SIGNANT HEALTH
THE EVIDENCE GENERATION COMPANY™

The Signal

Prepare for These 4 Common Scale Management Challenges

Due to Signant's extensive eCOA and scale management experience, we recognize that these processes can be unexpectedly complex, cumbersome, and lengthy for sponsors and scale management service providers alike.

Read on to learn about the common challenges that sponsors and their clinical research partners may face along the way and how proper planning for scale implementation can mitigate their impact.

- **Timing**

  Sponsors and scale management service providers like Signant must consider all the scales required for a single study – each scale is different, and each copyright holder's requirements will be different. Unfortunately, even if just one scale takes months to license, it will delay study launch and affect the entire project's ability to go live.

- **External Factors**

  Oftentimes, factors outside of our control can create a bottleneck in the startup process, such as copyright holder response time or inaccurate information. Plus, it is not always clear whether a scale is copyrighted or not – sponsors could receive conflicting information or will not receive enough information to understand the correct details. To give an example, Signant has experienced instances where a copyright holder informed us that a translation was available to acquire along with the license. However, when it came time to finalize the license, the translation was in fact not available.

  Yet another challenge from copyright holders' requirements can be mandated translation vendors and their processes, which limits Signant's choices in terms of vendor selection and can also impact timelines.

- **Evolving Requirements**

  Clinical outcome assessment (COA) requirements are constantly evolving, and it is crucial to stay updated with the latest and greatest information available. Copyright holders can transfer rights at any time, requirements from a previous study may not be the same when the sponsor wants to re-use the scale, or licensing fees can increase without warning, burdening the sponsor with unanticipated additional costs.

Copyright holders may even ask to review translations or screen shots of the sponsor's COA which, if requested without advance notice, will further increase timelines.

- **License or Scale Amendments**

  Initial licenses are completed based on the information we know at the start of a clinical study. Any change to that information, including an extension of Last Patient Out or the addition of new countries, languages, and administrations necessitates an amendment that will require extra time to implement. Sometimes, a sponsor will request a change to copyrighted scales, which requires approvals and can lead to many time-consuming discussions between the sponsor, Signant, and the copyright holder.

  Obtaining additional approvals for amendments is further complicated when scales involve more than basic administration and include subject interviews and observations or supplemental components such as stimuli books and manipulatives that need to be purchased. Other times, specific printing requirements or the process of navigating international publishers who have hard-copy-only scales can be another hurdle to overcome.

Prepare to face these common scale management challenges in your clinical study by first considering every scale in your protocol as well as their licensing and requirements. After all, even the best study design will have poor outcomes if scales are poorly implemented, so it is important for sponsors and clinical research partners like Signant to realize that proper planning, knowledge, and time are key to successful scale management and overall study outcomes.

To learn more about how we help sponsors and CROs navigate scale management processes, visit our resources or watch the recording of our webinar on Scale Management: Setting Up for Study Success.

Karrie Crocco, M.Ed.

Scale Management Architect