

# Aligning diagnostics to the POC: takeaways for innovators, decision-makers and evaluators from qualitative research

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# The challenges of innovating diagnostic technologies that work in different contexts

Analysis

BMJ Global Health

## Addressing the challenges of diagnostics demand and supply: insights from an online global health discussion platform

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STATE OF THE ART

STATE OF THE ART SERIES  
New Tools, Series editor: Wing-Wai Yew  
NUMBER 4 IN THE SERIES

## New tuberculosis technologies: challenges for retooling and scale-up

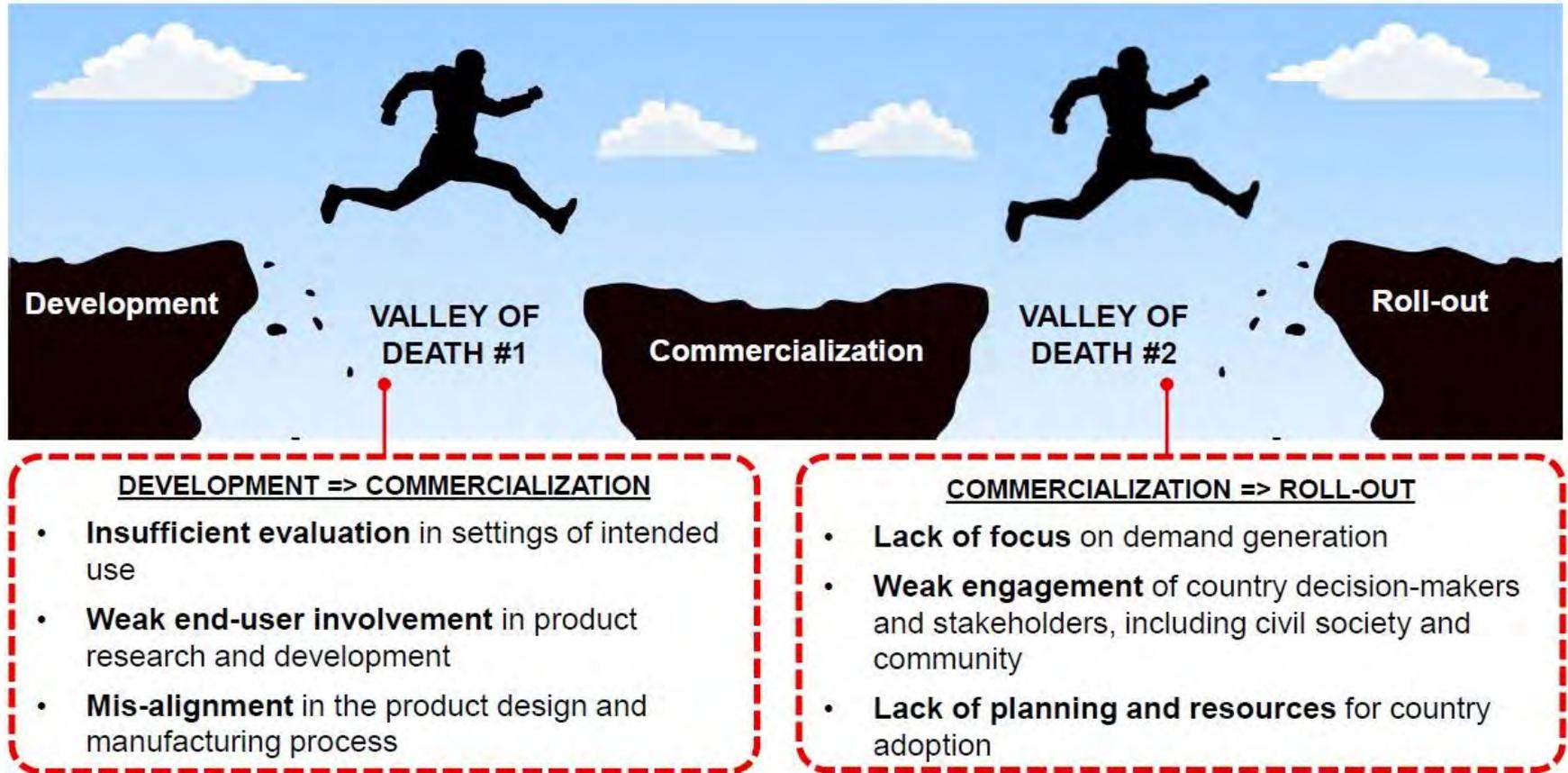
M. Pai,<sup>\*\*</sup> K. M. Palamountain<sup>†</sup>

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## Opportunities and Challenges for Cost-Efficient Implementation of New Point-of-Care Diagnostics for HIV and Tuberculosis

Marco Schito,<sup>1</sup> Trevor F. Peter,<sup>2</sup> Sean Cavanaugh,<sup>3</sup> Amy S. Piatek,<sup>4</sup> Gloria J. Young,<sup>5</sup> Heather Alexander,<sup>5</sup> William Coggin,<sup>7</sup> Gonzalo J. Domingo,<sup>8</sup> Dennis Ellenberger,<sup>6</sup> Eugen Ermantraut,<sup>9</sup> Ilesh V. Jani,<sup>10</sup> Achilles Katamba,<sup>11</sup> Kara M. Palamountain,<sup>12</sup> Shaffiq Essajee,<sup>13</sup> and David W. Dowdy<sup>14</sup>

# Crossing the valleys of death



L. Ditiu & C. Boehme, 2017, [http://gbchealth.org/crossing-the-valleys-of-death-in-tb-from-development-to-roll-out/#\\_ftnref2](http://gbchealth.org/crossing-the-valleys-of-death-in-tb-from-development-to-roll-out/#_ftnref2)

# Avoiding medical device graveyards



*Photo by Mike Niesen*

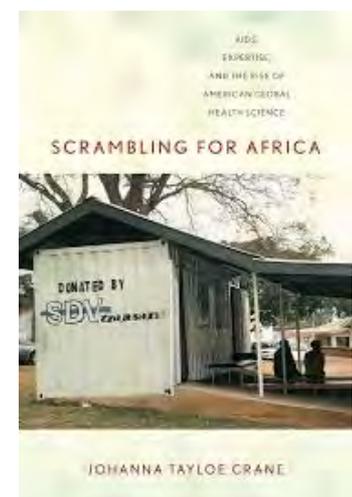
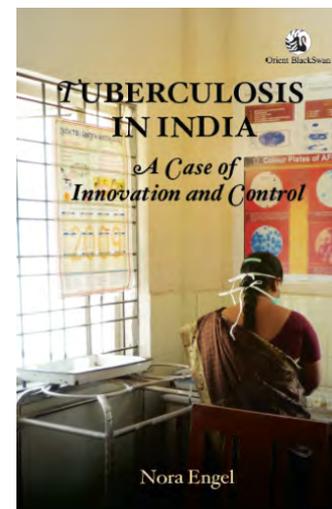
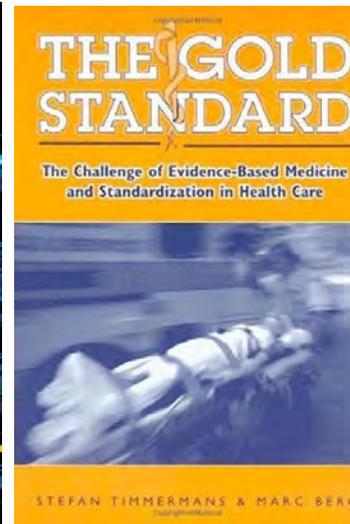
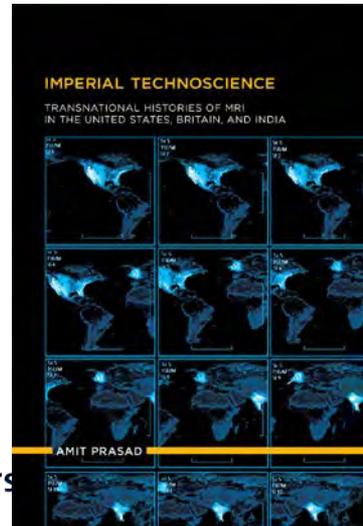
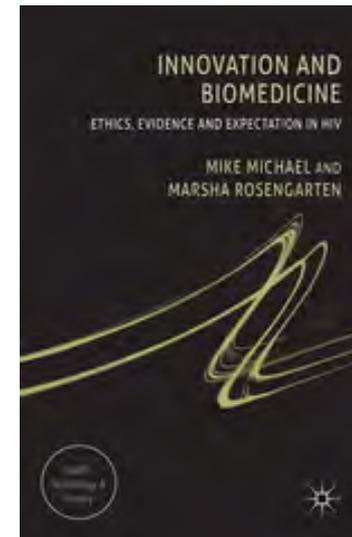


*Stephen Rudy/Courtesy of Gradian Health*

# Science & Technology Studies (STS): Medical technologies don't evolve in a vacuum

Business interest; scientific trends; regulatory environment; social, institutional and political processes shape how technologies look and are used

While things, technologies & materials shape human action as well



# STS study of diagnostic innovation

*How do those engaged with developing and implementing new POC diagnostics for TB & HIV ensure these technologies work at POC?*

## Qualitative study & data:

- **Global fieldwork: 52 semi-structured interviews** in Europe, North America and via Skype or telephone with manufacturers, donors, industry consultants, international organizations, policymakers, regulators and researchers based in Asia, Africa, Europe and North America are being combined with **fieldwork at workshops and companies, conferences and document research**.
- **Fieldwork in Bangalore, India: 15 interviews** with diagnostic developers, decision-makers, NGO program officers, scientists, TB and HIV program officers, laboratory managers, technicians and nurses using TB and HIV diagnostics as well as **visits to companies, clinics and labs**
- Funded by Dutch Science Foundation NWO, VENI grant



# Outline talk: Lessons for developers, implementers, decision-makers & evaluators

- Design phases
  1. Design & concept phase
  2. Research & development
  3. Evaluation & launch readiness
  4. Implementation & maintenance
- Key messages

# Main message

- when you are developing and implementing a (POC) Dx for global health, you are **not designing an artefact but a usage.**
- when you do that, all sorts of different actors & elements to consider enter the scene
- you need to align the technology to more settings than 'just' intended use

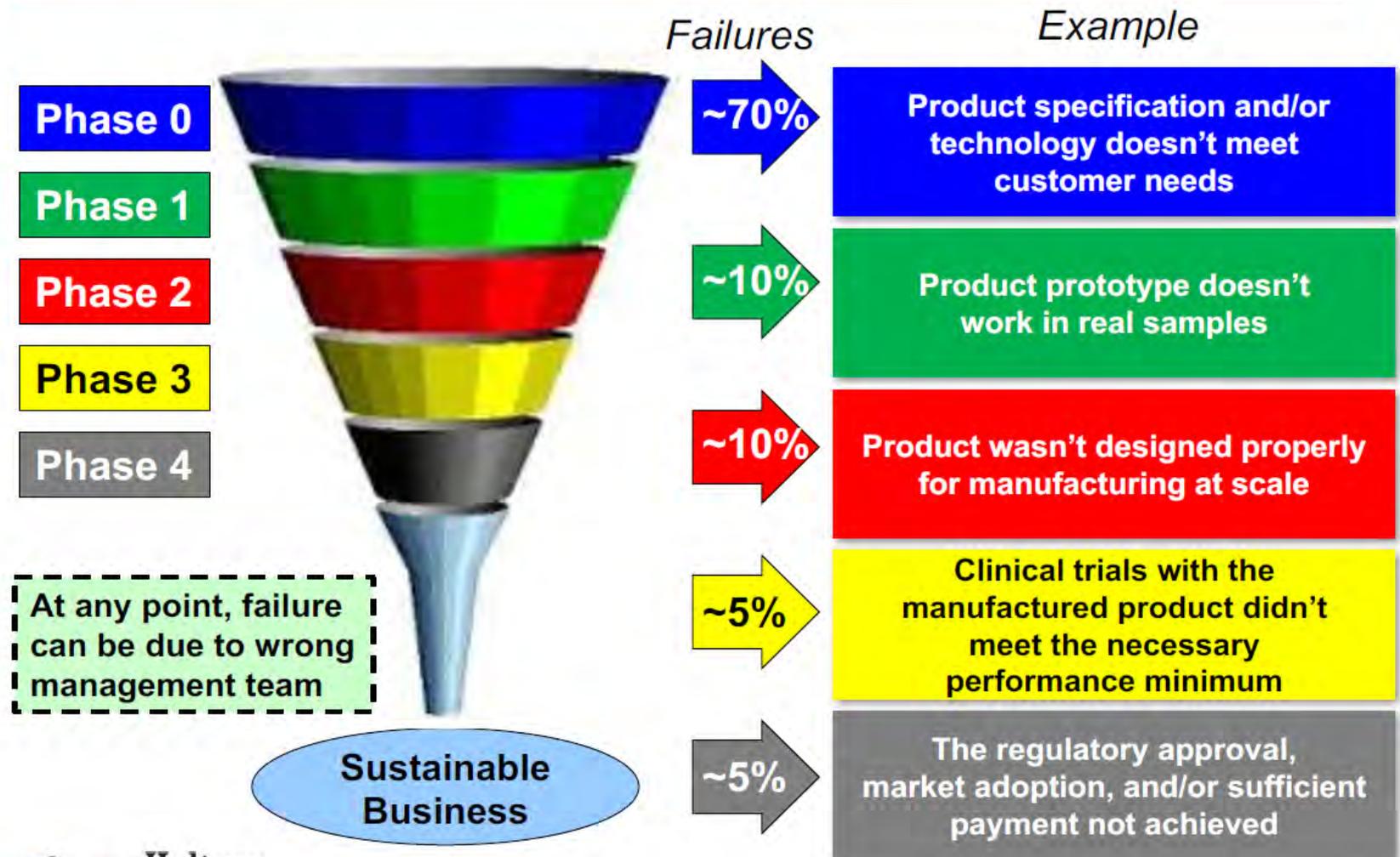
# 1. Design & concept phase:

## **Take away:** Getting to know the POC requires

1. ..substantive, ongoing investment because users vary, shift and are hard to access: spend time, challenge users, invest in relationships

# Why do diagnostic companies fail? (analysis commissioned by BMGF)

## Where the Failure Companies Failed

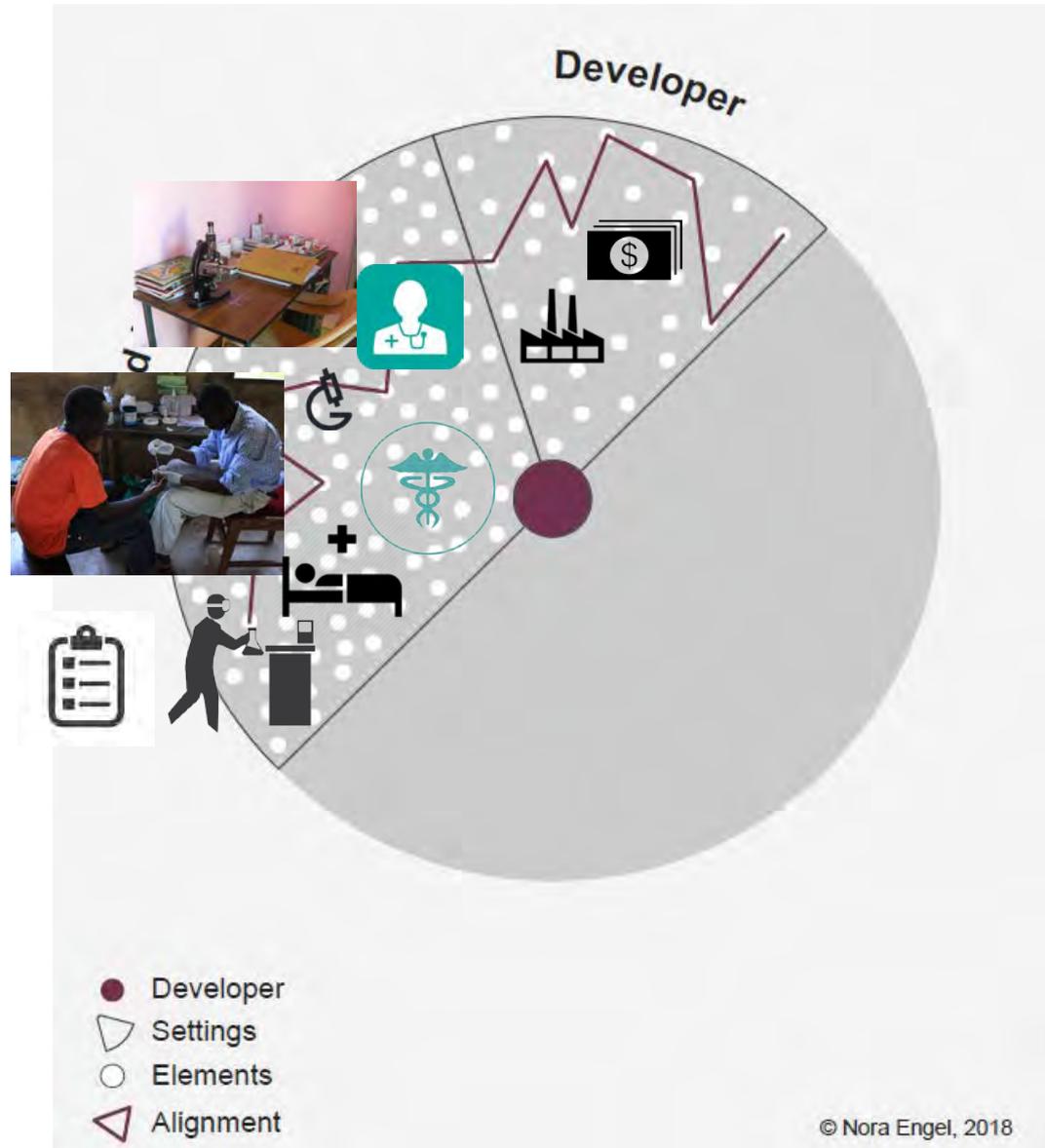


# Users of global health POC Dx are multiple and variable

- **Different users:** Technicians, patients, clinic staff (nurses, clinicians, community health workers), lab managers, ministries of health, NGOs, regulators and funders
- **What different users do:** supply a bodily sample and receive a result, order a test and act on its result, conduct the testing procedure, maintain the machine, evaluate safety and quality, oversee the deployment, utilization and reporting, and purchase devices and supplies [STS idea: user is a relational term]
- **Variable and multiple users:** many different countries, labs, clinics, communities
- How to appeal to donors, governments & NGOs (instead of individual hospitals)? Some overwhelmed and understaffed?

# Aligning the elements in intended use & developer setting

Alignment = attuning to..  
Bringing in line with..making a  
technology fit a particular use  
and user setting



# Users of global health POC Dx shift and are hard to access

- **Shifting users:** staff turnover & shifts, not one dedicated user
- “...you are not dealing with a dedicated lab personnel but nurses, doctors, etc. (..) They are dealing with patients not only with tests.” (Test developer 11)
- Data on users is difficult to access or generate
- Influencers affecting user data: institutional structures, procurement mechanisms, epidemiological context, clinician behavior, workflow changes, and changing global health arena and guidance
- → ‘Understand clinical use, not just operational design, engage clinicians, nurses etc; Understand markets, business case, market entry and the flexibilities you have in addressing them’ (programme officer CHAI 1)
- **Difficult to access** POC Dx users and use settings,

→ Often requires **intermediaries**

# Global intermediaries in Dx development



BILL & MELINDA  
GATES foundation



Joint United Nations Programme on HIV/AIDS  
**UNAIDS**  
UNICEF • UNDP • UNFPA • UNDCP  
UNESCO • WHO • WORLD BANK



Stop TB Partnership

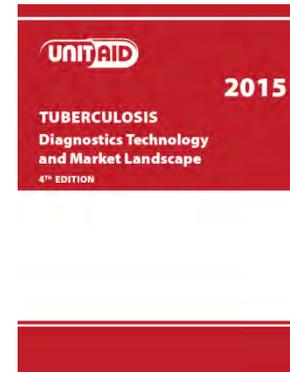
New Diagnostics  
Working Group



# Aligning to global intermediaries

## Example Biotech start-ups

- Willing to take risk – Innovative
- Rely heavily on global intermediaries:
  - getting to know the POC



*“You just need to spend some time in each country, talking with one or two people. And finding those two people and **getting the right person to make an introduction for you**, is the hardest part.” (Industry consultant 2)*

*“One of the biggest issues was actually just **getting sputum**. And so in the US of course there is not a lot of it – so we had to find partners who were going to give us sputum.”(Test developer 3)*

→ Intermediaries minimize risk

# Aligning to global intermediaries

## Intermediaries as gatekeepers

Example TPP: need to fit in for support

Example engineering advice: “.. both WHO and FIND said that really you should try and stick to the current protocol where people are coughing into a plastic cup that’s not been engineered. (...) And it’s a balance, because when we talk to users in clinics, (...) they were saying they really hate dealing with sputum in an open cup.” (Test developer 5)

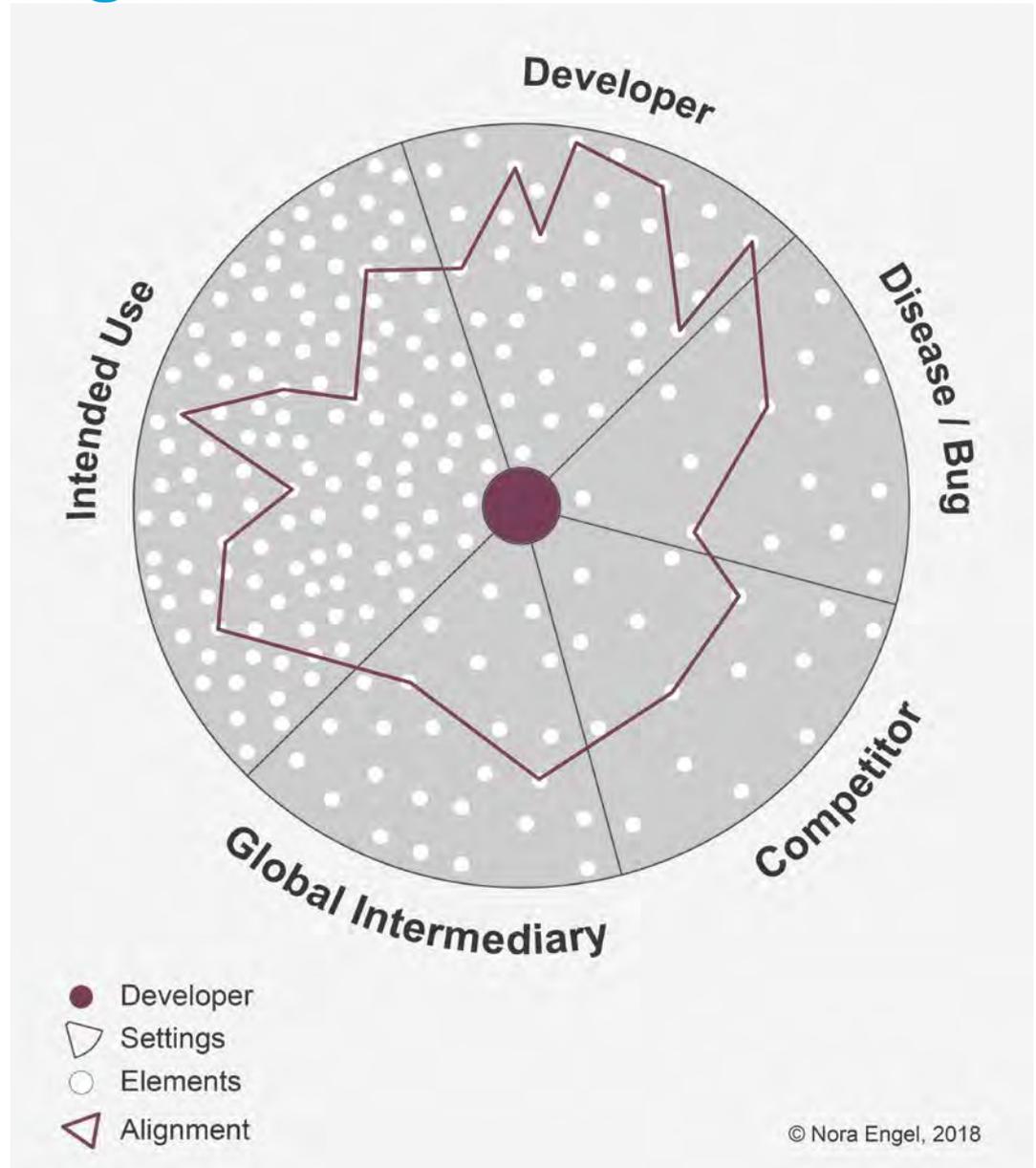
- **Aligning to global agendas and standards** (to access funding, samples, fieldsites, users and KOL for feedback, support for evaluation and regulation pathways and political will)
- **Aligning with one element can conflict aligning with another**
- **Politics of alignment**

# 1. Design & concept phase:

## **Take away:** Getting to know the POC requires

1. ..substantive, ongoing investment because users vary, shift and are hard to access: spend time, challenge users, invest in relationships
2. Developers need to know and align to more settings than the intended use but also global intermediaries, diseases/bugs, competitors

# There are more settings that matter than intended use!





# Developers aim to know and align elements to more settings than the intended use, but across the 5 settings of:

- **Developer:** and their techniques, different types of companies vary in support requirements/user involvement, starting points and ambitions
- **Intended use:** with its varied & shifting users, infrastructure, skills, capacities, routines, throughput, patient profiles, preferences and markets
- **Global intermediaries:** donors, groups such as FIND, CHAI, MSF, Stop TB Partnership, industry consultants, etcg.; lobal policies (WHO), markets, standards & regulations, and scientific data requirements
- **Disease/bug:** with its own dynamics of patient profile, funding availability, technical challenges, sample and regulatory requirements
- **Competitor:** companies with emerging/new tests, gold standards, including their ability to generate scientific data, funding, support and political will



# Aligning to competitors

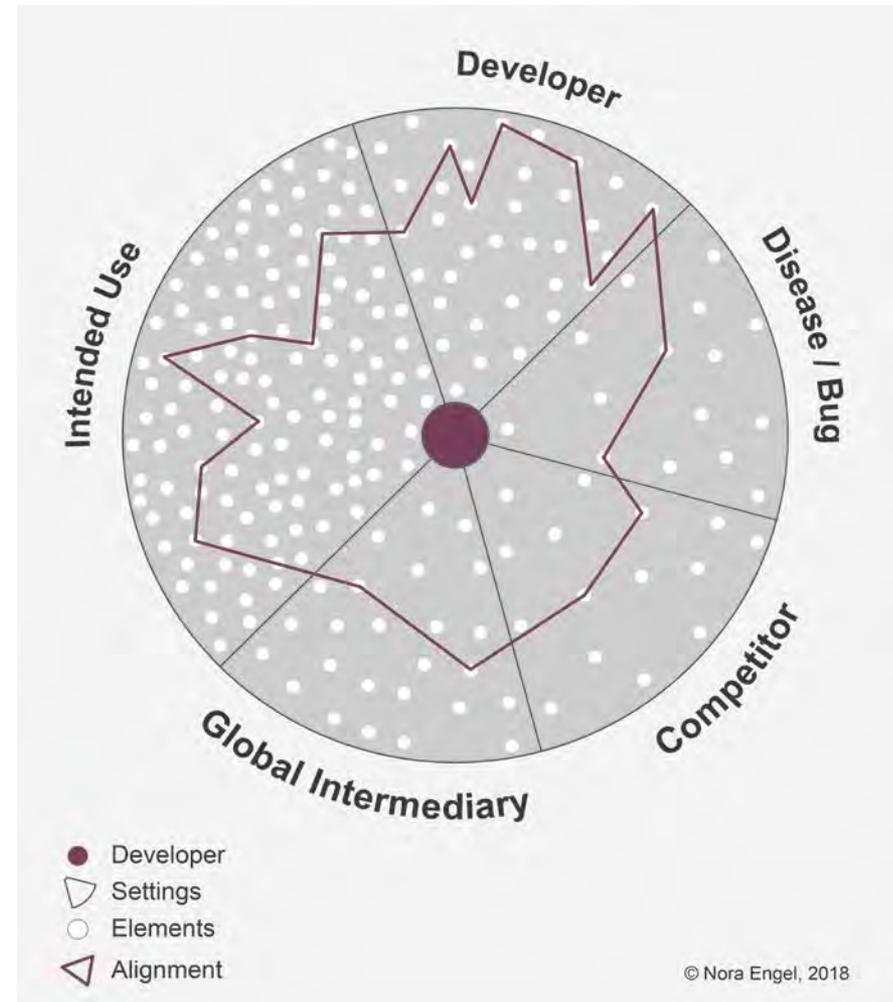
Other innovators/competitors set expectations, standards and define market:

- Gene Xpert used as reference standard in evaluation studies → can you give away on accuracy to reach lower price point? (#51)
  - Gene Xpert raised expectations as to the amount of data availability
  - 10USD per test (#18)
- what a 'good' test is is also defined by competitors

# Aligning elements across different settings

Alignment = attuning to.. Bringing in line with..making a technology fit a particular use and user setting

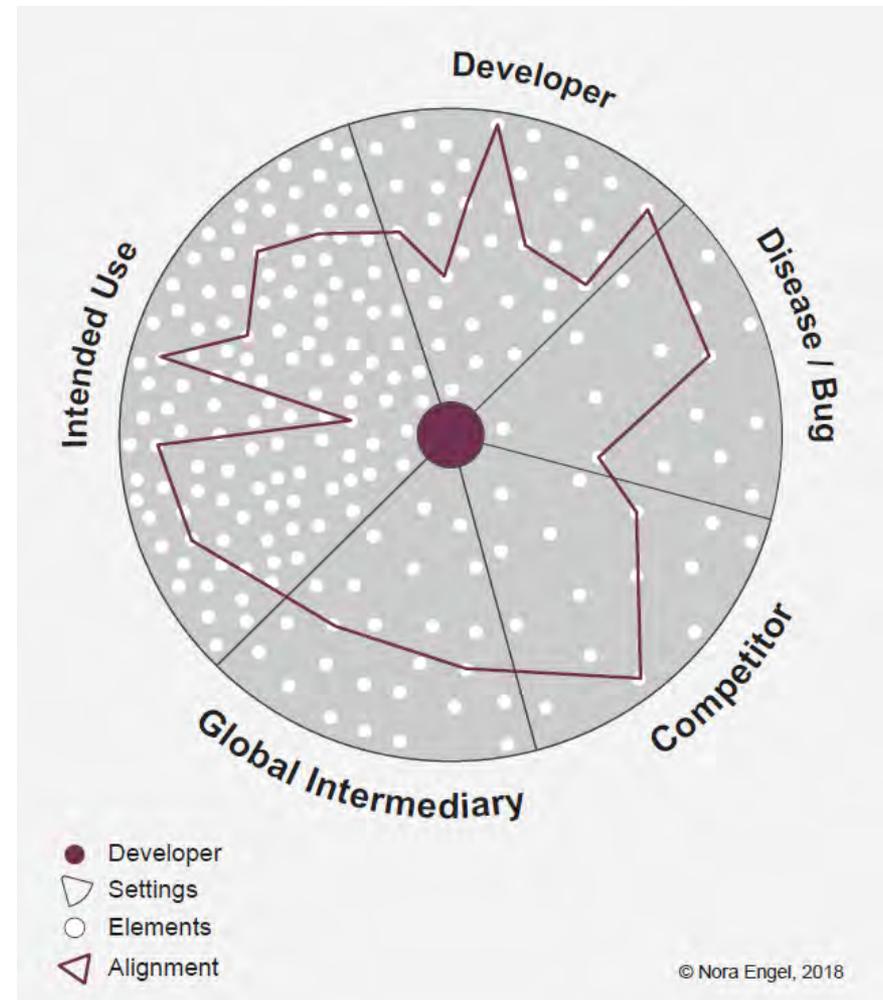
- You have to make a choice what to align
- There are lot of options across different settings
- You might not be aware of all the elements or that you are linking them



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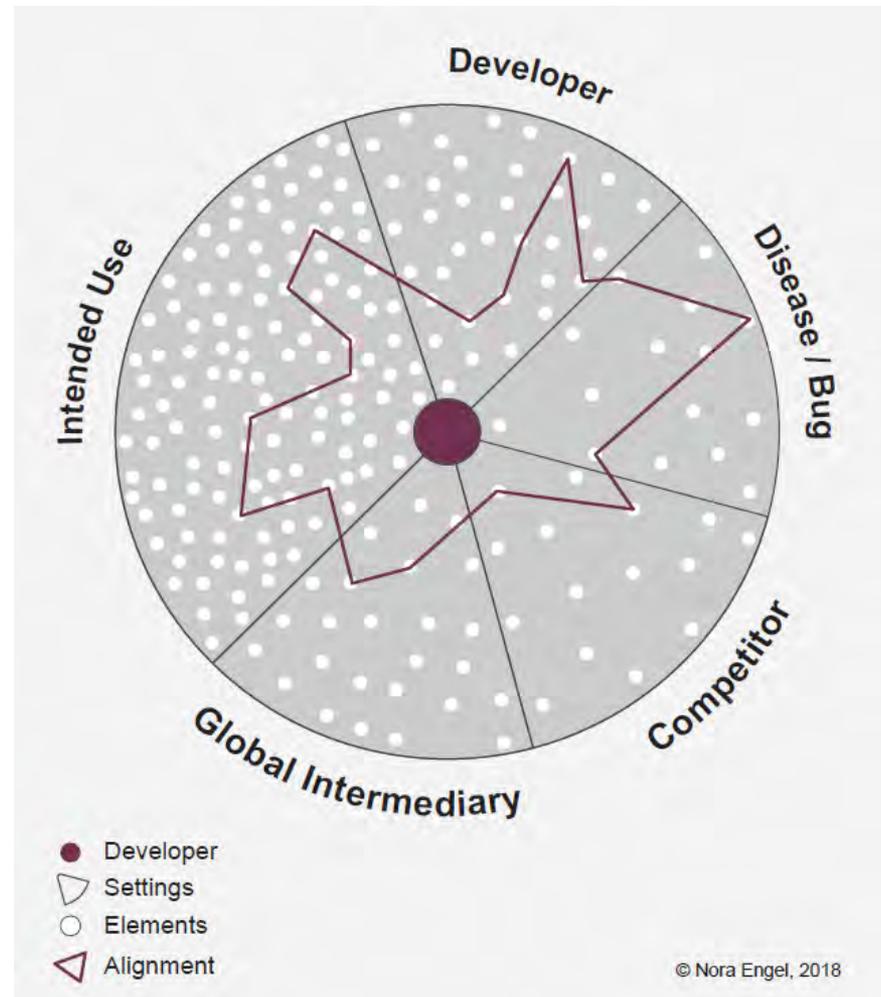
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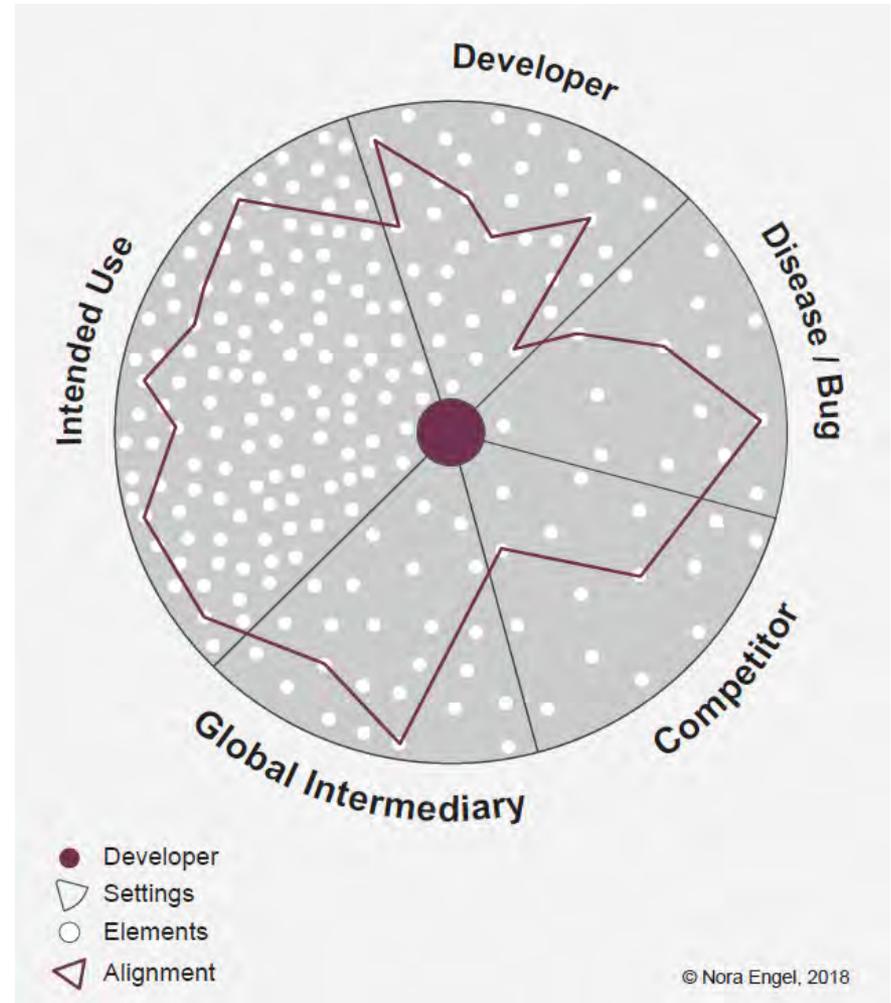
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# 1. Design & concept phase:

## **Take away:** Getting to know the POC requires

1. ..substantive, ongoing investment because users vary, shift and are hard to access: spend time, challenge users, invest in relationships
2. Developers need to know and align to more settings than the intended use but also global intermediaries, diseases/bugs, competitors
3. Needs assessment is a core business:
  - needs to be continuously done in all phases, not something you do only once or twice before you start with R&D
  - There is no linearity
4. A certain amount of uncertainty will remain



# Aligning in the dark? No control over all elements, uncertainty remains

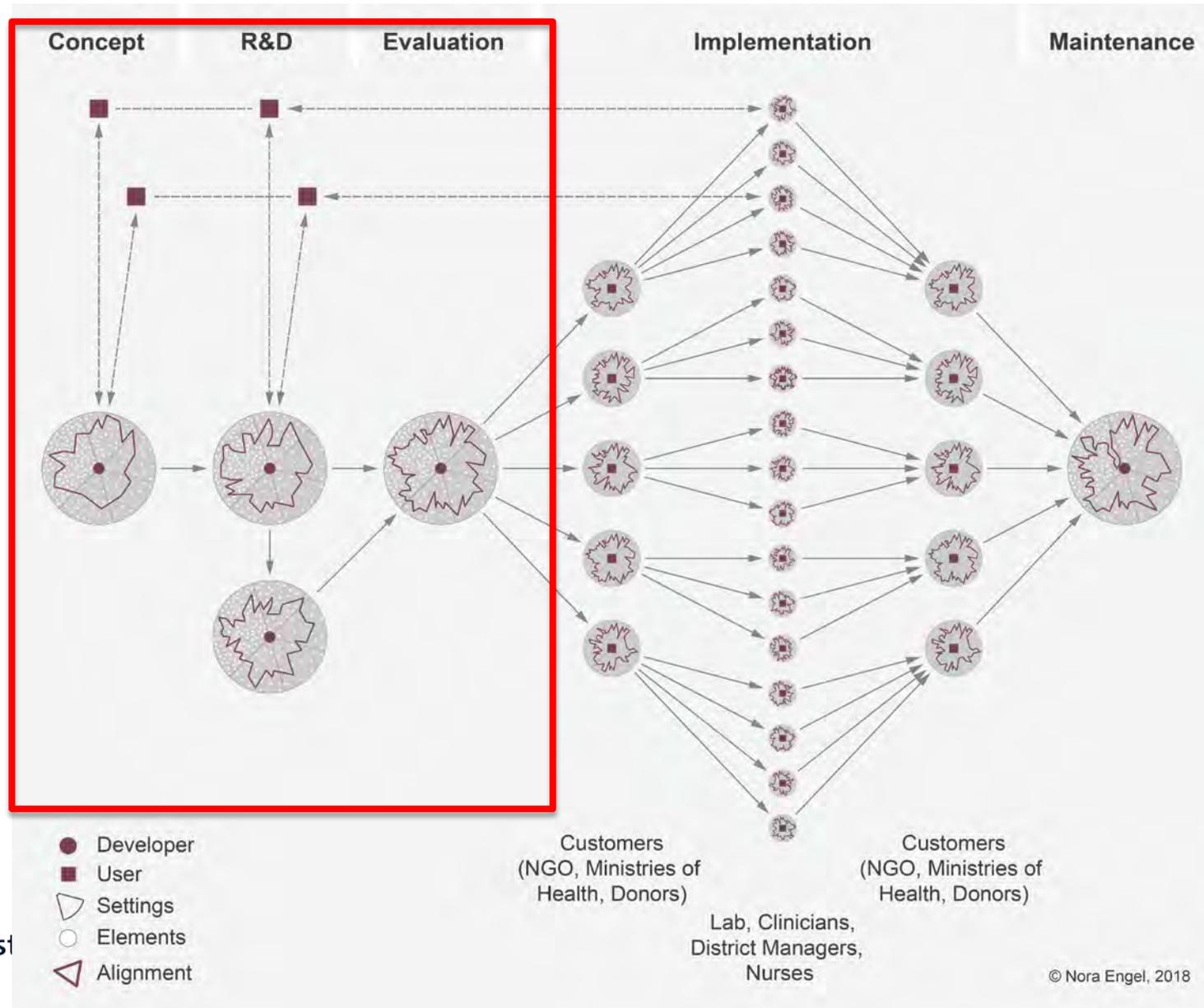
- many of these elements that ensure usage at POC are not under control of test developers.
- *“There has to be good reason for people to use it [the diagnostic technology], and you have to get rid of all these things that are standing in the way between the technology that you have developed and the use of it. And most of these things are completely not under your control. Because they are influenced by all kinds of other things, budgetary constraints, policies.”* (Test developer 9).

## 2. Research & development

### **Take away:**

- Knowing the POC does not stop after design and concept phase; It remains core business
- Flexibility and closer cooperation with evaluators, different users and better understanding of changing settings helps:
  - when deciding on continuous trade-offs and going through design iterations
  - when contextualizing isolated, shifting, variable user wishes and understanding the temporal aspect in these processes

# Alignment work throughout development phases



## 3. Evaluation & launch readiness

### Take away:

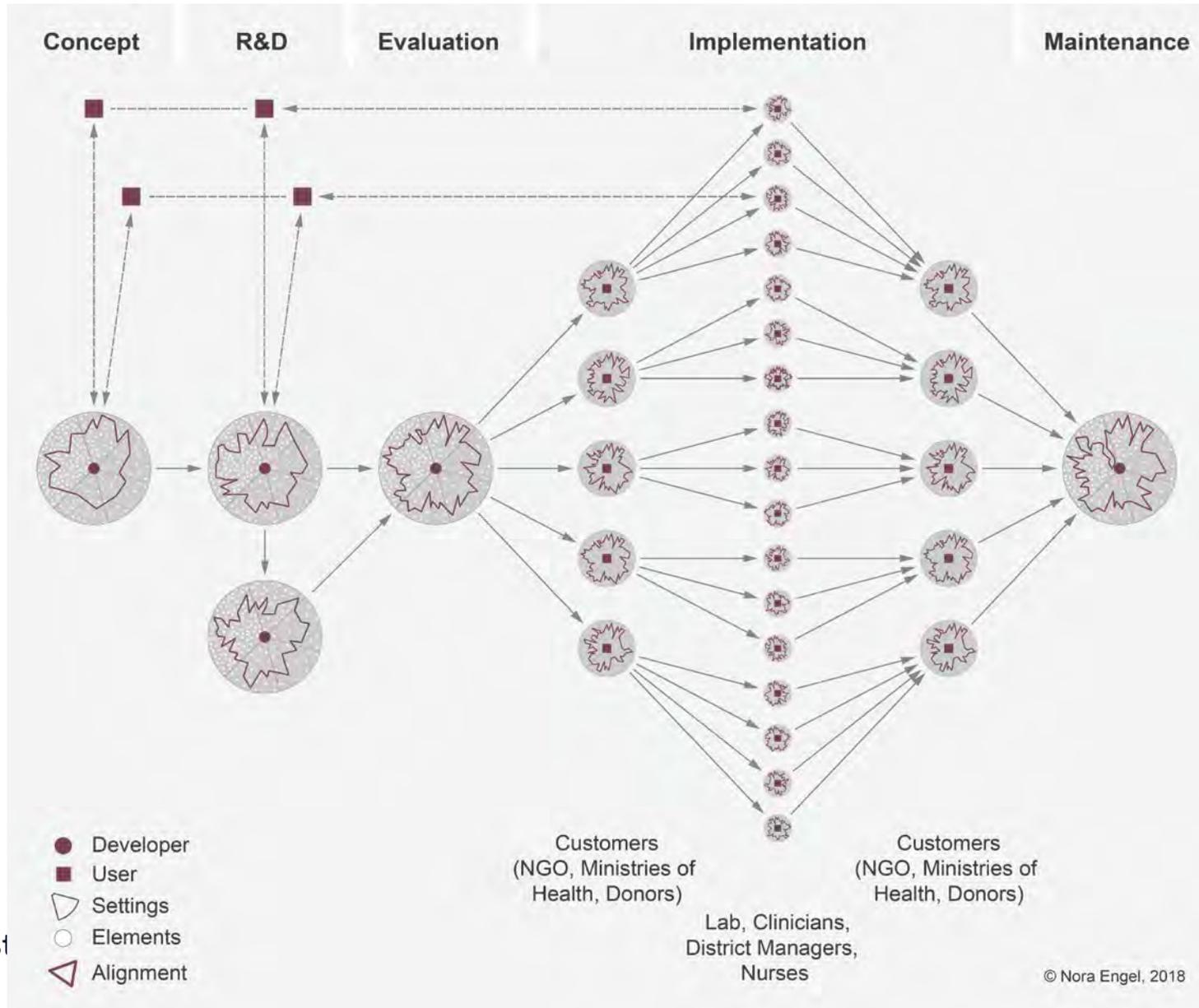
- **Temporality:** the reality of getting things done (regulation, design lock, launch etc) clashes with the alignment & iterations that is ongoing
- Greater flexibility in evaluation practices to respond to changing pathogens (PW); to allow iterations and assess technical and implementation aspects separately (Cobelens et al. 2012)
- **Realistic expectations:** the implicated norms of simple, rapid, cheap, etc are assumed possible (promises) esp by funders; but developers often need to give somewhere → once promises are made it is difficult to go back on them

# 4. Implementation & maintenance

## Take away:

- Continuous (re)alignment by implementers
- Requires HR and resources
- Impact on access & utilization & equity of earlier alignment choices becomes clear
- Knowing the POC never stops, investing in ways to get feedback from users, managing multiplicity

# Alignment work throughout development phases



# Implementers continue to align diagnostics and setting:

## Tests are shaped by local practices bringing forward other priorities:

- Rapidity → TATs expanded and analysis cycles batched (HIV rapids, GeneXpert)
- Simplicity → sample processing complicated (HIV rapids, venous instead of finger prick)
- Connectivity → avoided (GeneXpert)
- Readability → stability more important than rapidity (HIV rapids)

# Implementers continue to align diagnostics and setting:

- Alignment to some elements happen **after implementation** of Gene Xpert (f.i. linkages to care, connectivity, repair, training (Albert et al., 2016))
- **F.i. linking GeneXpert results to care:** A district TB officer managed to arrange a deal with the nearby medical college:  
*" ..we had a dialogue with the Medical College Director, we requested them [to care for MDR-TB patients diagnosed at our site], because it needs Isolation Ward, staff to engage them, without giving funds other institutions may not accept. So we were able to convince the Director and started this. For the treatment part and other medicines we're paying for the institution. The rest will be free of cost."(Implementer 5).*
- → **requires HR & resources**
- **Increased funding and attention for system strengthening to support diagnostic services**
- Diagnostic delay not cut & continued problems with access & underutilization → impact of earlier alignment choices becomes clear



# Key messages

1. Aligning POC Dx to the local context means **aligning to 5 settings**: intended use, developers, intermediaries, competitors and diseases/bugs
2. What a **good test** is, is defined by 5 different settings, needs might **conflict and change over time**
3. **Needs assessment** is core business: its continuous & non-linear, it requires substantive investment to access and manage multiplicity
4. **Implementers** continue to (re)align and **require resources to do so**
5. **Users** are multiple, variable and shift
6. A certain amount of **uncertainty** remains ('aligning in the dark')
7. There is no right or wrong alignment but developers/implementers are made to chose and these **choices have implications** for access & utilization & equity
8. Therefore: Working through design-iterations and trade-offs should be done in **closer relationships with different actors, users & settings**
9. Developing a Dx and aligning it to POC involves **politics**
10. Current expectations (cheap, easy, rapid), design locks, business models and evaluation **practices clash with continuous nature of alignment** → favours certain products/processes over others
11. Health system strengthening and technology design are inseparable and have to be thought through together, yet currently there is a **disconnect between designers**



# Some concrete suggestions

- Creating safer more welcoming spaces to engage with a variety of user needs & build relationships:
  - in **clinics** (set up welcoming learning environment), engage clinicians/nurses early to understand clinical use
  - in **guideline development meetings** (better representation of different user needs by using more diverse evidence (operational, qual research), safer space for community/patient group members to speak up),
  - in **MoHs** (coordinate country needs, creating a formal mechanisms for MoHs to get feedback from their users before and during implementation)
  - in **global TPP consultations** (more flexible TPPs and stronger consultative writing process, clarify role of global intermediaries (avoid overlap) and involve early on)
  - Clarify understanding of POC & more comprehensive outlook on health
- More & new forms of funding for continuous needs assessment
- More funding and attention to alignment work of implementers
- Plan for technology design & health system strengthening in parallel



# Suggestions cont.

- Be more realistic/honest: timelines, funding, team, in country support feasibility
- Harmonized, simplified regulatory process:
  - Type of data: it might not always be necessary to go through RCTs, more evaluations in less controlled sites than demonstration studies
  - Timing
  - Rethink gold standards: possibly apply some of the POC criteria to lab based tests (improve TAT, getting results back)
  - Different indicators/measurements are needed for clinical utility of tests to contrast/compare to accuracy measurements
- Improved business models: f.i. not for profit; collaborative instead of exclusive; global consortium; different supply/deployment model via central labs instead of individual suppliers; different incentives and new kind of funding mechanisms for Xpert followers
- Local development of POC Dx requires additional/different support

# Conclusion

- When you are developing and implementing a (POC) Dx for global health, you are not designing an artefact but a usage
- And you are aligning the technology to more settings than 'just' intended use
  
- Developing a POC Dx is a **social process**, and **technology and society mutually interact**; the way it is currently organized, leads to particular kind of development process and product
  
- Social science research can document and analyze these processes

Thank you!

Thoughts? Feedback? Questions?

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