

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

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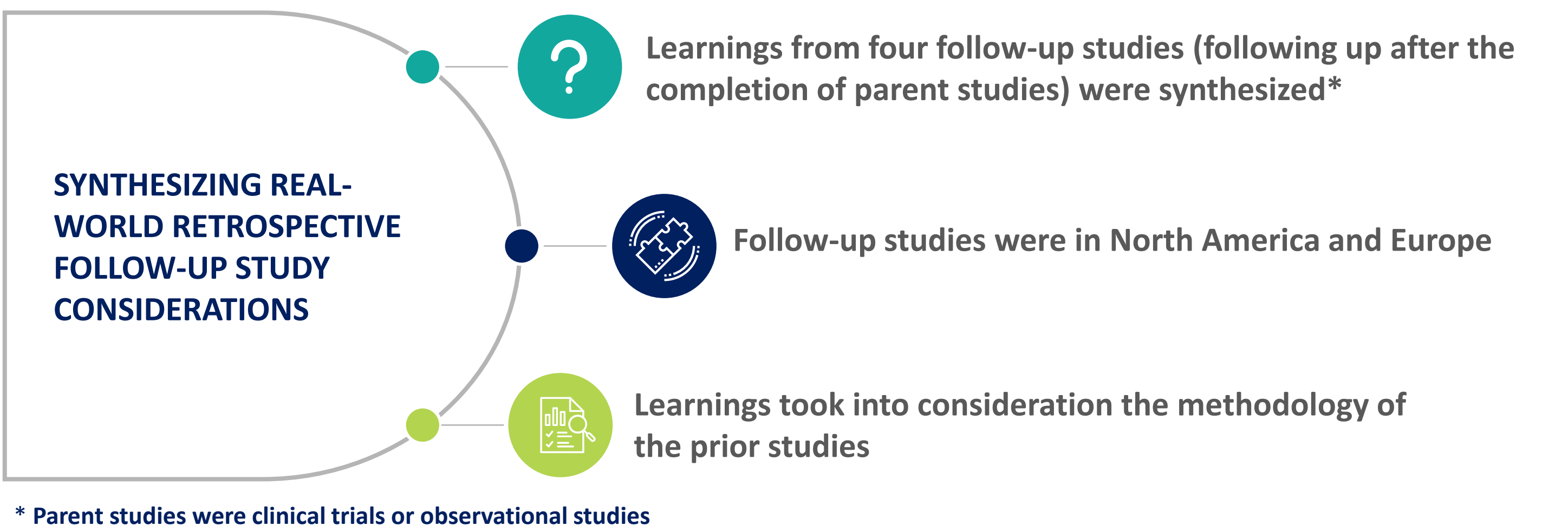
Background

- 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

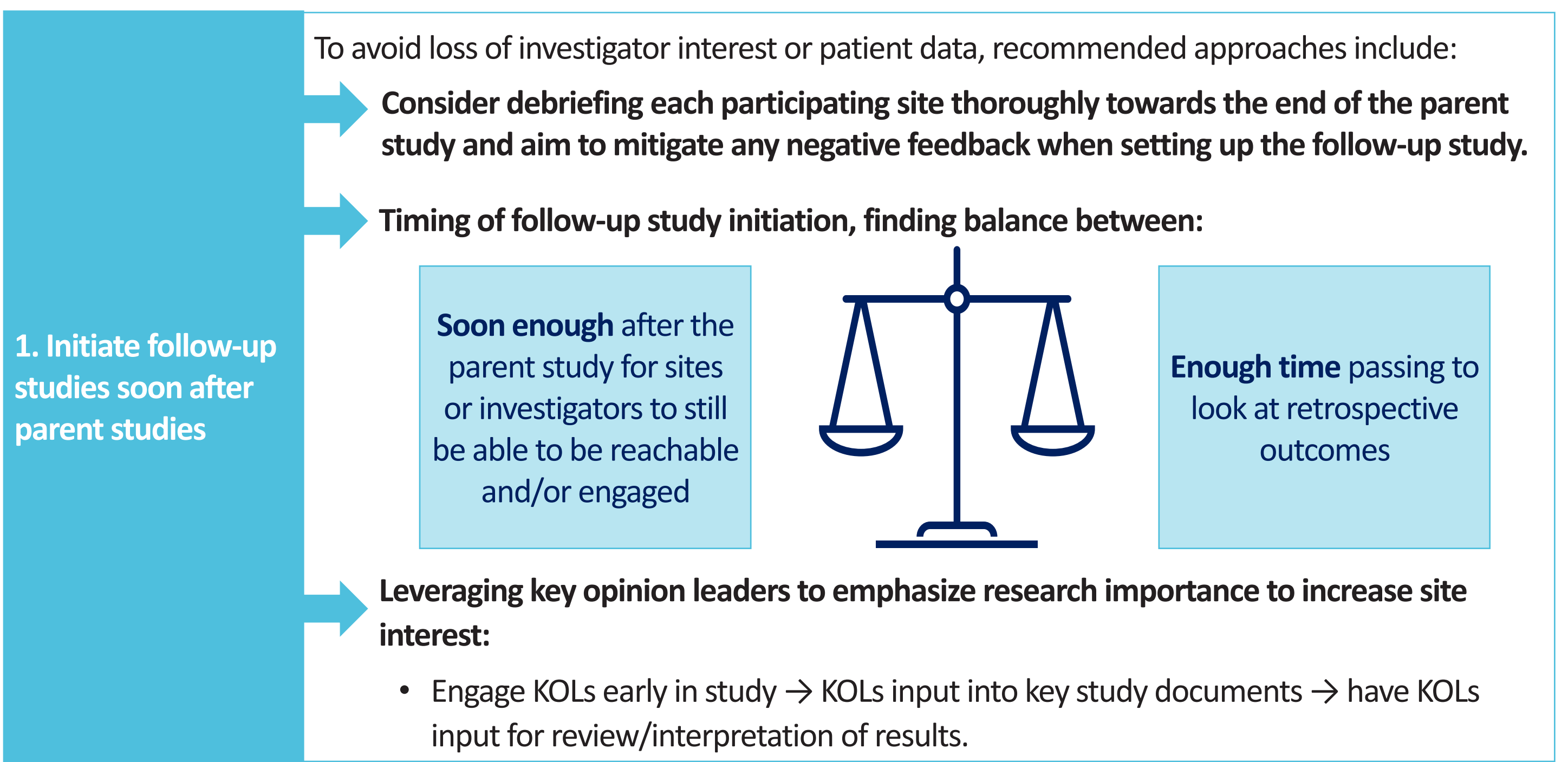
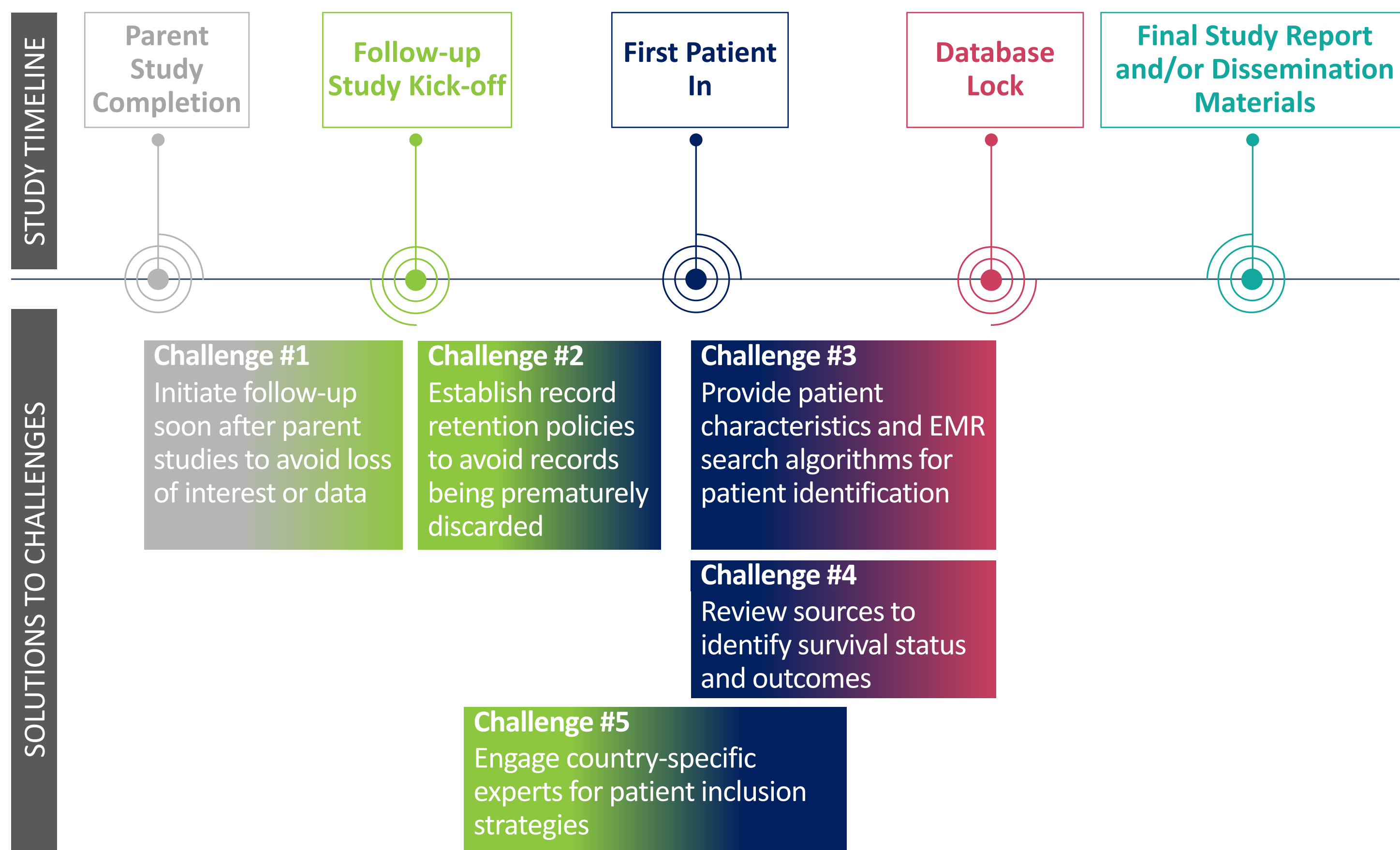


Results

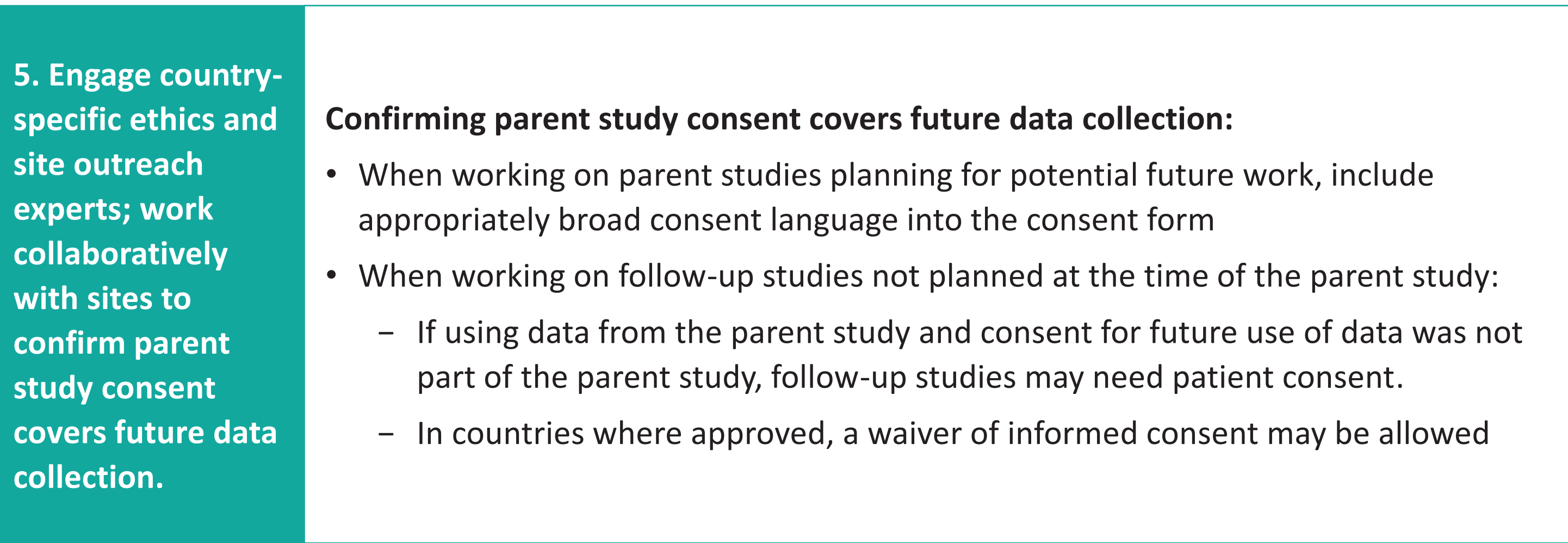
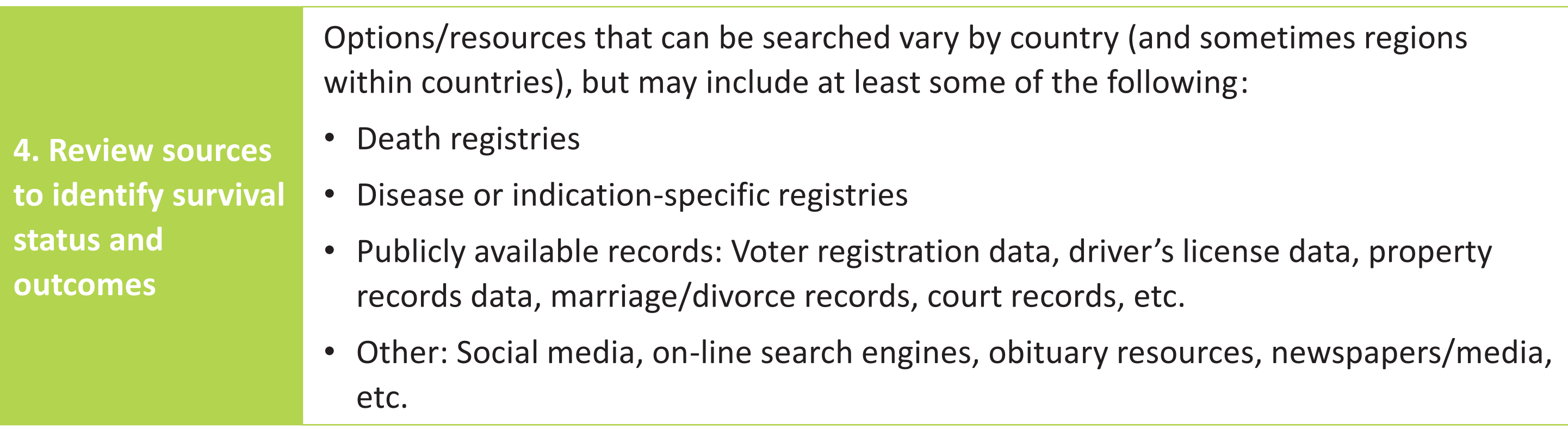
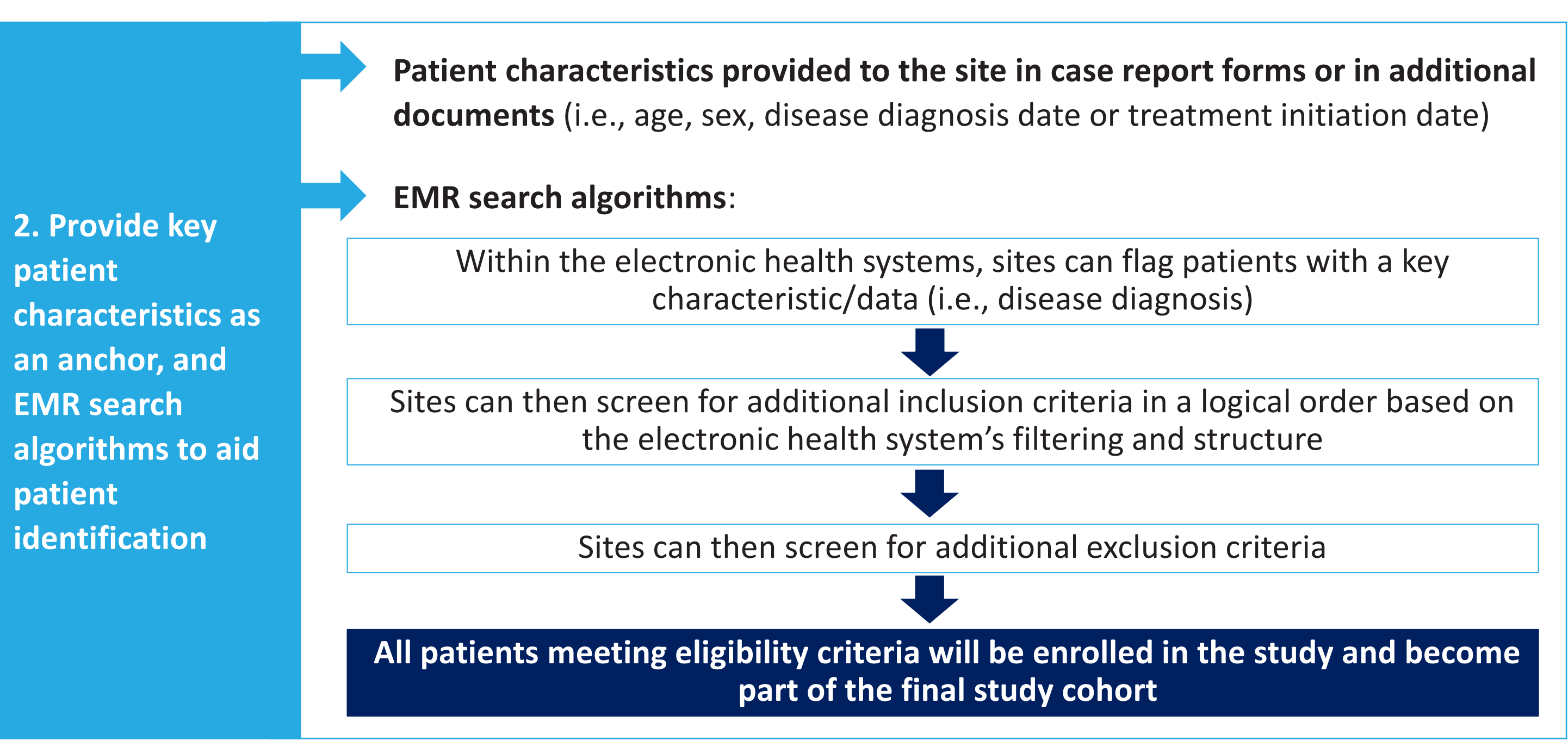
Challenges to patient enrolment included:

- 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
- Inability to access patient charts
- Patients lost to follow-up (LTFU)
- Inability to engage patients for consent or re-consent.

Overview of Potential Solutions to the Challenges



Results (cont'd)



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

- Bartlett VL, et al. *JAMA Netw Open*. 2019;2(10):e1912869.
- Cowie MR, et al. *Clin Res Cardiol*. 2017 Jan;106(1):1-9.
- González-Barca E, et al. *Ann Hematol*. 2021 Apr;100(4):1023-1029.

Disclosures

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