SEVEN LABORATORIES, ONE HARMONIZED EUCAST PLATFORM

Building and deploying multicentre MIC capacity to support regulatory development of anti-TB assets in ERA4TB

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FACTS & FIGURES (ERA4TB)

Start date:	01/01/2020
End date:	31/12/2026
IMI funding:	89 815 600,00 €
EFPIA in kind:	118 148 291,00 €
Total Cost:	207 963 891,00 €
Project website:	https://era4tb.org/
Social media:	LinkedIn: @ERA4TB

CHALLENGE

GENERAL CHALLENGE ADDRESSED BY ERA4TB.

Developing new TB regimens requires coordinated evidence across preclinical and clinical stages. ERA4TB brings public and private partners together to accelerate this translation.

CONCRETE CHALLENGE ADDRESED BY MY RESEARCH

Drug development need

Drug development requires the generation of robust evidence aligned with regulatory requirements throughout the development pathway.

EMA requirement

For anti-TB assets, the European Medicines Agency (EMA) requires drug susceptibility testing using the EUCAST reference method across large panels of clinical isolates to support regulatory dossiers.

European capability gap

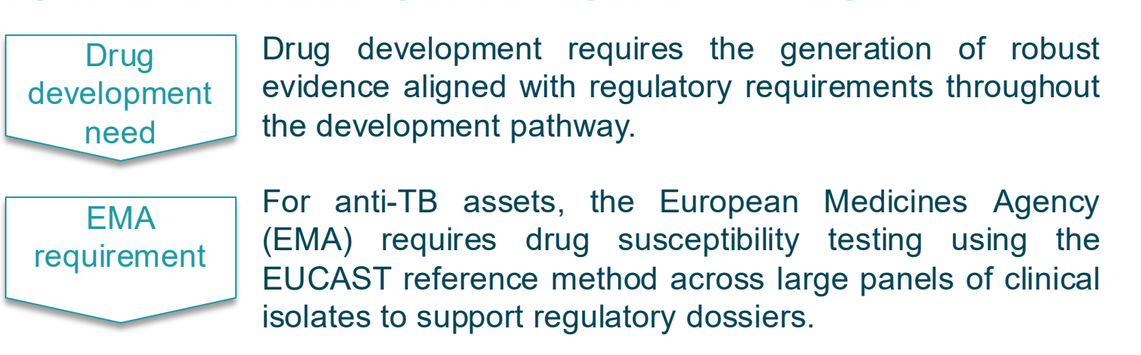
However, no harmonized, validated multicentre European network existed to perform anti-TB MIC testing using this reference method.

My challenge

The challenge was to establish and validate this capability across seven ERA4TB laboratories to generate precise, reproducible and regulatory-grade MIC data.

APPROACH & METHODOLOGY

The **EUCAST reference method was implemented** in parallel across seven laboratories in four European countries



EUROPEAN MULTICENTRE NETWORK

1. PLAN
- Governance
- Objectives
- Timelines
- Resources from academic partners
- Resources from EFPIA partners

PLATFORM DEVELOPMENT

2. HARMONIZE
- Data collection
- Materials & reagents
- Equipment
- Strains
- Batches
- Training

3. VALIDATE

Study	Purpose
• Inoculum validation	Across-site performance
• SOP comparison*	Assess impact on MIC interpretation
• Inoculum-size study	Determine drug-dependent MIC effects

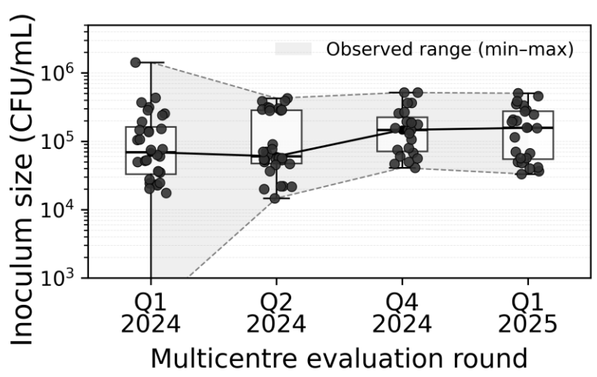
4. DEPLOY
- EUCAST v8.2-aligned ERA4TB workflow
- 1 EFPIA asset vs 120 clinical isolates*
- Target MIC & ECOFF

**Standard Operational Procedures (SOP).*
Implementation while EUCAST SOPs were evolving: SOP v6.1 → v7.0 → v8.2

RESULTS

1 SEVEN LABORATORIES SUCCESSFULLY HARMONIZED FOR EUCAST REFERENCE-METHOD TESTING

Repeated training and validation improved consistency in inoculum preparation across all seven ERA4TB laboratories



Early EUCAST engagement

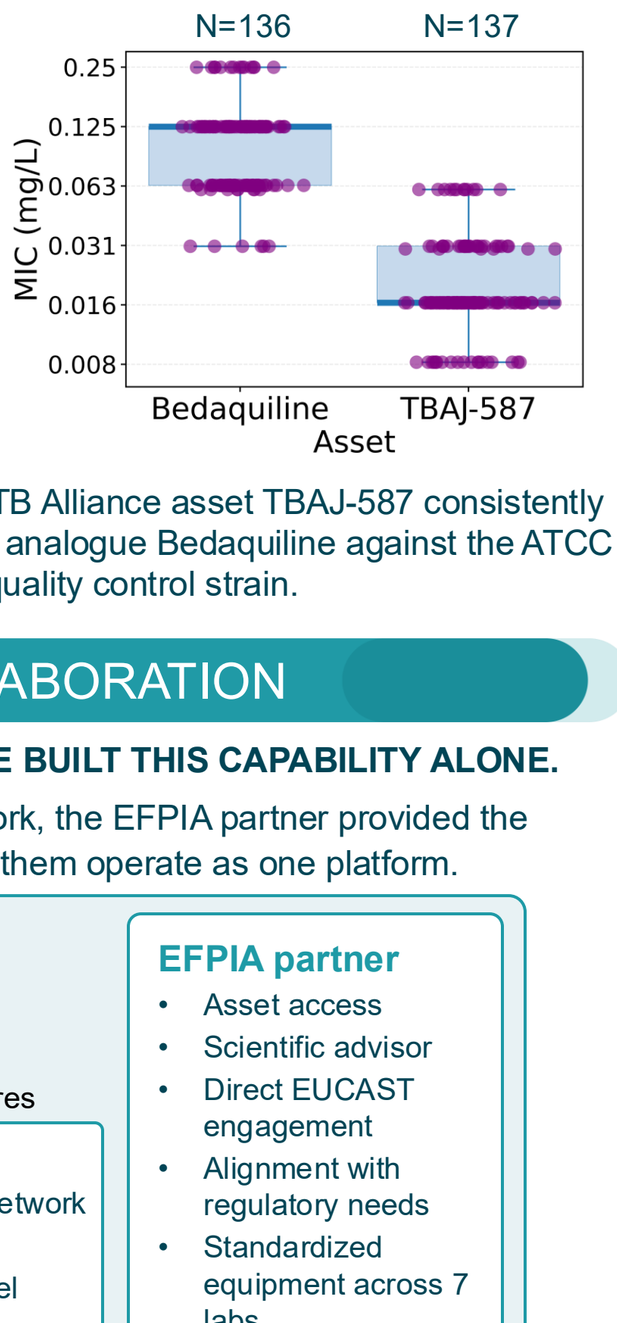
Q1 – Q2 2024 multicentre evidence supported participation in the EUCAST public consultation and expert discussion

100% of inoculum concentrations were within the EUCAST tolerance range from Q2 2024 onwards

2 HARMONIZED MIC CAPACITY NOW SUPPORTS ASSET PROGREESSION: The validated workflow is being applied to an EFPIA asset for regulatory-oriented MIC characterization.

Translational deployment

Quality control (QC) target/range MIC
+
Epidemiological cut-off (ECOFF) on >100 clinical isolates
**Ongoing study*



Across seven laboratories, TB Alliance asset TBAJ-587 consistently showed a lower MIC than its analogue Bedaquiline against the ATCC 27294 quality control strain.

VALUE OF IMI COLLABORATION

NEITHER SECTOR COULD'VE BUILT THIS CAPABILITY ALONE.

Academia provided the network, the EFPIA partner provided the bridge & ERA4TB made them operate as one platform.

ERA4TB
- Governance
- Workplans
- Defined responsibilities
- Data management procedures

ACADEMIA
- Pan-European laboratory network
- Infrastructure
- Highly specialized personnel
- Critical scientific expertise

EFPIA partner
- Asset access
- Scientific advisor
- Direct EUCAST engagement
- Alignment with regulatory needs
- Standardized equipment across 7 labs

OUTCOME
One harmonized multicentre platform for regulatory-oriented MIC testing

CAREER IMPACT

WHAT I LEARNED
How PPP governance links standardized preclinical evidence to asset progression.

SKILLS I DEVELOPED
Multicentre leadership, harmonization, project planning & cross-sector communication.

HOW IT SHAPED MY CAREER
From experimental scientist → implementing methods → to translational capability builder.

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