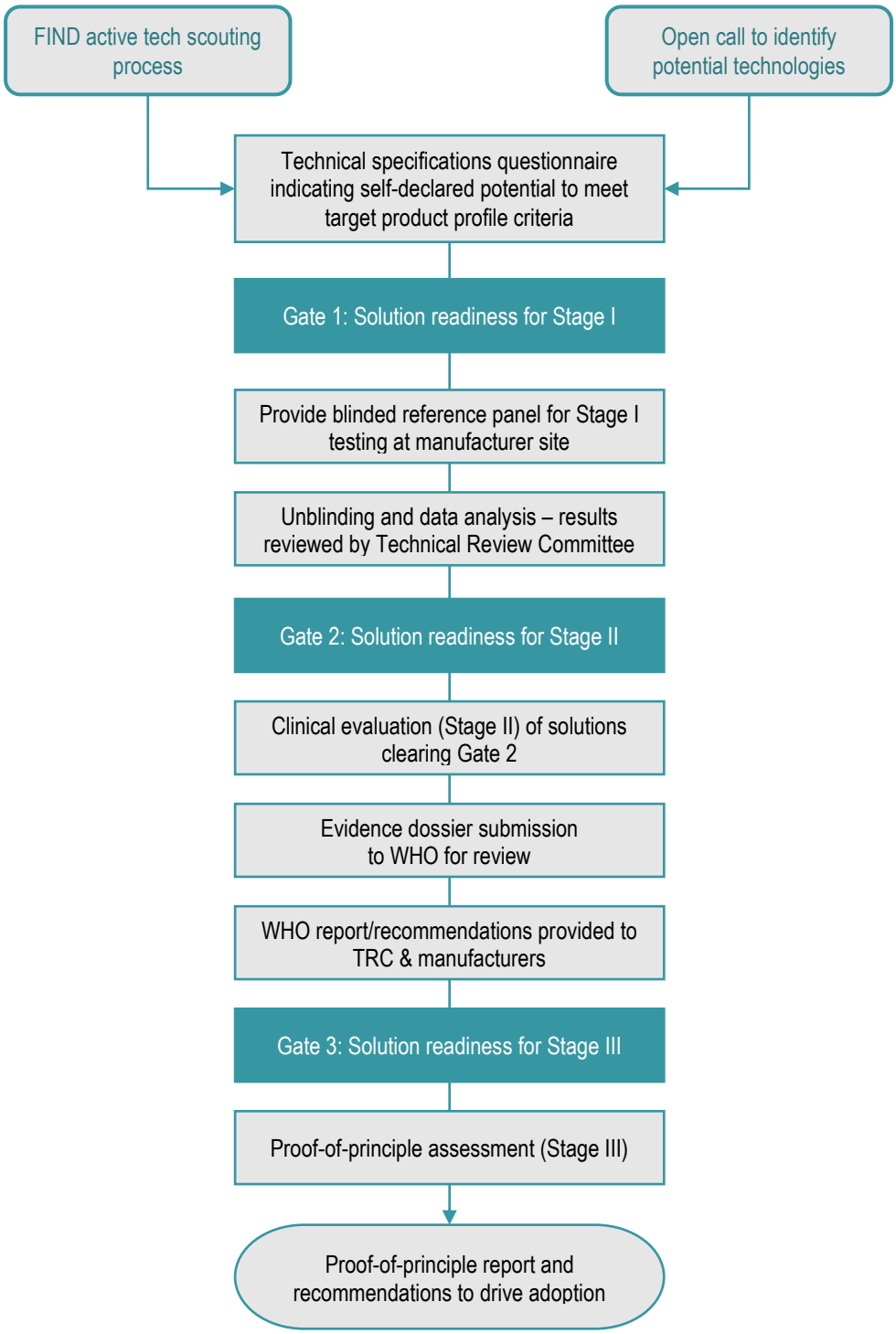
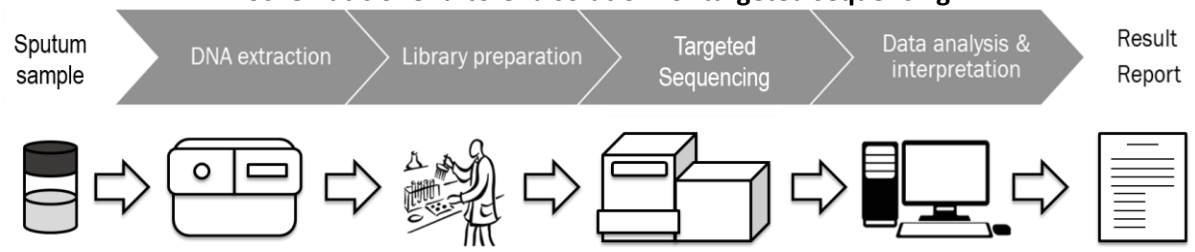
Seq&Treat Technology Selection Process Flow



Definitions

- Gate 1 involves down-selection of End-to-End solutions for analytical validation (Stage I) based on potential to meet target product profile criteria.
- Gate 2 involves the down-selection of End-to-End solutions for inclusion in the clinical evaluation (Stage II) based on results of Phase 1 analytical validation.
- Finally, Gate 3 will involve the selection of one or more End-to-End solution(s) that receive positive recommendation upon WHO review for proof-of-principle of delivery models in LMICs (Stage III).
- Stage I: Stage I refers to Phase 1 of Output 1, comprising the analytical validation of selected End-to-End solutions to determine inclusion in clinical trial based on technical performance using reference strain panels.
- Stage II: Stage II refers to Phase 2 of Output 1, comprising the multi-centre clinical evaluation to assess diagnostic accuracy and operational characteristics of End-to-End solutions for diagnosis of DR-TB.
- Stage III: Stage III refers to Output 3, comprising the proof-of-principle study to assess delivery models for use of End-to-End solutions in LMICs.

Schematic of end-to-end solution for targeted sequencing



Questions? Contact us: sequencing@finddx.org