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

\(^1\) O. Strohmeier, et al., Chemical Society Reviews, 2015, 44, 6187 – 6229
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

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
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

“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**:  
  - Regulatory 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-performance-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 European 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)

Reference: JPIAMR-funded working group AMR Rapid Diagnostic Tests (AMR-RDT)
https://www.ed.ac.uk/pathway-medicine/antimicrobial-resistance/jpiamr-amrrdt/overview
Target Product Profile-simplified overview workflow

A. Input for TPP creation

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

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

C. Output and call for response to TPP

Diagnostics Innovators (Academia, Research, Industry)

B. Shape up of TPP

D. Assessment of response to TPP

Reference: JPIAMR-funded working group AMR Rapid Diagnostic Tests (AMR-RDT)
https://www.ed.ac.uk/pathway-medicine/antimicrobial-resistance/jpiamr-amrrdt/overview
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

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