OEvidera PPD

Considerations for Patient Identification and Enrolment for Retrospective Studies for the Collection of Long-Term Follow-up Data

Poster SA77

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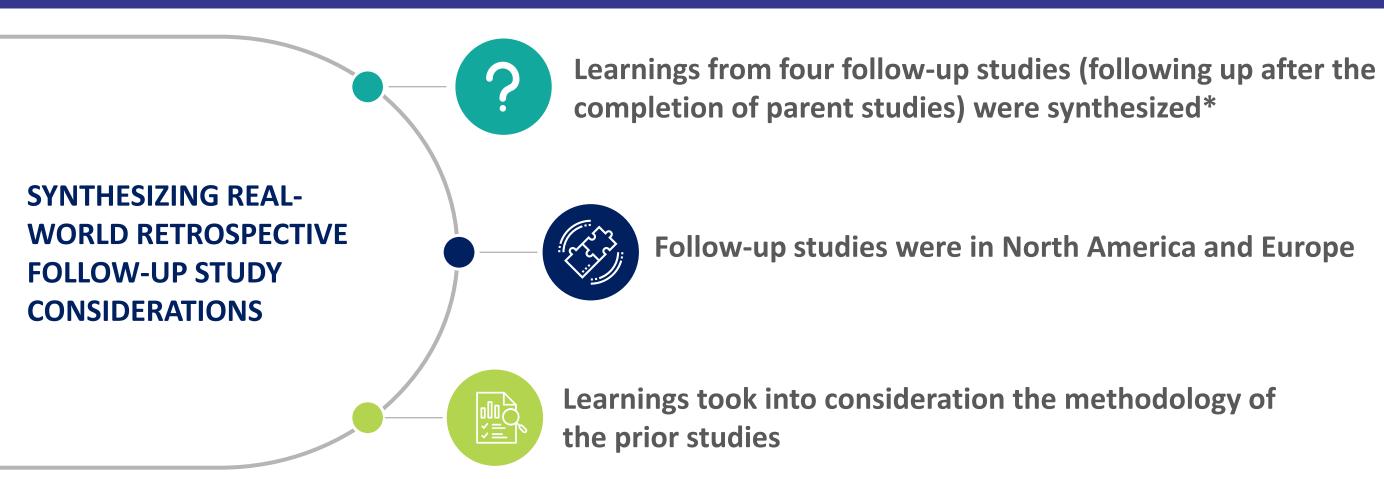
Background

- Retrospective chart review studies aiming to collect longer-term data following completion of parent studies (i.e., studies planned months/years after the parent study) can be important for:
 - Assessing long-term effectiveness, survival and safety^{1,2,3}
 - Understanding health resource utilization and treatment patterns. 1,2,3
- Retrospective follow-up studies are challenged by several factors, including patient identification and site recruitment.
- It is critical to study success to:
 - Maximize patient retention
- Identify considerations for ethics and data archiving which may depend on the original study methodology.

Objectives

Our aim was to describe challenges and solutions for executing long-term, retrospective follow-up studies, based on the authors' experience and lessons learned from conducting these.

Methods

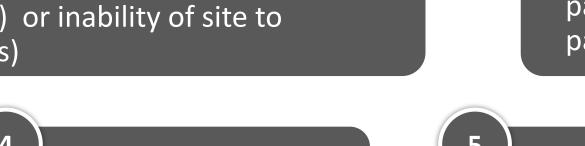


* Parent studies were clinical trials or observational studies

Results

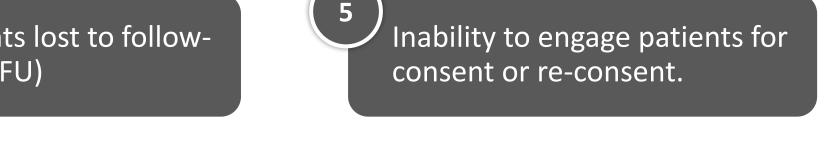
Challenges to patient enrolment included:

Low interest (i.e., sites that had an unsatisfactory experience with the study methodology, or with their sponsor or CRO relationship on the parent study) or inability of site to participate (i.e., lack of resources)

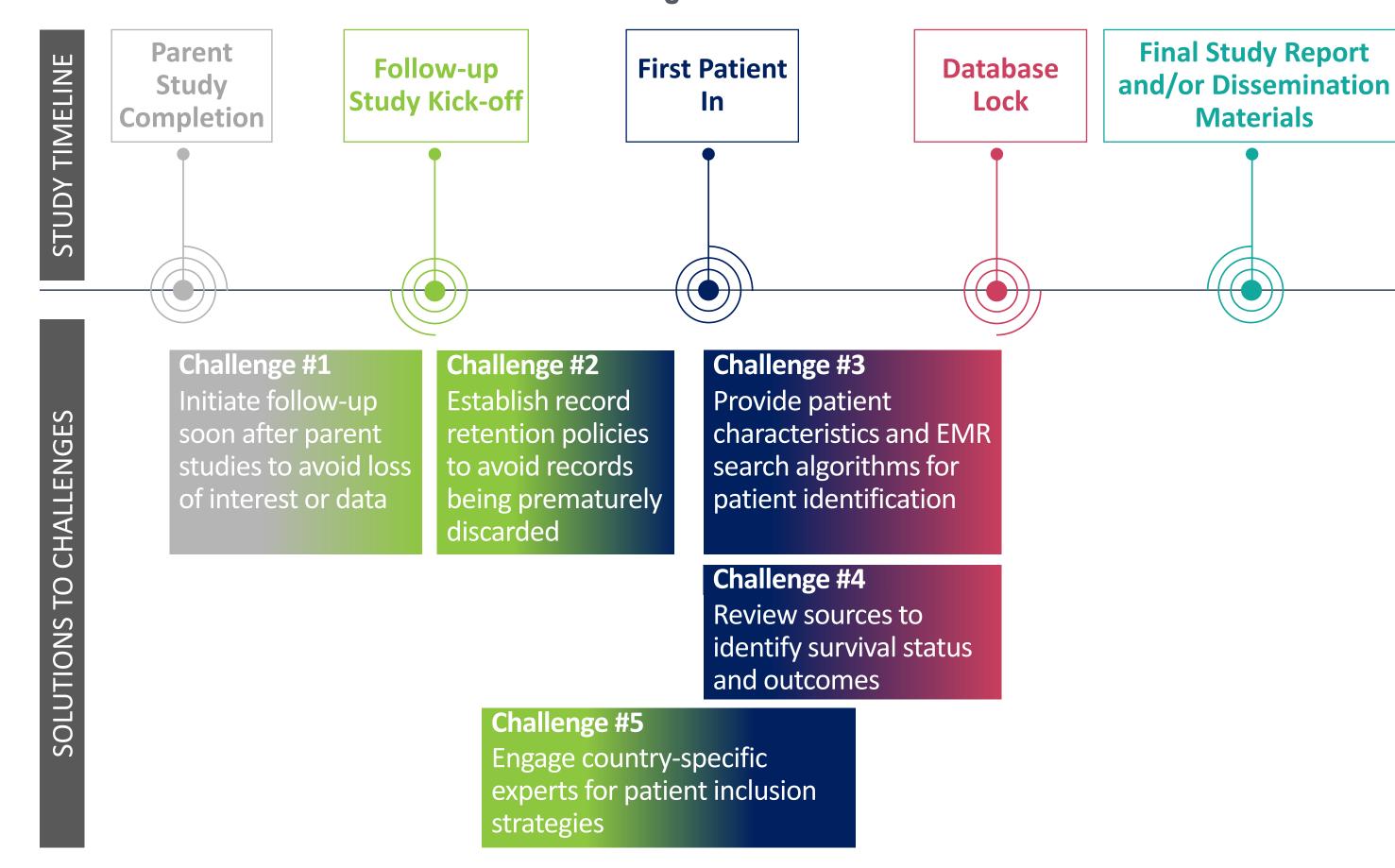




Data not retained from parent studies to identify patients



Overview of Potential Solutions to the Challenges

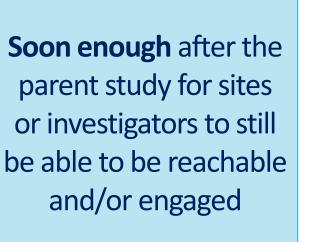


To avoid loss of investigator interest or patient data, recommended approaches include:

Consider debriefing each participating site thoroughly towards the end of the parent study and aim to mitigate any negative feedback when setting up the follow-up study.

Timing of follow-up study initiation, finding balance between:

1. Initiate follow-up studies soon after parent studies





Enough time passing to look at retrospective outcomes

Leveraging key opinion leaders to emphasize research importance to increase site interest:

• Engage KOLs early in study → KOLs input into key study documents → have KOLs input for review/interpretation of results.

Results (cont'd)

Patient characteristics provided to the site in case report forms or in additional documents (i.e., age, sex, disease diagnosis date or treatment initiation date) **EMR** search algorithms: 2. Provide key Within the electronic health systems, sites can flag patients with a key patient characteristic/data (i.e., disease diagnosis) characteristics as an anchor, and Sites can then screen for additional inclusion criteria in a logical order based on **EMR** search the electronic health system's filtering and structure algorithms to aid patient identification Sites can then screen for additional exclusion criteria All patients meeting eligibility criteria will be enrolled in the study and become part of the final study cohort

3. Clearly establish record retention policies/ requirements to avoid records being prematurely discarded

Examples and recommendations of broad policies that may be detailed in protocols and agreed with sites, as applicable:

- Records/document archiving at the study sites and by the sponsor a minimum number of years after final study report
- Sites transferring/moving or disposing of study documents should be approved by the study sponsor.

4. Review sources to identify survival status and outcomes

Options/resources that can be searched vary by country (and sometimes regions within countries), but may include at least some of the following:

- Death registries
- Disease or indication-specific registries
- Publicly available records: Voter registration data, driver's license data, property records data, marriage/divorce records, court records, etc.
- Other: Social media, on-line search engines, obituary resources, newspapers/media, etc.

5. Engage countryspecific ethics and
site outreach
experts; work
collaboratively
with sites to
confirm parent
study consent

covers future data

collection.

Confirming parent study consent covers future data collection:

- When working on parent studies planning for potential future work, include appropriately broad consent language into the consent form
- When working on follow-up studies not planned at the time of the parent study:
 If using data from the parent study and consent for future use of data was not part of the parent study, follow-up studies may need patient consent.
 - In countries where approved, a waiver of informed consent may be allowed

Conclusions

- Obtaining data for retrospective follow-up chart reviews can be complex. Tailored solutions are needed to maximize sample size.
- Early identification of challenges and solutions is essential for study success.
- Strategic decision-making and bespoke solutioning should be led by experts in scientific design and operational conduct of retrospective follow-up studies.

References

- 1.Bartlett VL, et al. *JAMA Netw Open*. 2019;2(10):e1912869.
- 2. Cowie MR, et al. Clin Res Cardiol. 2017 Jan; 106(1):1-9.

3. González-Barca E, et al. Ann Hematol. 2021 Apr;100(4):1023-1029.

Disclosures

All authors are full-time employees of PPD, Part of Thermo Fischer Scientific. There was no medical writing support.