# Health technology translation from lab to market – from the perspective of Diagnostics (Dx) Innovator

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Osteba, 25 years evaluating health technologies, 24.10.2017

# Disclosure / Declaration of interests

- Research support has been granted by the European Commission and National Agencies via public funding

- LifeAssay Diagnostics Ltd (South Africa) subcontracts Hahn-Schickard in the project "Antimonia" funded by the Angloamerican and the South African Medical Research Council

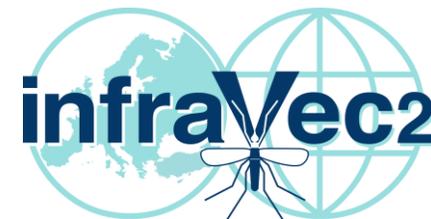- There is no conflict of interests in the presented work

www.discognosis.eu

www.diagoras.eu

www.dmc-malvec.eu

https://infravec2.eu/

# Hahn-Schickard
# Our services, from idea to production

- Private, Non-Profit Research Organisation

- ~200 employees

- DIN EN ISO 9001:2008 certified (expected 13485 till end 2018)

- Design & Foundry Service for industry, national, EU contracts

- R&D Services in Lab-on-a-Chip & Analytics

- Infrastructure on polymer & molding microfabrication
  - Prototype and Scale-Up

- Life Science facilities for lab validation

Institut für Mikroaufbautechnik
Stuttgart→**manufacturing**

Institut für Mikro- und Informationstechnik
Villingen-Schwenningen→**MEMS, sensors**

Institut für Mikroanalysesysteme (from 2016)
Freiburg→**Lab-on-a-Chip, diagnostics**

Strategic alliance with IMTEK-Department of Microsystems Engineering, University of Freiburg, Germany

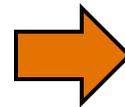# Hahn-Schickard, Lab-on-a-Chip & Analytics
# Our mission

- Development (design & simulation), manufacturing and packaging of microfluidic cartridges

- Transfer of developed assays from the lab to integrated and portable systems

- "Plug-and-Play" of microfluidic modules (library of unit operations[1])

- Fully automated sample-to-answer analysis
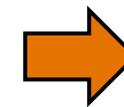


Reagent kit & protocol          Multiple samples/analytes          LabDisk          LabDisk Player

[1] O. Strohmeier, et al., Chemical Society Reviews, 2015, 44, 6187 – 6229

# Overview

**Definition: Health _Technology_ in this presentation refers to:**

- A Point-of-Care / near-patient diagnostic tool for infectious (and/or non-communicable) diseases
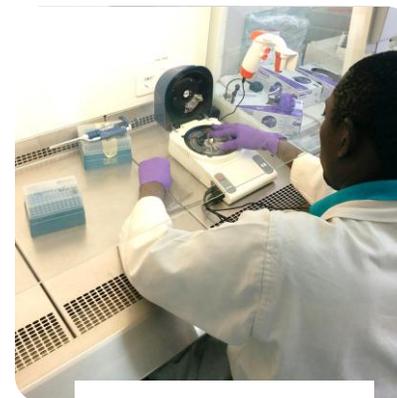
**In-house examples:**

- EU-FP7 "DiscoGnosis" (tropical infections)
  - ➤ Successful proof-of-principle in Senegal, Sudan (2016)

- H2020 "DMC-MALVEC" (mosquito Dx and data management systems) – in progress till 2020
  - ➤ Validation in Cote D' Ivoire, Cameroon, Zambia, Ethiopia

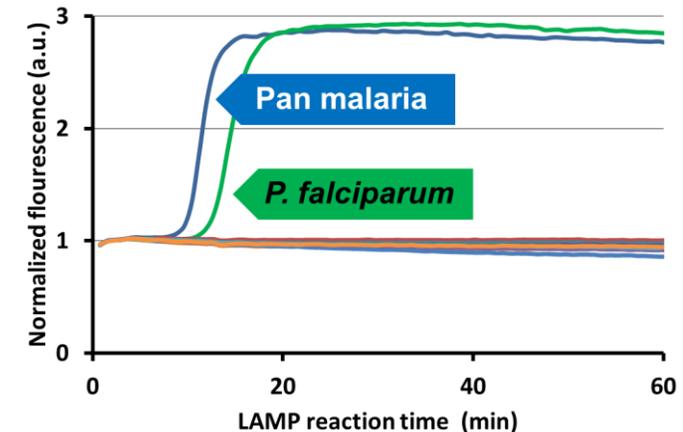- H2020 "DIAGORAS" (oral, respiratory infections & resistances) – in progress till 2019



**The LabDisk**



**Packaged cartridges**



**Pasteur, Dakar**

# Exploitation & roadmap to market (1)

**Not technology-specific, but general scheme**

| Product prototype; lab proof-of-principle | → | Manufacturing upscale from manual to small series & QC | → | Pre-clinical testing performance | → | Deployment & testing @ POC & clinical settings | → | Field evaluation; large scale clinical trials | → | Guidelines, registration | → | Market |

**Timeline depends on**

- Sustainability/continuity of funding

- Number of iteration cycles @ prototype level before clearance

- Transfer from prototyping to production

- Access to validation sites & samples

# Exploitation & roadmap to market (2)

## Some lessons learned (from POC development projects)

- Start early enough to liaise with potential stakeholders and networks even if the technical performance is not perfect yet

- If the project is about integrated system:
  - Try to think early enough the integration and the upscale phase
  - Consider also component (sub-system) exploitation (or with limited function system) so as to be faster in the market

- Try to plan/do validation as early as possible so that there is enough time to implement the feedback from end-users (e.g. on technical performance and usability assessment)
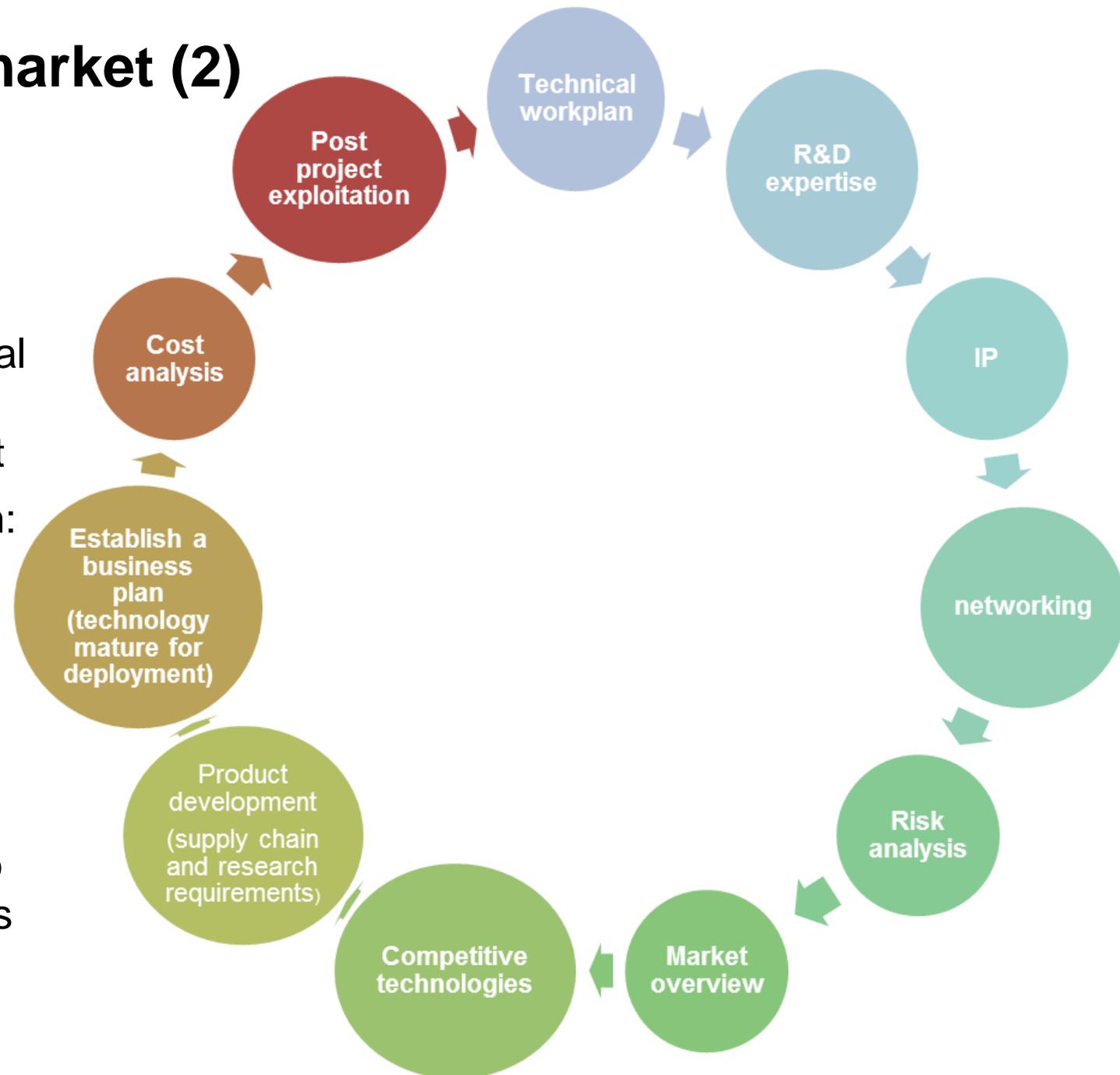
# Transition to the "real world"
(some typical examples of challenges for POC Dx Developers & Innovators)

# Challenges in validation

## The "chicken-and-egg" problem

- **Example/problem:** Implementation of POC platform at GPs offices
  - ➤ The GPs say "*show us data and we will test the system in our settings*"
  - ➤ The Dx Developers say: "*allow us to test our system in your settings in order to acquire & generate data*"

- **Possible solution:** A more coordinated interaction is needed between these two communities, by independent Bodies
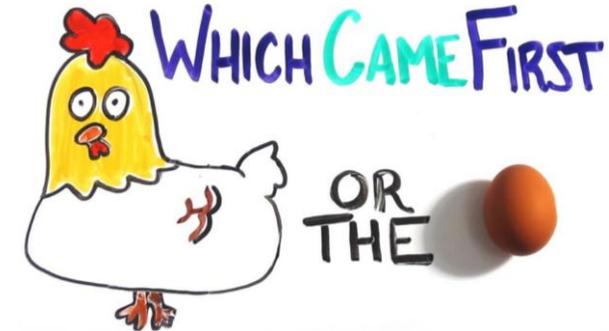


## The lack of standardized samples

- **Problem:** To show data and impact in the validation stage, we need well-characterized and good quality samples. These are often unavailable

- **Consequence:** The new Dx technologies cannot demonstrate their full capacities

- **Possible solution:** HTA Bodies could partner with central hospitals to generate biobanks specifically for the purpose of validating new technologies

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# "People don't talk to each other" (1)

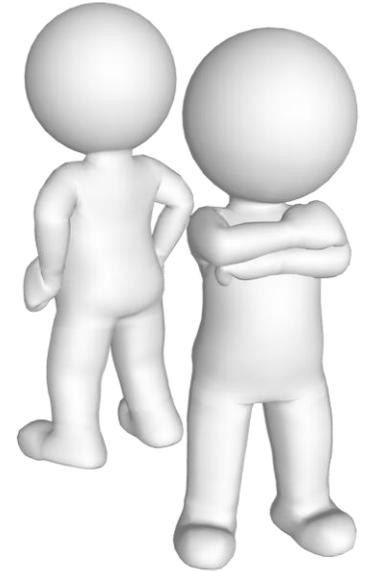## Dx Innovators with Pharma

- **Problem**
  - ➢ Antimicrobial resistance is an undisputed global threat
  - ➢ The coin has 2 sides: Diagnosis ←→ Therapy/treatment (Pharma)

- **Possible solution**
  - ➢ New business models that will give the incentives to the Pharma to cooperate with the Dx
  - ➢ Promote the added value of Dx **before** treatment

- **Consequence**
  - ➢ Synergies → better health solution within a "holistic" approach

# "People don't talk to each other" (2)
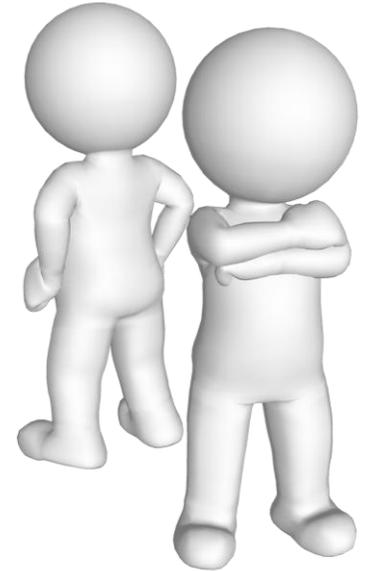
## Dx Innovators with HTA bodies

- Despite the technological competition between Dx companies,
  there are **common hurdles**:
  - Reguatory approval
  - Re-imbursement: Is there a clear & standardized protocol, especially for POC devices,
    to inform the Dx Innovators how their tool can enter the health systems?
  - Health economics: Do the Innovators ever contact the HTA Bodies to help
    generate a cost-performace-impact analysis?

- **Proposition:** How about the HTA Bodies organize training workshop(s) specifically
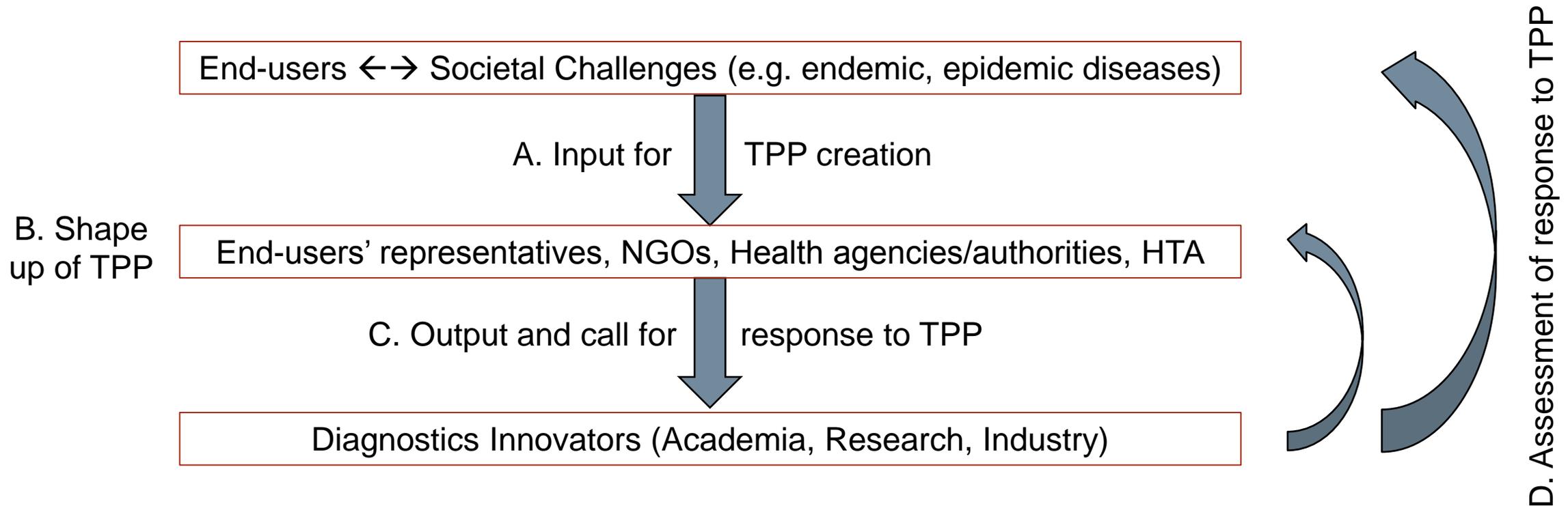  **targetted** to Dx Innovators (perhaps first on national level and then on Europen level?)
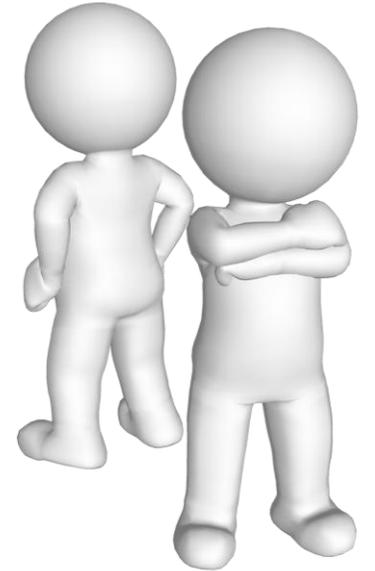
# "People don't talk to each other" (3)

## Dx Innovators with clinicians/end-users

- Do the Dx Innovators know the clinicians' needs?
  - ➤ If yes → avoid "over-engineering"

- Do the clinicians know what the Dx Innovators can do?
  - ➤ If yes → speed up adoption of new technologies

- If not? → Bidirectional communication
  - ➤ Online surveys, questionnaires
  - ➤ Interviews, workshops
  - ➤ Creation of technology databases / Knowledge Platforms
  - ➤ Set up Target Product Profiles (TPPs)

# Target Product Profile-simplified overview workflow



End-users ←→ Societal Challenges (e.g. endemic, epidemic diseases)

A. Input for TPP creation

B. Shape up of TPP

End-users' representatives, NGOs, Health agencies/authorities, HTA

C. Output and call for response to TPP

Diagnostics Innovators (Academia, Research, Industry)

D. Assessment of response to TPP

# Sustainability of the health technology/tool (future proofing)

- **Problem**
  - Changing genome of viruses
  - Emergence of new resistances
  - Emergence of new vaccines
  - Might make even the best Dx tool outdated!

- **Possible solution**
  - As adaptable as possible to the changing...
    - therapeutic
    - vaccine and
    - epidemiological environments
  - Always be at the forefront of development
  - Innovation management

# As Conclusion: Behavioral Change

- **From regulatory perspective**
  - Make it less "easy" to prescribe antibiotics, e.g.:
    "*before prescription, the health provider must have used at least one POC tool besides the gold standard method(s)*"

- **From healthcare providers' perspective**
  - Establish "POCT scouting teams"
  - Generate internal (e.g. intra-hospital) POCT implementation plans → Screening, Evaluation
  - Educate their own personnel

- **From patients' perspective**
  - More informed audience
  - More committed & involved patients' associations

# Acknowledgements

- Funding agencies

- Project partners

- Colleagues at Hahn-Schickard & IMTEK