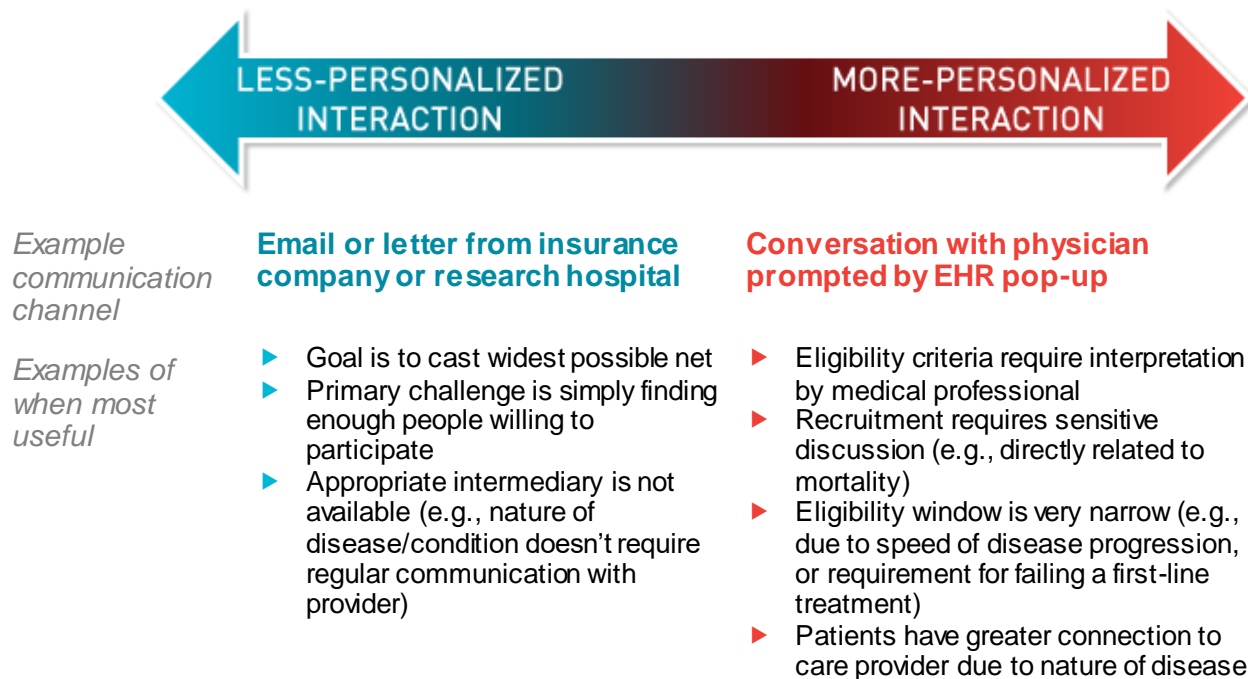# Planning RWD-Supported Recruitment Strategies

This resource is intended to help sponsors plan a successful and patient-centric real-world data (RWD) supported recruitment approach, focusing on factors that are unique to or particularly important for recruitment through electronic health records (EHRs) and claims data.[a]

Step 1: Identify Potential Communications Channels

After identifying patients via RWD sources, initial recruitment communication can occur along a continuum that ranges from less-personal "broadcast" communications at one end, to more-personal and individualized approaches at the other. See figure below.

	LESS-PERSONALIZED INTERACTION	MORE-PERSONALIZED INTERACTION
Example communication channel	**Email or letter from insurance company or research hospital**	**Conversation with physician prompted by EHR pop-up**
Examples of when most useful	▶ Goal is to cast widest possible net ▶ Primary challenge is simply finding enough people willing to participate ▶ Appropriate intermediary is not available (e.g., nature of disease/condition doesn't require regular communication with provider)	▶ Eligibility criteria require interpretation by medical professional ▶ Recruitment requires sensitive discussion (e.g., directly related to mortality) ▶ Eligibility window is very narrow (e.g., due to speed of disease progression, or requirement for failing a first-line treatment) ▶ Patients have greater connection to care provider due to nature of disease

Step 2: Consult with Patients and Sites

Selecting appropriate communication channels should be done in close consultation with patients, caregivers and other stakeholders—including IRBs and institutions—during the study planning process.

RWD-related questions to discuss with patients may include:

▶ **What level of personal interaction is needed to feel comfortable enrolling?** A "low-touch" approach, such as recruitment and enrollment conducted primarily online, can potentially empower patients, enable faster recruitment, increase diversity by reaching patients who might not be accessible through referral centers, and reduce burden on providers. However, these approaches will not always be appropriate, such as when recruitment requires discussions directly related to mortality, and may not be as successful when high levels of trust are required.

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[a] For general considerations on recruitment communication planning, refer to CTTI's Recruitment recommendations.

▶ **Will the communication be perceived as an invasion of privacy?** For example, depending on the disease/condition being studied and patient understanding about what data from their providers and payers are available to others, a given communication could feel like an invasion of privacy if not carefully worded.

▶ **What expectations does the communication approach set for patients?** For example, there is potential for the relatively easy enrollment facilitated by "low-touch" recruitment approaches to make retention more challenging—participants may be less likely to stay involved in a study if they have invested less upfront, or if the burden of participation is substantially greater than might be assumed based on the ease of enrollment.

RWD-related questions to discuss with providers/sites may include:

▶ **How can the recruitment approach best integrate with site workflows?** When the recruitment approach includes patient-provider discussion, recruitment workflows should leverage EHR and practice management data to determine how to best engage patients to discuss trial opportunities. For example, knowing a patient will see their provider for a follow-up appointment in one week creates an opportunity to prepare the care team in advance.

▶ **Can patients be recruited from across the practice setting?** Study sites will not always correspond exactly to the practice setting at which the patient presents. When patients are given opportunities to join studies across sites, sites tend to have more success with recruitment.

Step 3: Test and Optimize

Across the continuum from less-personalized to more-personalized recruitment communication channels, consider:

▶ **Automation:** How can the automation afforded by RWD-supported systems increase recruitment efficiency and effectiveness? In general, as sample size needs increase, the need for automated approaches to recruitment becomes stronger.

▶ **Personalization:** In what ways does information available from RWD facilitate appropriate personalization of recruitment communications? (Even with strategies such as large-scale email and letter recruitment campaigns, substantial degrees of personalization can potentially be achieved through appropriate use of RWD.)

▶ **Messaging:** It may be appropriate to test and update recruitment communications as enrollment proceeds. As an example, see the approach used in the mHealth Screening to Prevent Strokes trial to test outreach methods for a fully remote trial to patients identified and contacted through a claims database.

For studies that incorporate investigative sites, also consider:

▶ **Site Outreach Strategy:** Site selection should include an assessment of site workflows for querying data sources through to operationalizing insights for recruitment purposes. In most cases, a proactive recruitment approach (e.g., calling identified patients) should be in place. Questions to ask the site may include who will run the query and how, how data will be used to define the best candidates, and how data queries will be operationalized to patient recruitment.

▶ **Providing Support:** Sponsors should provide appropriately developed and tested messaging to support providers and investigative site personnel in discussing the trial with potential participants.

Step 4: Plan Ahead for Incorporating RWE into Informed Consent

Some studies that use RWD for recruitment will also analyze RWD for study endpoints (i.e., Real-World Evidence, or RWE). In such cases, it is important that approaches for providing information to potential participants about the study, including through the informed consent process, account for the following:

- ► **Clarify Scope of Data Capture and Use:** Ensure that the informed consent process appropriately conveys the potential for broader and/or more frequent capture and use of participant data, as well as the potential for longer duration of use of data. The use and flow of data should be clearly understood and reflected in the protocol in order to facilitate clear description in the informed consent document.

- ► **Ensure Clear and Effective Communication:** Just as for traditional trials, consider that long and complex informed consent documents can obscure the information that is most relevant to potential trial participants. A tiered approach, as described in CTTI's Informed Consent Recommendations, may be helpful to convey information about participant data capture and use in a clear and effective way.

- ► **Consider Potential Impact of Modular Consent:** Explore the value (e.g., with patient advisory groups) and feasibility of using a modular consent document that allows for separate enrollment/withdrawal for the RWE-supported elements of the study (i.e., those aspects of the study that require access to patients' EHR, claims, or other real-world data sources).

    - o In some cases, making the RWE elements of the study optional may increase overall enrollment rates. However, there is also the risk that meaningful conclusions from RWD-derived endpoints may be lost if insufficient numbers of patients agree to enroll in that portion of the study.

    - o Some participants who decide to withdraw from the main study may be willing to allow researchers to continue to follow them via EHR or claims data (e.g., if a patient moves and can no longer get to the study site).