

Challenges & Opportunities in the European MNBS landscape through EC-funded and Industrial activities

EPoSS WG AMNBS Jesus M. Ruano-Lopez IK4-IKERLAN

About Project and Business development





13.00 he wanted the complete system, not just a component

13.30 we didn't know what we're doing!

18.10 nobody knows why they do what they do 33.20 We visited 80 manufacturing companies, and we made the first worldline

1.06.24 how do you know you go in the right directions?





- Description of the situation.
- Description of different actions running in Europe
- Description of the opportunities
- Description of a strategy
- The Challenge
- Conclusions

AMNBS Added Value Chain



No yet a consolidated Added Value Chain -> Handcraft prices-> Low market penetration Fragmented market



equipment

AMNBS IVD News

EPOSS European Technology Platform on Smart Systems Integration

Alere



BioMérieux



- BD Diagnostics
- Cepheid
- Bio-Rad
- Roche
- Lifetechnologies
- microLIQUID





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Internal diagnostic of the AMNBS WG



ECSEL JTI

- WP from MASRIA 2014
- New call 2015
- New MASRIA 2015 (end of 2014)



- EU Industry driven Technologycal Platforms (EPoSS, ARTIMES-ARTIMISIA and ENIAC-AINEAS). A reminder that this industrial Associations are open.
- □ Working on opportunities (regulation, niche market, architecture)
- □ Not enough companies dealing with In Vitro Diagnostics within AMNBS WG.
 - After discussed in the EPoSS Executive Committee Meeting, AMNBS WG is launching a plan to invite IVD companies.
- Several AMNBS actions in different forums
 - MNBS EU funded projects
 - AMNBS EPoSS
 - MF 5 (http://www.cfbi.com/microfluidics.htm)
 - Academic groups (e.g. mTAS)
 - Different Support Actions (e.g. EXPRESS)



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New European Standards & Medical Devices Directive (2012/0267(COD))



- Medical Devices Directive (98/79/EEC)
 - Exemption of laboratory developed tests (LDTs)
- New EU regulations for medical devices and IVDs (entry into force 2015-2019)
 - Mechanism to ensure safety and effectiveness of IVD devices
 - Address lack of evaluation of laboratory developed tests (LDTs)
- Under the new regulations:
 - LDTs may be under strict regulation
 - New IVD systems need:
 - Readily fit into new EU regulations for certification
 - More appealing to diagnostic laboratories versus requirements to perform LDT
- This regulatory landscape might increase the demand of customised IVD systems.

http://www.europarl.europa.eu/oeil/popups/summary.do?id=1225597&t=e&l=en

Niche Market left between Robots and PoCs





AMNBS Sector Needs



Technical Barriers	AgroFood Testing	Forensic & Military	Medical Emergency	Infectious diseases	Environment testing	Biomarkers Screening
Multiplex assays	X	X	X	Х	X	X
45' per analysis	Х			Х	Х	X
15' per analysis		Х	Х			
Increase Resistance		Х			Х	
Simple sample extraction			X	Х	Х	X
Complex sample extraction	Х	Х				
Positive control required	X		Х	Х		Х
Prevention of contamination system	Х		Х	Х		Х
Sensitivity	1-10 c.f.u	1 c.f.u.	ng/ml	1-10 cfu	10 cfu	0.3ng/l
Certification ISO HA			Х	Х		Х
Acceptable price per assay	< 20€	<30€	<80€	35-70€	5€ (water) 35€ (Research)	<40€
Number of samples per run	8 or more	From 2 to 6(3+3)	From 2 to 6(3+3)	8 or more	8 or more	8 or more

"Classifying is to compress and compress is to comprehend", Jorge Wagensberg

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Technological maturity level



European Technology Platform

- EU microfluidic reached maturity level in issues such as fabrication, materials, techniques, and fluidic components.
- The convergence (or scientific selection) of most of these previous solutions into similar approaches allowing an integration into components.
- The better knowledge of the microfluidic needs in several aspects such a minireactors, or protein/DNA based diagnostics.
- An IVD system has many common components: washing, elution, concentration, incubation, amplification...











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Innovation Process





- Don't go to applications where you can not offer a competitive **advantage** to the existing gold standard.
- First demonstrate if we can make it by selecting the **easiest** route to do it. Then, take the following one and so on.
- **3. Integrate** a Diagnostic **system** that involve sample preparation **reliably.**
- 4. Take advantage of all IVD research tools to get there and not focus on one (e.g. Biosensor).

PoC or IVD=Control Unit +Sample preps.+Channel+ Biology + Material + Microfab. Tools On/Off chip Jesus M. Ruano-Lopez 14

A system is waiting for you

On chip

Off chip



PoC or IVD=Control Unit +Sample preps.+Channel+ Biology + Material + Microfab.

Tools

 Standard PC, iPAD or Tablet PC

- Data base software
- Standard **Operative System**
- Hardware based on commercial components
- USB, SDIO connectors
- Bluetooth, WIFI. 3G, ZigBee
- Smartphone for remote control or portability

The requirements of each application defines how acceptable is the Off chip manipulation

It is very convenient to use as much sample as possible to increase sensitivity.

Concentration steps

- If it is possible, we should use Molecular **Biology Techniques**
- Syringes, Filters, Swabs, eppendorfs tubes
- On chip sample preparation provides enough clean substance to be detected on the biosensor

A channel is a must to confined the liquid on top of the sensor

A channel is formed by:

A cavity

or

A flat cover bond to the channel

Low temperature for reagent storage



 Biology to help simplify what it is difficult

 Molecular **Biology on tube** needs to be transferred to Chip

 Reactions such as Enzymatic amplification are helpful since amplify the target molecule

Preferably non contact sensing mechanism labels

Inert Low

autofluorescenc

e/transparent

Low cost

in the prototypes than

- Same material
- in the final
- Polymer product replication

Good sealing

Low cost

producible

fabrication

through put

Simple

to obtain

high

process

Mass

Jesus M. Ruano-Lopez, Salzburg, February 2012

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Validation







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To consolidate the AMNBS Added Value Chain



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EPoSS

European Technology Platform on Smart Systems Integration

To create a IVD Microfluidic European Industry



European Technology Platform on Smart Systems Integration









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From dispersion to concentration by a competitive race for an EU standard



NOW 2028

2019

- This winning standard will enable the possibility of carrying out other actions such as the development of:
 - One common methodology
 - One simulation
 - One designing software
 - One fabrication technology
 - One validation strategy





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Conclusions



The AMNBS added value chain is not yet consolidated



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We may not know what we are doing, but we are going to try