FHI CLINICAL

Mission-driven clinical research

Improving equity in clinical trials using biosurveillance methodology

Ghiorghis (George) Belai

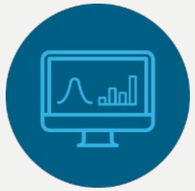
Vice President, Global Strategy

FHI Clinical

BIOSURVEILLANCE METHODOLOGY

Primary focus on epidemiology is critical to site identification to ensure that vaccine efficacy endpoints can be measured.

We implemented biosurveillance methodology to conduct global site feasibility.

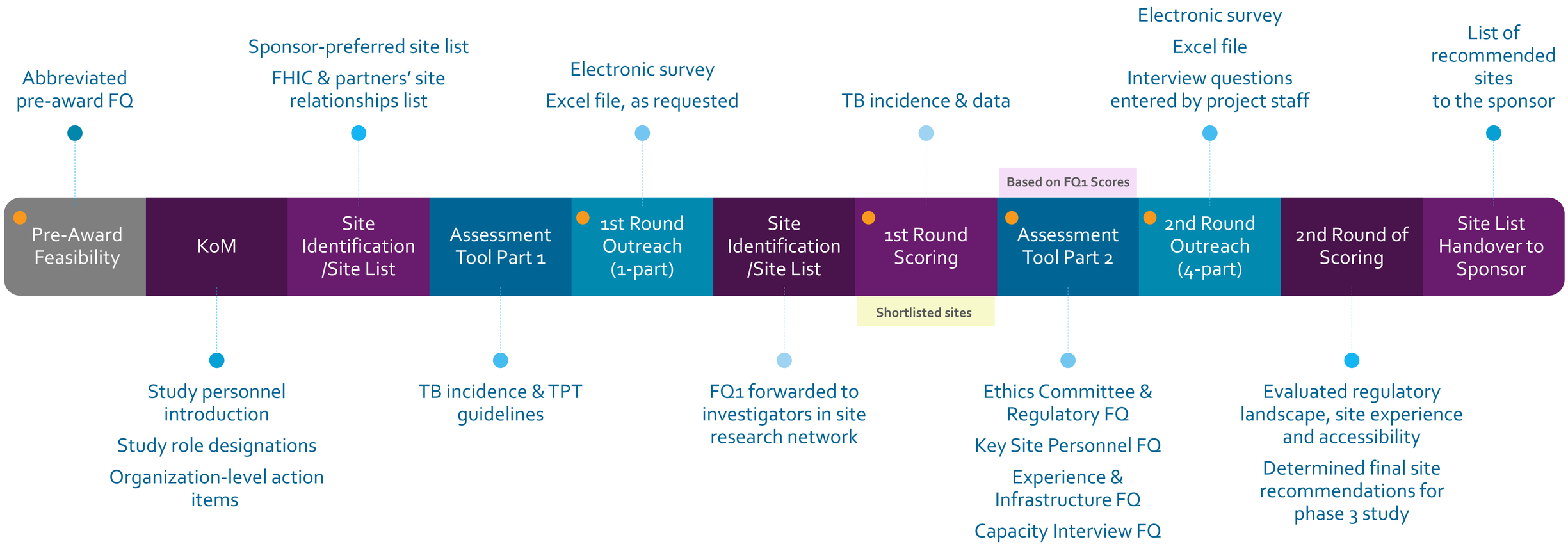


We utilized an integrated data science approach to identify key criteria relevant to trial conduct, including TB incidence and site capacity, to inform site selection.

Site-specific epidemiologic and capacity-related data were evaluated in the context of these criteria.

FHI CLINICAL

TB FEASIBILITY PROCESS



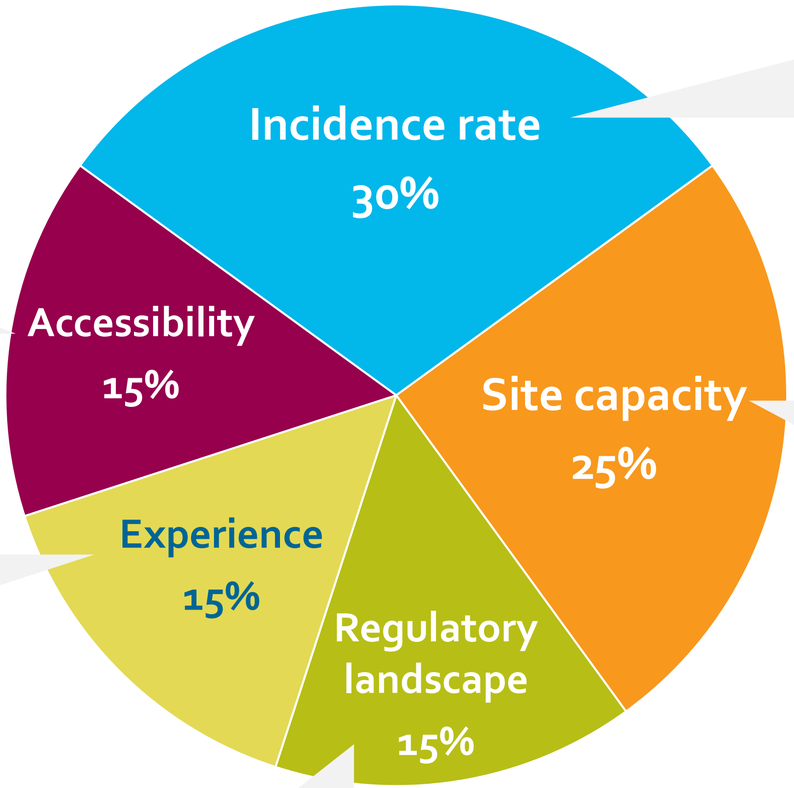
KEY LEGEND

- FHI Clinical Strategy team and external partners managed outreach
- Pre-determined objective scoring methodology

FHI CLINICAL

ASSESSMENT TOOL

Five key criteria and their weights:



Known local and catchment area TB burden/prevalence within the target population above 300/100,000 population.

Ability to manage an active TB trial, lab access to collect and ship variety of samples, proper equipment, infrastructure to support study

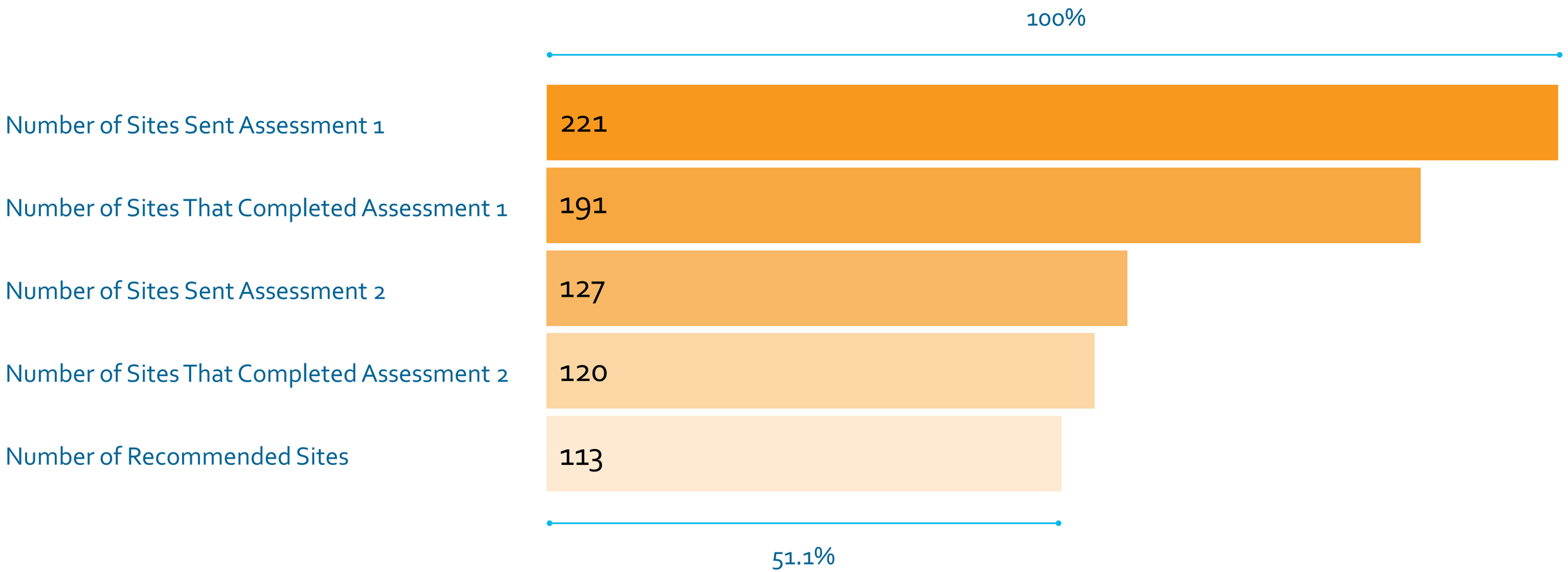
Country-level clinical trial application filing requirements, submission approval timelines, layers of regulatory constraints

Ability to recruit participants, oversee activities to maintain study, previous familiarity with population-based vaccine trials

Geographic accessibility, logistics/supply chain challenges, political instability

FHI CLINICAL

ASSESSMENT RESULTS



FHI CLINICAL

WHO NATIONAL-LEVEL TB INCIDENCE VS LOCAL HOT-SPOT ESTIMATES

Country	Data Source	2017 Incidence	# of Sites (FHI Clinical)	2018 Incidence	# of Sites (FHI Clinical)	2019 Incidence	# of Sites (FHI Clinical)	2020 Incidence	# of Sites (FHI Clinical)
Brazil	WHO	44 (38 - 51)		46 (39 - 53)		46 (39 - 53)		45 (38 - 52)	
	FHI Clinical	225 (135 - 427)	4	461 (145 - 1,311)	5	432 (144 - 1,404)	6	212 (130 - 337)	4
DRC	WHO	322 (208 - 461)		321 (207 - 459)		320 (207 - 457)		319 (206 - 456)	
	FHI Clinical	646 (280 - 1303)	10	2137 (312 - 16,536)	22	1,866 (109 - 12,828)	22	2,035 (83 - 8,228)	24
India	WHO	204 (136 - 286)		199 (134 - 276)		193 (132 - 266)		188 (129 - 257)	
	FHI Clinical	738 (38 - 1,091)	3	703 (38 - 1,487)	8	976 (40 - 1,899)	9	747 (26 - 2,003)	5
Kenya	WHO	319 (175 - 505)		292 (170 - 446)		267 (163 - 396)		-	
	FHI Clinical	90 (70 - 111)	2	110 (109 - 112)	2	153 (66 - 308)	3	142 (52 - 308)	3
Pakistan	WHO	267 (188 - 359)		265 (187 - 356)		263 (187 - 353)		259 (185 - 346)	
	FHI Clinical	225 (10 - 896)	21	234 (9 - 1,240)	21	234 (9 - 1,080)	21	244 (10 - 1,480)	21
Peru	WHO	119 (91 - 150)		119 (91 - 150)		119 (91 - 150)		116 (87 - 149)	
	FHI Clinical	286 (167 - 412)	6	293 (130 - 389)	4	517 (136 - 1,616)	6	119	1

TB Burden Countries, 2021. Accessed: Oct-26-2021. Brazil, DRC, India, Kenya, Pakistan, Peru. Retrieved from: https://www.who.int/teams/global-tuberculosis-programme/data

OBJECTIVE, DATA-DRIVEN SITE FEASIBILITY ASSESSMENT

This methodology enabled a systematic, objective, data-driven assessment of sites and identification of catchment areas with high levels of TB.

Some sites had significant incidence but would need time to build capacity prior to starting the trial.

- Identifying these needs is critical for trials conducted in LMICs.
- Targeting these sites enhances the accessibility to underrepresented populations and therefore equity in clinical trials.

FHI CLINICAL

THANK YOU

FHICLINICAL.COM

FHI CLINICAL