identified through claims data).
Will the ability to identify eligible patients be adequate?	<ul style="list-style-type: none"> ▶ It will often not be possible to perfectly match patient information in EHR and claims data against all study eligibility criteria, and some degree of error in identifying eligible patients based on RWD will generally be acceptable. False positives, for example, will be addressed in most cases with systems to confirm eligibility prior to enrollment (e.g., screening calls with study coordinators). ▶ The goal will usually be to identify patients with a high likelihood of eligibility that are worthwhile to contact for interest and additional information. ▶ Plans for determining which patients to refer for screening should be established in advance, through collaborative discussions that include individuals with both clinical and RWD expertise.
Will data recency meet recruitment needs?	<ul style="list-style-type: none"> ▶ In many cases, recency of data will be of substantially greater concern for recruitment purposes than for planning eligibility criteria. ▶ For example, studies of acute conditions may have very short enrollment windows that will make claims data (which often is 30 to 90 days old, or older) infeasible to use for recruitment purposes. In such cases, EHR data may be much more useful (see EHR vs. claims table on Page 7 of Recommendations).

Is there local context to support insights from the data?

- ▶ Involving knowledgeable staff from healthcare systems providing RWD, as well as in-country sponsor staff for global studies, can offer important information on the validity and use of the data, as well as on the feasibility of various approaches to recruitment.
- ▶ For example, data may suggest the presence of an appropriate patient population that, in reality, is particularly challenging to recruit because they are in rural areas or because there is competition with other healthcare institutions for patients.

What manual screening will be necessary?

- ▶ Although advancements in artificial intelligence and other technologies are increasing the efficiency of identifying potential research participants, it will generally still be necessary for sites to conduct some level of manual chart review, ask screening questions in interviews, and similar. These activities, which may be carried out at the site level or by technology providers, should be planned for in recruitment timelines and study budgets.

Do the data support identification of appropriate research sites?

- ▶ RWD can support site selection and enhance interactions with sites when used alongside other appropriate information, such as prior site performance data.
- ▶ Within a healthcare system, heat maps generated with RWD can also help to identify physicians with high numbers of potentially eligible patients that recruitment teams can work with proactively.
- ▶ RWD can also support direct-to-patient recruitment when appropriate.