# Business, Market Dynamics, and Commercialization Hub (BACH)

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MATRIX IM meeting, Johannesburg

on behalf of co-leads (Remilekun Peregrino, Aurum Institute; Mutsumi Metzler, PATH; Bethany Young Holt, PHI)

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Advancing R&D of Innovative HIV Prevention Products for Women

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# BACH's goal

The **B**usiness, M**a**rket Dynamics, and **C**ommercialization **H**ub (BACH) is co-led by PATH, Aurum Institute, IAVI, and PHI.

BACH's goal is to support MATRIX product developers in identifying and fostering collaboration with potential public- and private-sector resources and generating evidence to ensure sustainability and long-term impact from U.S. Agency for International Development (USAID)/U.S. Government (USG) microbicide R&D investments.

BACH efforts focus on support in the following areas:

- Financing and manufacturing linkages
- Development of business cases and market analytics
- Commercialization strategy and planning
- Partnership structure and access terms
- Understanding cost/cost considerations

# BACH activities

**Activity 1: Collaborative needs assessment**

**Activity 2: Stakeholder inventory and landscape assessment**

a. **Investor advocacy**: Optimize novel and innovative funding and investment approaches to ensure successful development of MATRIX HIV prevention and MPT products.

b. **Assessing demand of payers**

**Activity 3: Manufacturing capacity, market demand, and conduct cost and health economic analyses**

a. **Manufacturing capability assessment**

b. **Development of a commercialization roadmap** (formally Product lifecycle management document)*

c. **Demand assessment**

d. **COGs estimate and supply chain cost analysis**

e. **Costing of delivery and cost effectiveness analysis**

**Activity 4: Technical assistance**

Collaboration between Activities 2 and 3

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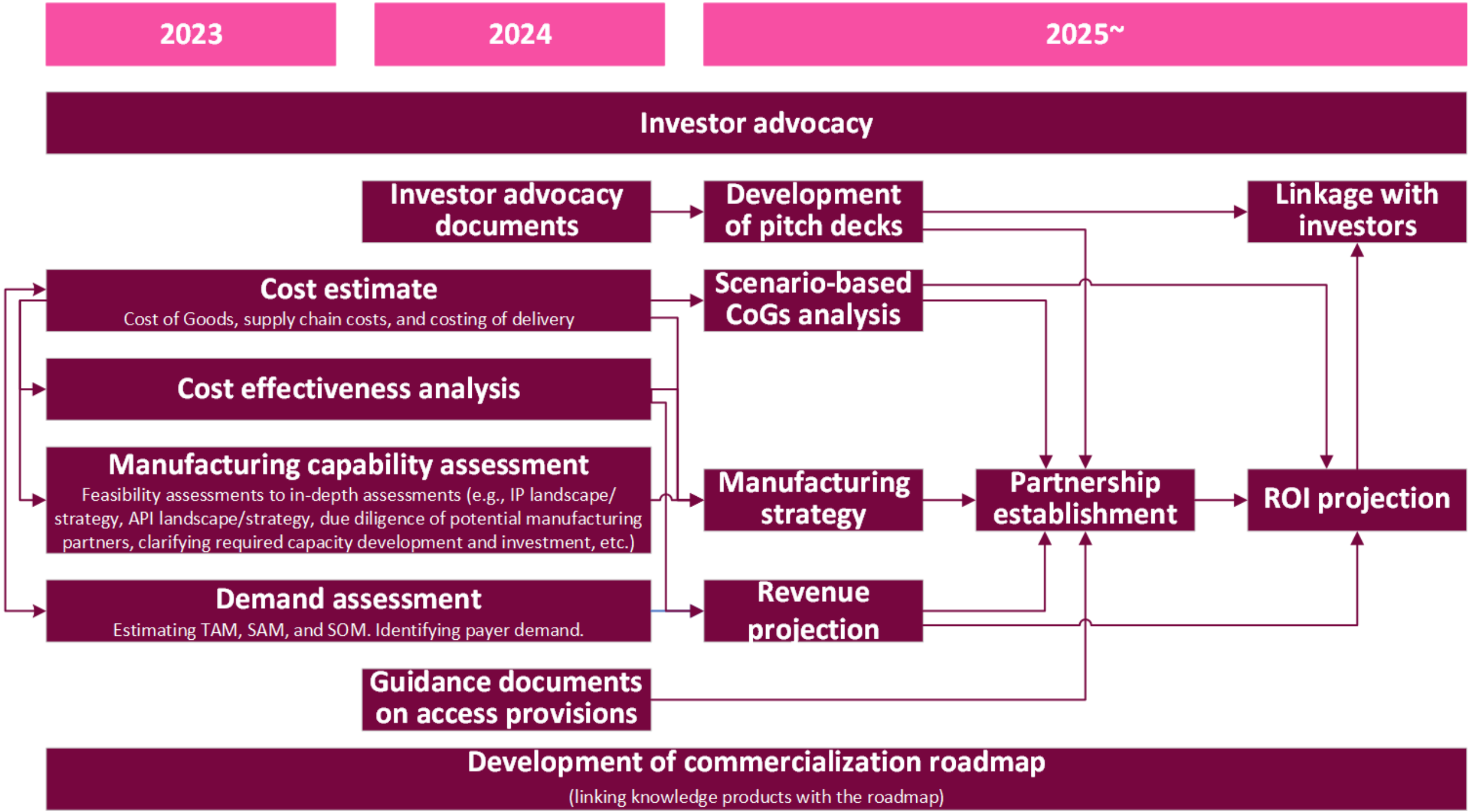
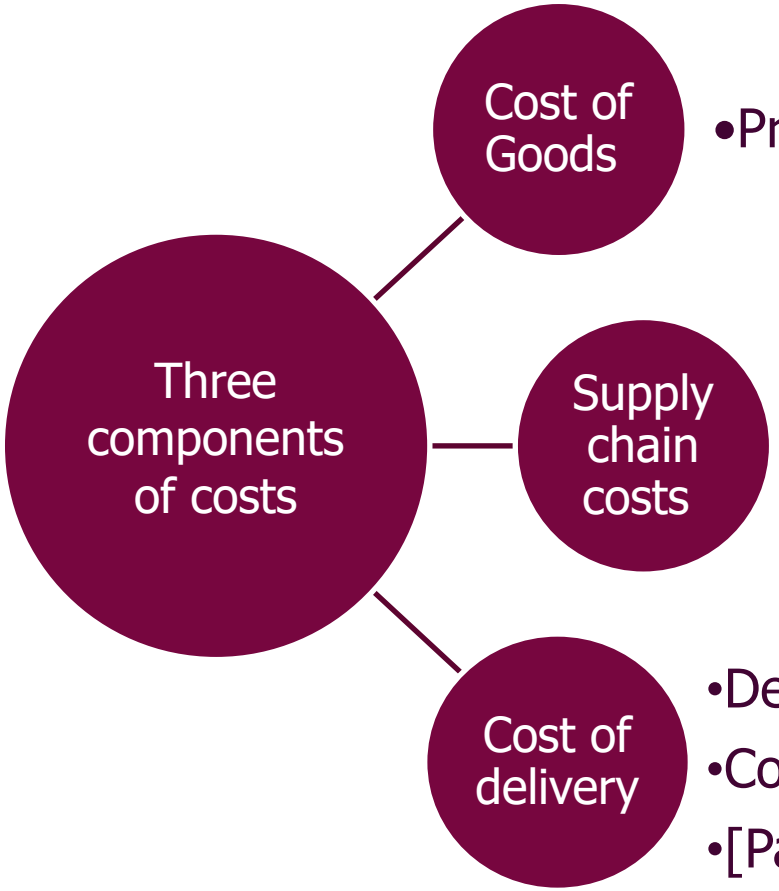

2023
2024
2025~
Investor advocacy
Investor advocacy documents
Development of pitch decks
Linkage with investors
Cost estimate
Cost of Goods, supply chain costs, and costing of delivery
Scenario-based CoGs analysis
Cost effectiveness analysis
Manufacturing capability assessment
Feasibility assessments to in-depth assessments (e.g., IP landscape/ strategy, API landscape/strategy, due diligence of potential manufacturing partners, clarifying required capacity development and investment, etc.)
Manufacturing strategy
Partnership establishment
ROI projection
Demand assessment
Estimating TAM, SAM, and SOM. Identifying payer demand.
Revenue projection
Guidance documents on access provisions
Development of commercialization roadmap
(linking knowledge products with the roadmap)

# Estimating costs

**Estimating costs is an iterative process. Continual updates will be needed as the level of uncertainties is reduced, with products moving along development pipelines.**




- Production costs
- Logistics costs associated with distribution products from a port of export to entry port at target countries
- Delivery strategies from entry port to user
- Costs to the health system in key markets
- [Patient-incurred costs]

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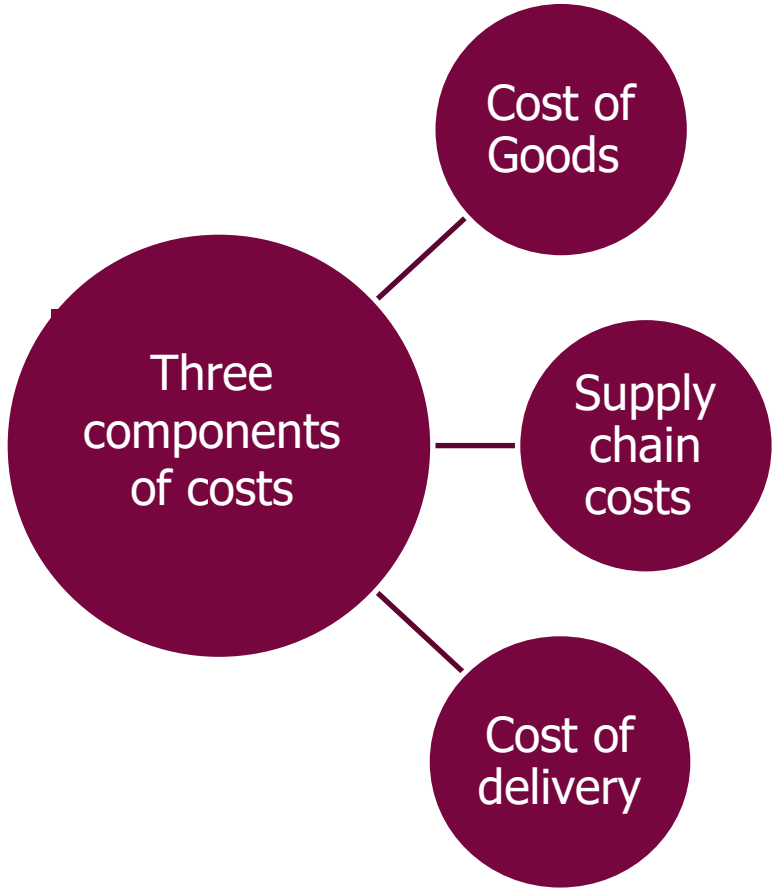


Using the CoGs framework developed in CY2022 to estimate current CoGs. The estimated CoGs will be used to identify cost drivers and inform manufacturing strategies. The framework will also be modified with inputs from PDs.

Assumptions and scenario-based approaches are used, with inputs from PDs and logistic experts, in the analysis of supply chain costs. These outputs, together with CoGs, will inform manufacturing strategies.

Normative costing of probable delivery strategies – detail to follow

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# Cost and cost effectiveness modelling

- 4 objectives
- 4 components
- Mixed-methods
- 2 countries (Kenya and South Africa)

| | Obj 1 | Obj 2 | Obj 3 | Obj 4 |
|---|---|---|---|---|
| Summary | Defining plausible implementation strategies and delivery models | Collecting cost inputs and resource use data | Estimating delivery costs | Exploring value for money drivers and willingness to pay thresholds |
| Methods | Interviews | Focus groups, observation of practice and financial records review | Cost modelling | Cost effectiveness modelling |
| Participants | Product developers, practitioners and key HIV/SRH policy experts | Primary healthcare staff during consultation and local programme experts | n/a (desk research) | n/a (desk research) |

# Estimating delivery costs

- Set up costing model using existing template for delivery of health interventions
  - Semi automated, breakdown by input and activity
  - Data will be highly disaggregated (facilitate transparency)
- Costs presented in USD 2023
- Output: Unit cost per person year of delivery for each technology

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# Cost effectiveness modelling

- To combine cost model estimates with a static model of product impact across multiple indications
- To explore combinations of efficacy and price that could be considered cost effective under different willingness-to-pay thresholds in two countries

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# Considerations

- Early in R&D and need for a portfolio-wide view
  - Explore multiple indications (in women at different risks), prevention of HIV with or without contraception
  - Explore drivers of cost effectiveness (likelihood of recommendation) across efficacy and price assumptions, under uncertainty in future country practices and delivery strategies
  - Avoid biases between products: different indications, different delivery strategies
  - Avoid biases in comparators across settings: time to scale up of PrEP products available (oral, ring, CAB-LA)
- MATRIX is not set up to do the full economic evaluation before country introduction when transmission models may be required, and decision making is country-led

# Model adaptation

- Static model: current incidence → sensitivity analysis on different incidence values taking into consideration impact of current prevention programs; mix of cohorts defined by HIV/pregnancy risk
- Short timeframe: 1 year → 2 years at least
- Multiple indications: HIV and pregnancy → sensitivity analysis for STI prevention
- Roll out scenarios based on product availability after roll out: importance of products available at the time, of introduction (not at which point of scaling up the SOC technology is) → CAB-LA and ring become standard of care

Quaife et al. J Int AIDS Soc. 2018 Mar; 21(3): e25064.

# Key parameters and assumptions

**UPTAKE:** lit reviews and aligning with preference considerations from D2D and other initiatives

**INCIDENCE:** Empirical evidence of current incidence in key countries used across subgroups to calibrate the model (South Africa and Kenya), analysis based on assumptions on roll out of CAB-LA and ring

2 cohorts will be high and low risk (behavioral)

**PROTECTION:** reduction of incidence due to use of product

**HEALTH IMPACT** (DALYs)**:** HIV infections averted, reduction in maternal mortality through prevention of unintended pregnancies

**COSTS:** estimates of fixed and variable costs

**COST-EFFECTIVENESS:** estimates of impact across a variety of efficacy/price scenarios for a range of WTP thresholds

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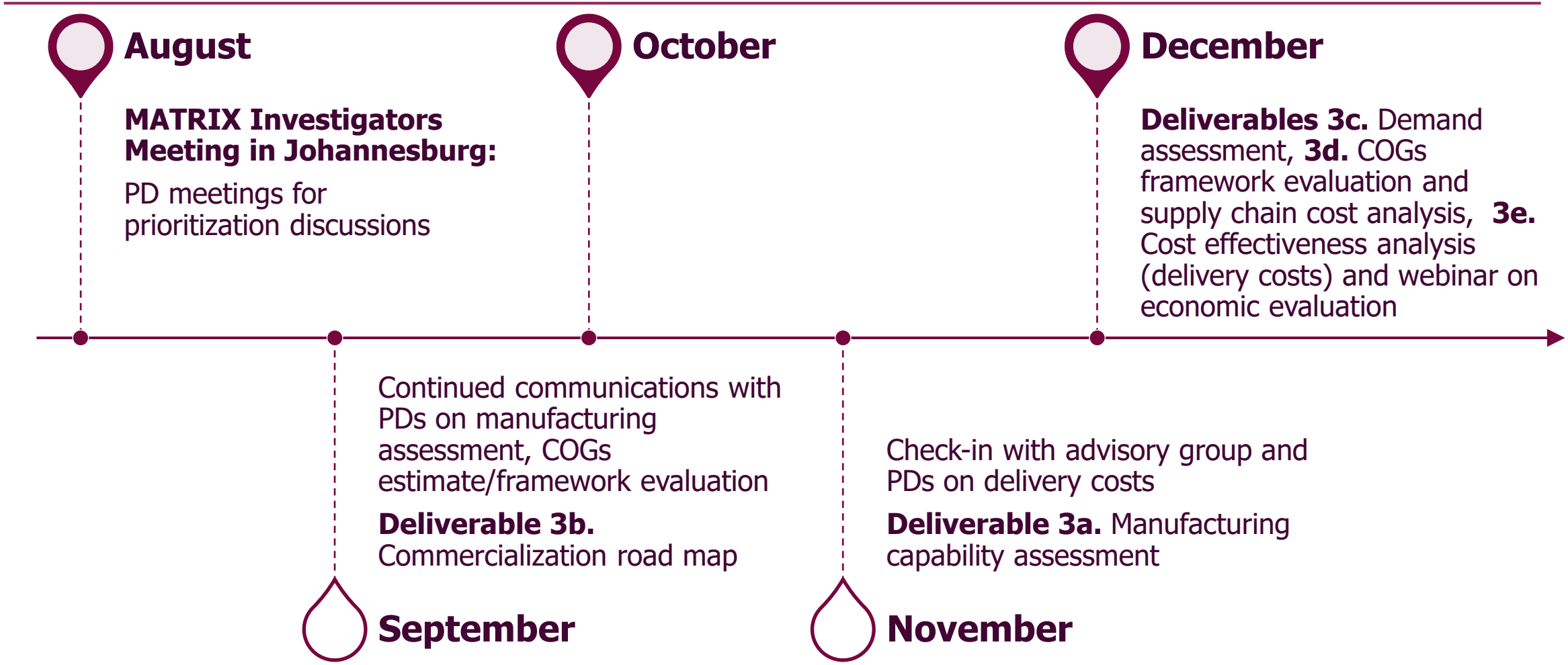
# Upcoming deliverables and engagements



# CY 2024: priorities

| Activity 2 | Activity 3 | Activity 4 |
|---|---|---|
| Facilitate linkages between PDs and potential funders/partners:<br>• Facilitate introductions and support due diligence between potential funders/investors and PDs<br>• Ongoing opportunities to engage with potential partners and supporting agencies (e.g., family foundations, angel & impact investors, commercial partners etc.) including SSA-based women's health investor meetings<br>• Develop advocacy "one-pager" to communicate funding and partnership opportunities for product development | Continue manufacturing capability assessments | CaSE mentorship |
| | Support IP landscape/ licensing strategy development[1] | Webinars to be determined based on priority needs/ interest from PDs<br>• Innovative business and partnership models<br>• Understanding expectations & requirements of procurers & funders<br>• Building access-friendly agreement terms<br>• Funders/financing panel<br>• Licensing considerations for MPTs<br>• Product development lifecycle |
| | API landscape/support API strategy | |
| | Guidance document on access provisions[2] | |
| | Update COGs estimate | |
| | Transfer the supply chain analysis to a user-interactive framework | |
| | Estimate serviceable available market (SAM)[3] | |
| Tailored guidance on developing pitch decks | CE analysis[4]: patient-incurred cost estimates, data collection Zimbabwe and read out of CE results for Kenya, South Africa and Zimbabwe; last advisory group meeting. | |

[1]e.g., licensing in/out, tech transfer, upfront licensing fees/royalty schemes, etc. [2] i.e., review of access provisions across PDPs and recommendations on equitable access language with examples of potential approaches. [3]after addressing Total Addressable Market (TAM) in 2023. [4]to explore combinations of efficacy and price that could be considered cost effective under different willingness-to-pay thresholds in key countries for a variety of uptake/adherence scenarios.

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# THANK YOU


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# Acknowledgements

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