



Introduction & project structure

Project kick-off meeting
30 March – 3 April 2020
By teleconference



The EDCTP2 programme is supported by the European Union's Horizon 2020 research and innovation programme

Aim



The aim of PreFIT is to validate the **clinical performance**, **cost** and **feasibility** of a package of ready-to-use new and existing candidate diagnostic assays for prediction of the development of active TB disease.

It will focus on tests that can be done at **point-of-care**, and entail an **evaluation-phase trial in populations of intended use** across different TB high-burden settings in Southern and Eastern Africa.

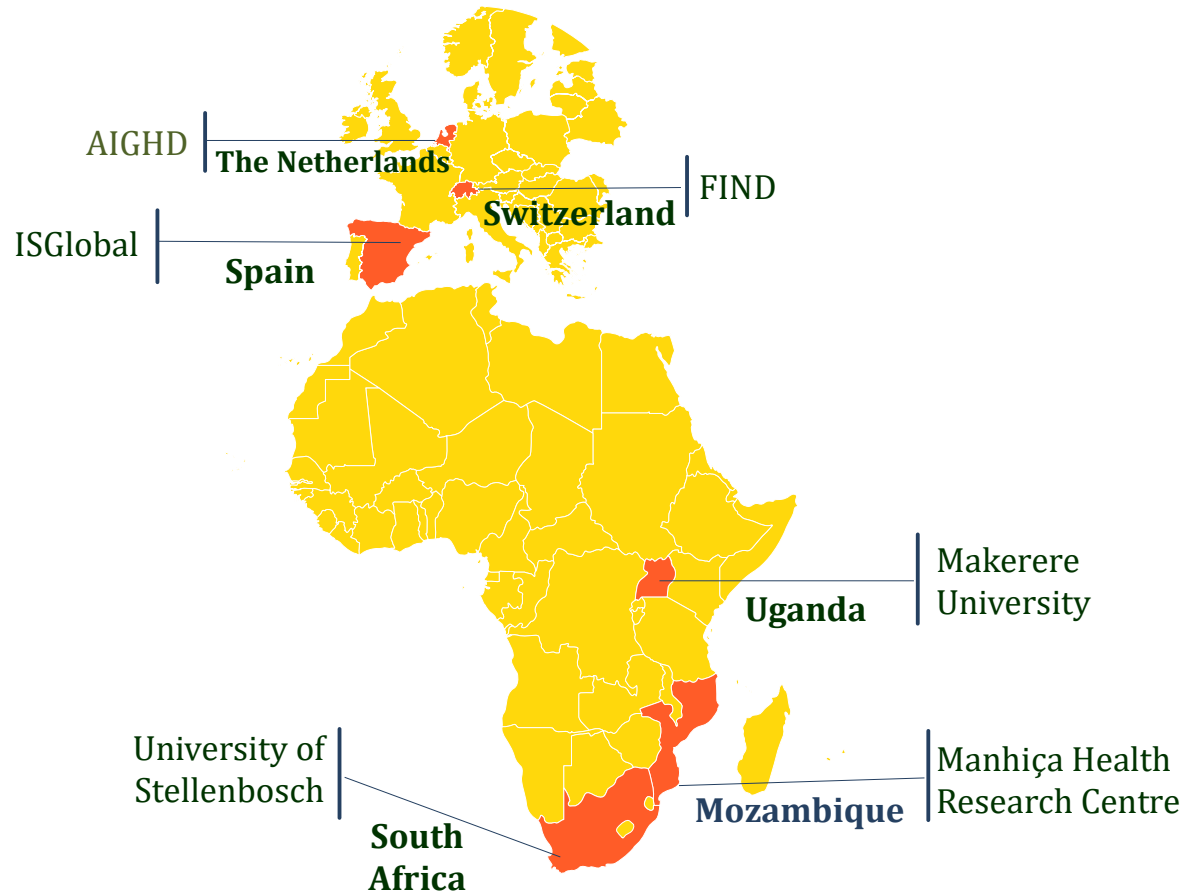
PreFITs results will contribute to the **development and uptake of accurate, cost-effective, scalable and field friendly diagnostic tools**, in order to facilitate scale-up of preventive treatment in sub-Saharan Africa and beyond.

Objectives



1. Establish a multi-country diagnostic evaluation cohort of 4040 highly exposed TB household contacts free of active TB disease at baseline, followed prospectively for development of bacteriologically confirmed TB disease over a 12 months period, and collect and store biological specimens from these contacts at preset timepoints for laboratory testing (**WP 2**).
2. Validate a package of candidate assays for their predictive accuracy (sensitivity, specificity, positive and negative predictive values) for incident TB, feasibility and cost. Based on combining results for the different tests, cost-optimised predictive algorithms will be derived (**WP 3**).
3. Raise awareness about the project and ensure the acceptance and conduct of the trial, disseminate the project's findings to a broad audience of stakeholders, and ensure uptake of the evaluated predictive point of care tests beyond the borders of the project (**WP 4**).
4. Further capacitate participating sites on TB diagnostic procedures, train local scientists on diagnostic validation studies and strengthen the collaboration and networking among the partners and between the EDCTP Networks of Excellence TESA-2 and EACCR-2 (**WP 5**).

Partners



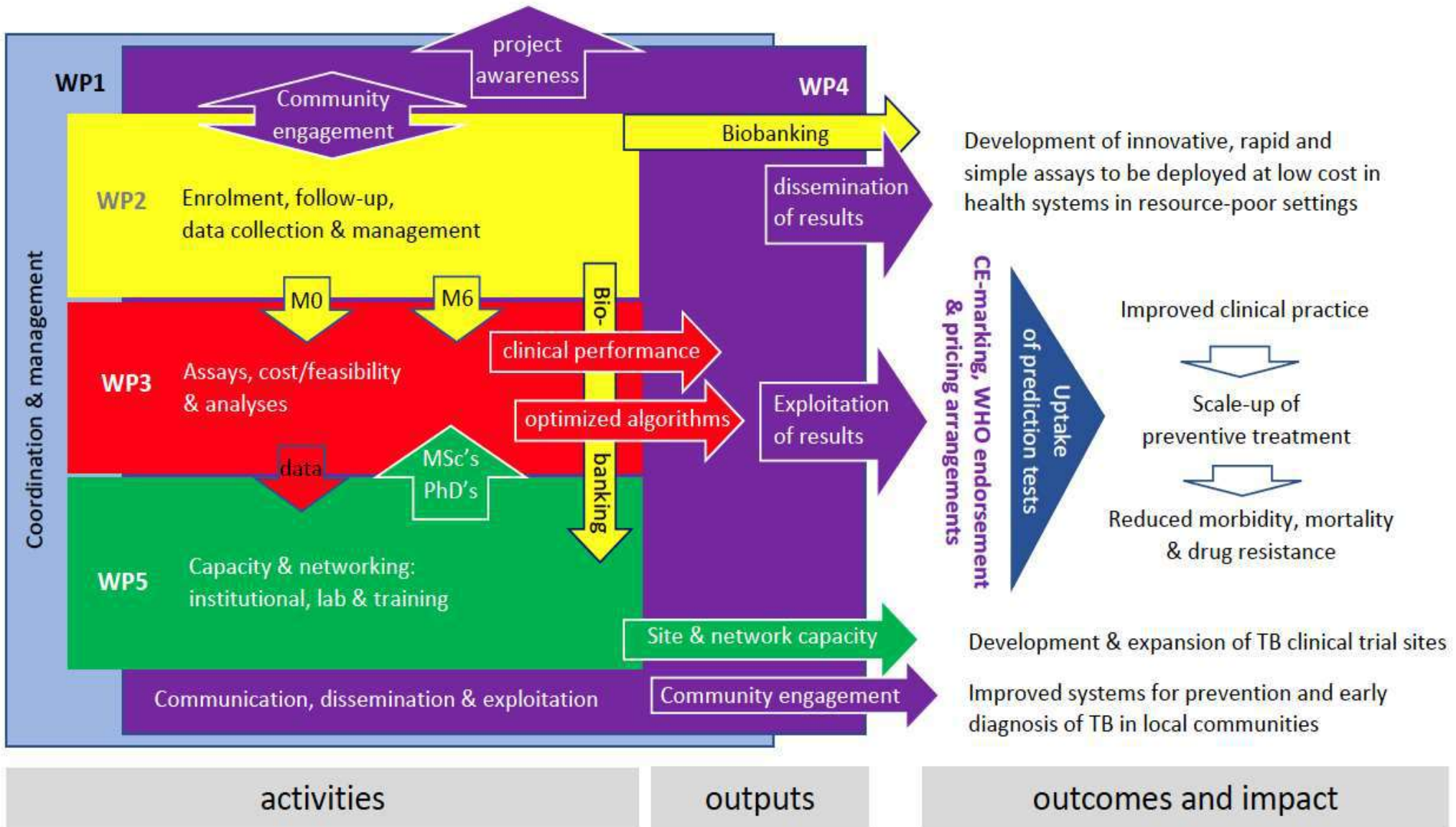
26 March 2020



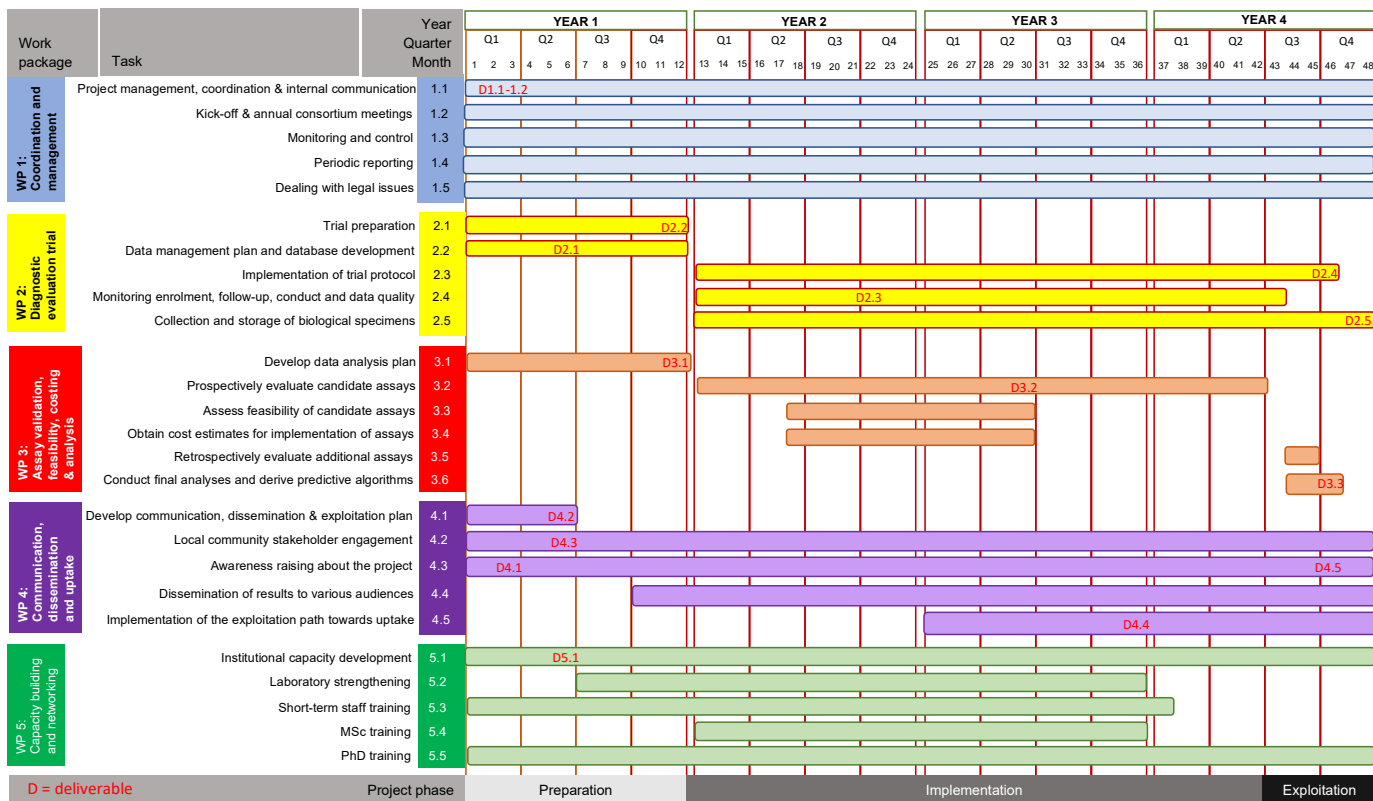
Workpackages



WP	Title	Responsible partner	Months
1	Coordination and management	AIGHD	1 - 48
2	Diagnostic evaluation trial	SU	1 - 42
3	Assay validation, feasibility and costing, and data analysis	MU	6 - 48
4	Communication, dissemination and uptake	ISGlobal	1 - 48
5	Capacity building and networking	CISM	1 - 48



GANTT



D = deliverable

Project phase

Preparation

Implementation

Exploitation

26 March 2020

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Project timeline



WP 1 activities



- 1.1 Project management, coordination & internal communication
- 1.2 Kick-off & annual consortium meetings
- 1.3 Monitoring progress towards deliverables and milestones
- 1.4 Periodic reporting to EDCTP
- 1.5 Address legal issues with regard to the intellectual property management

WP 1 deliverables



No	Title	Type & dissem	Due	Contributors
1.1	Internal Communication Plan	R / PU	1 April 2020	AIGHD
1.2	Procedure for immediate reporting to EDCTP	R / CO	1 April 2020	AIGHD
1.3	M&E logframe	R / PU	1 Aug 2020 + 6-monthly	AIGHD
1.4	Project plan & GANTT chart	R / PU	1 April 2020 + 12-monthly	AIGHD
1.5	Trial Steering Committee Charter	R / PU	1 May 2020	AIGHD
1.6	TSC meetings	R / CO	1 May 2020 + 12-monthly	AIGHD
1.7	Monitoring visit & QA plan	R / CO	1 Aug 2020	AIGHD, CISM, MU, SU
1.8	Materials Transfer Agreement	R / CO	1 Aug 2020	AIGHD, CISM, FIND, MU, SU
1.9	Data Transfer Agreement	R / CO	1 Aug 2020	AIGHD, all partners
1.10	Consortium meetings	R / PU	1 April 2021 + 12-monthly	AIGHD

WP 1 milestones



No	Title	Due	Contributors
1.1	Kick-off meeting held	3 April 2020	AIGHD
1.2	Project governing bodies established	3 April 2020	AIGHD
1.3	M& system developed	1 Sept 2020	AIGHD
1.4	First Advisory Board meeting held	1 Aug 2020	AIGHD

WP 2 activities



2.1 Development of trial protocol and SOPs, obtaining approvals and clearances

2.2 Data management plan and database development

2.3 Implementation of trial protocol

2.4 Monitoring the enrolment, follow-up, conduct and data quality

2.5 Collection and storage of biological specimens

WP 2 deliverables



No	Title	Type & dissem	Due	Contributors
2.1	Data management Plan	R / PU	1 Aug 2020	CISM, MU, SU, ISGlobal
2.2	Final approved version of study protocol incl. IC	R / PU	1 Feb 2021	SU, all partners
2.3	Registration number of clinical study	DEC / PU	1 Feb 2021	SU
2.4	Incidental findings policy	R / PU	1 Feb 2021	SU
2.5	Declarations on compliance with national/EU legislation for (...) personal data	R / PU	1 Feb 2021	SU, all partners
2.6	Clinical trials insurance	R / CO	1 Feb 2021	AIGHD
2.7	Clinical trial progress plan with projected dates	R / CO	1 Feb 2021	SU
2.8	All approvals package	R / PU	1 Feb 2021	SU, all partners
2.9	Midterm recruitment report	R / CO	1 Dec 2021	SU
2.10	Report on status of posting results	R / PU	1 Dec 2023	SU
2.11	Long-term sample storage report	R / PU	31 Jan 2024	FIND

WP 2 milestones



No	Title	Due	Contributors
2.1	Study sites initiated	1 Feb 2021	SU, all partners
2.2	First trial participant in (start of recruitment)	1 March 2021	SU, CISM, MU
2.3	25% recruitment point	1 Aug 2021	SU, CISM, MU
2.4	75% recruitment point	1 Oct 2021	SU, CISM, MU
2.5	Enrolment completed	1 Aug 2022	SU, CISM, MU
2.6	Last trial participant out	1 Aug 2023	SU, CISM, MU
2.7	Study sites closed	1 Aug 2023	SU, CISM, MU, AIGHD
2.8	Database ready for analysis	1 Sept 2023	CISM, MU, SU
2.9	Results posted in clinical study register	1 Dec 2023	SU
2.10	Stored specimens selected and shipped to FIND TB Bank	1 Dec 2023	FIND, CISM, MU, SU
2.11	Final database shared with assay manufacturer(s)	1 Dec 2023	CISM

WP 3 activities



- 3.1 Develop data analysis plan
- 3.2 Prospectively evaluate candidate assays for predictive accuracy
- 3.3 Assess feasibility of candidate assays
- 3.4 Obtain cost estimates for implementation of the assays
- 3.5 Retrospectively evaluate additional assays for predictive accuracy
- 3.6 Conduct final analyses and derive predictive algorithms

WP 3 deliverables



No	Title	Type & dissem	Due	Contributors
3.1	Data analysis plan	R / PU	1 Feb 2021	MU, all partners
3.2	Study database	DEC / CO	1 Feb 2021	CISM, ISglobal, MU, SU
3.3	Interim analysis report	R / PU	1 Aug 2022	SU
3.4	Costing analysis report	R / PU	1 Jan 2024	MU
3.5	Final analysis report	R / PU	1 May 2020	AIGHD

WP 3 milestones



No	Title	Due	Contributors
3.1	Final analyses completed	1 Dec 2023	MU, all partners

WP 4 activities



4.1 Development of the communication, dissemination and exploitation plan

4.2 Awareness raising about the project

4.3 Local community stakeholder engagement

4.4 Dissemination of results to various audiences

4.5 Implementation of the exploitation path towards uptake

WP 4 deliverables



No	Title	Type & dissem	Due	Contributors
4.1	PreFIT website	DEC / PU	1 May 2020	ISGlobal
4.2	Communication, dissemination and exploitation plan	R / PU	1 Aug 2020	ISGlobal
4.3	Dissemination toolkit	R / PU	1 Aug 2020	ISGlobal
4.4	ORCID accounts for students	R / PU	1 Aug 2020	ISGlobal
4.5	Exploitation agreement	R / CO	1 Feb 2023	FIND
4.6	PreFIT symposium programme and abstracts	R / PU	1 Dec 2023	ISGlobal
4.7	Publications in open access journals	R / PU	1 Feb 2021 + 12-monthly	ISGlobal, all partners
4.8	Participation in the EDCTP Forum	R / PU	1 Nov 2020*+ 24-monthly	ISGlobal, all partners

* May be postponed

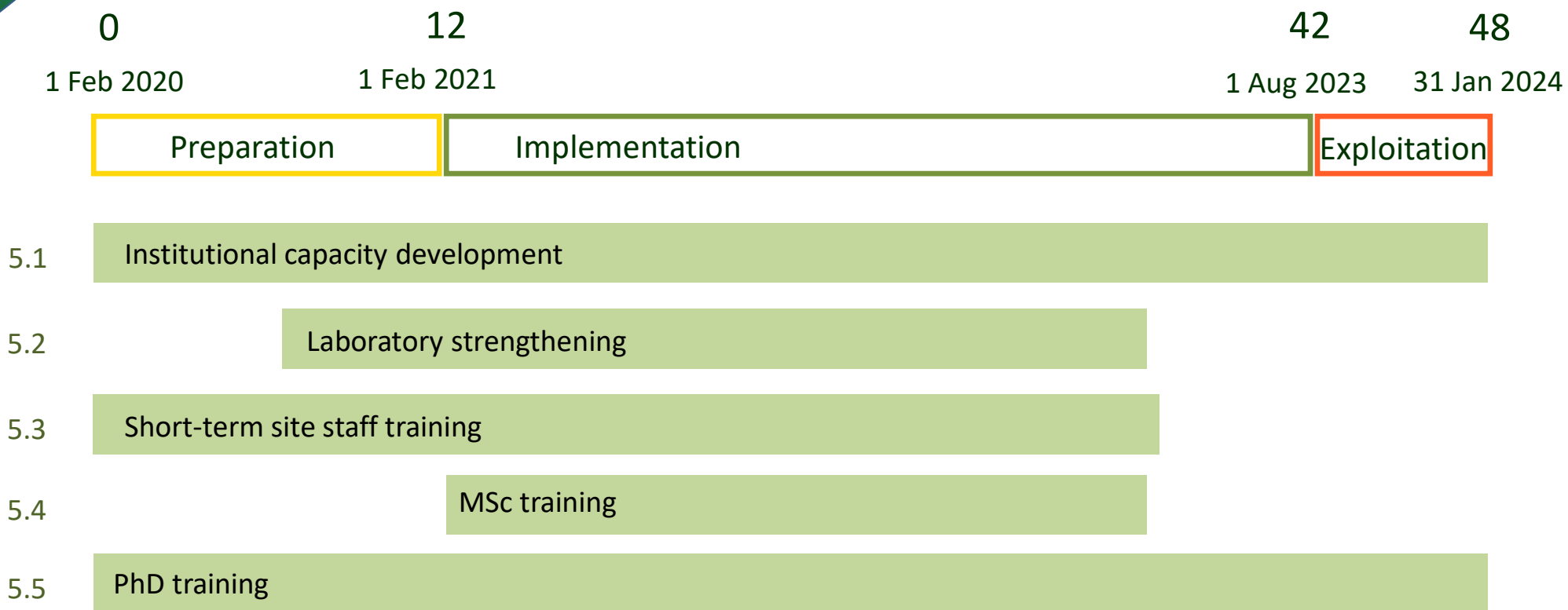
WP 4 milestones



No	Title	Due	Contributors
4.1	Community advisory boards established	1 May 2020	ISGlobal, CISM, MU, SU
4.2	Interim results shared with manufacturer, national stakeholders and WHO	1 Oct 2022	ISGlobal, FIND, CISM, MU, SU
4.3	Agreements reached about pricing arrangements	1 Feb 2023	FIND
4.4	National stakeholders WHO informed about final results	1 Dec 2023	ISGlobal, CISM, MU, SU

* May be postponed

WP 5 activities



WP 5 deliverables



No	Title	Type & dissem	Due	Contributors
5.1	Annual short-term Training workshops	R / PU	1 May 2020 + 12-monthly	CISM
5.2	Institutional capacity building and training plans	R / PU	1 Aug 2020	CISM , MU, SU
5.3	2 MSc and 3 PhD candidates recruited	R / PU	1 Aug 2020	CISM , MU, SU, AIGHD, ISGlobal

WP 5 milestones



No	Title	Due	Contributors
5.1	SOPs shared and harmonized	1 Feb 2021	CISM, FIND, MU, SU
5.2	MSc courses completed	1 March 2023	CISM, MU, SU
5.3	Lab exchanges held	31 Jan 2024	CISM, MU, SU
5.4	PhD trainings completed	31 Jan 2024	CISM, MU, SU, AIGHD, ISGlobal

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