



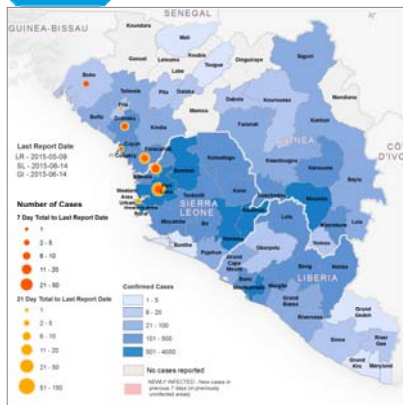
## MOBILE FILOVIRUS NUCLEIC ACID TEST (MOFINA) – ETABLIERUNG DES ALERE Q-FILOVIRUS ASSAYS

Thomas Ullrich  
10 | 04 | 2018

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## Ebola Virus Disease Outbreak 2014/2015 (2015)



Zeit zwischen Verdacht  
und Diagnose zu lang,  
schlecht Zugänglichkeit  
zu Patienten



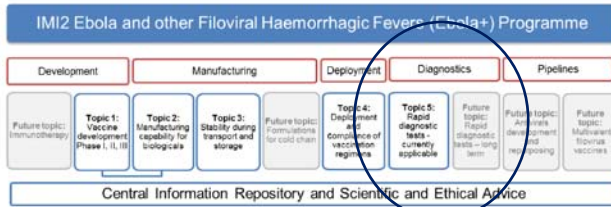
Die Erkennung dieser Krankheiten nur anhand der Symptome ist nicht eindeutig möglich. Dazu muss eine genaue **virologische Diagnostik** durchgeführt werden. Gefahr der Verwechslung mit anderem (Hämorrhagisches) Fieber.

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<http://apps.who.int/ebola/ebola-situation-reports>



## Innovative medicine initiative (IMI) Call for Proposals (2015)

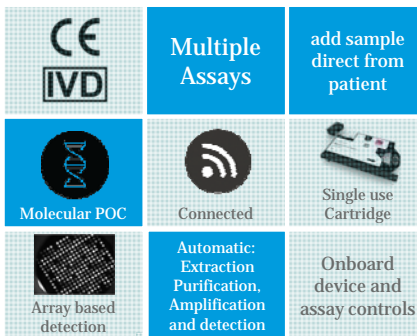


*IMI Struktur des Programms IMI2 Ebola. Themen sind in blauen Kästchen hervorgehoben. Mögliche Zukunftsthemen, die zu einem späteren Zeitpunkt gestartet werden sollen, sind grau unterlegt.*

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## Alere q Technology, Quantitative and qualitative molecular platform for PoC Diagnostics



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## Alere / Altona Diagnostics® Technology merger

Alere™ q point of care modular instrument and cartridge design

CE IVD and EUA marked and field tested real-time PCR based assay(s) Realstar® Ebolavirus RT-PCR Kit 1.0 (Altona Diagnostics)



Development of molecular point of care (POC) system for the safe, rapid, specific and sensitive detection of Filovirus Infection in capillary (or venous) blood samples

➔ Product verification/validation and field testing with real virus and patient samples

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## MOFINA collaboration facilitated by IMI



Mobile Filovirus Nucleic Acid Test



Partner	Function
Altona Diagnostics GmbH (DE, Hamburg)	-support R&D, technical documentation and approval process
Alere Technologies GmbH (ATJ)	-R&D -Manufacturing site -Technical documentation -CE-approval/EUA FDA approval
Bernhard Nocht Institute for Tropical Medicine BNITM	-BSL4 facility performance evaluation
Istituto Nazionale Malattie Infettive L. Spallanzani (Italy) INMI	-BSL4 facility performance evaluation
Foundation of Innovative New Diagnostics (Switzerland) FIND	-Facilitate Clinical (field) studies
Public Health England (United Kingdom) PHE	-BSL4 facility performance evaluation

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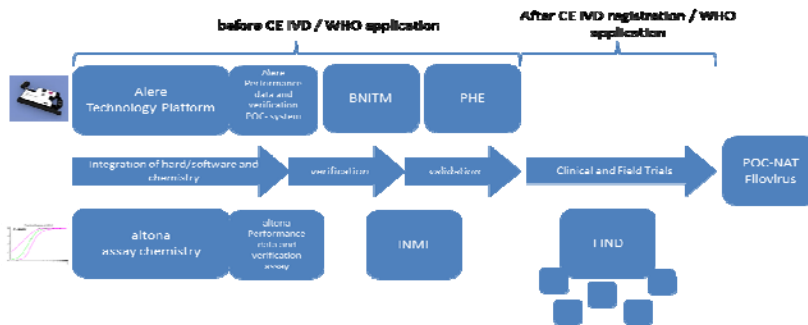
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## MOFINA Project PROPOSAL

Entwicklung eines molekularen Point of Care (POC)-Systems für den sicheren, schnellen, spezifischen und sensitiven Nachweis von Ebola Virus Infektionen in kapillaren (oder venösen) Blutproben. Das Anliegen der Industriepartner ist hierbei der Transfer bestehender CE IVD zertifizierter Real-Time-PCR basierter Labortests in den Alera™ q. Das Ziel in der Anwendung ist die Erweiterung von Molekulartests an Standorten, an denen keine High-End-Laborinfrastruktur verfügbar ist.

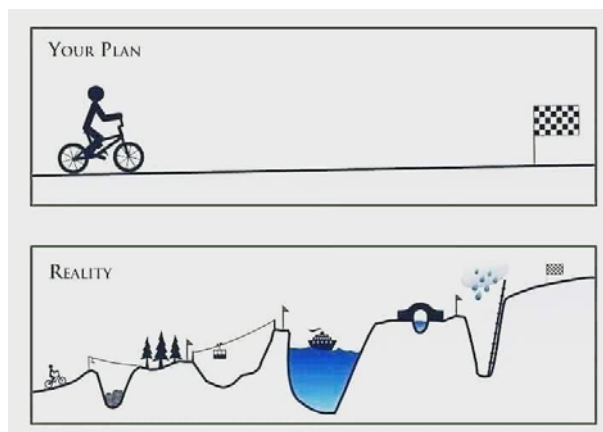


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## MOFINA - From Start to ...



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MOFINA -

... Finish

English Search

European Commission > Research and Innovation > Projects > Success Stories >

### Faster testing for deadly Ebola

EU and industry-funded researchers have developed a portable device to test in the field whether a person has caught the deadly Ebola disease. It gives reliable results in 75 minutes, which can help contain outbreaks and save lives.

Horizon 2020  
Innovation  
Public Health

Published: 18 September 2017

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## MOFINA Project WORKPACKAGES

- **WP1 Assay and Tech Platform → Working prototype, product feasibility**  
→ **10 %**
- **WP2 Development of production process → design control/ design transfer to operations incl. QC methods development and validation**  
→ **40%**
- **WP3 Verification and Validation → In- House product verification and validation studies**  
→ **25%**
- **WP4 Clinical and field studies → clinical studies with patient samples in Sierra Leone**  
→ **15 %**
- **WP5 Technical documentation and registration → reparation/review of technical dossier**  
→ **10%**

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## MOFINA - Value of IMI collaboration

- This project would not have been possible without the collaboration facilitated by IMI.
- Not only did this collaboration bring together a close and successful working relationship between Alere and Altona, but it also allowed those commercial entities to use the facilities of national public health institutes (INMI, BNITM and PHE-Porton Down) to carry out the essential testing of the product in high-containment conditions using their unique collection of live, characterised filovirus stocks.
- Collaborating with FIND allowed the devices to be tested in field conditions in West Africa with real patient samples collected/banked during the West African Ebola outbreak. FIND are well placed to arrange such work and ensure all ethical approvals are in place.
- Test validation performed by three independent national public health institutes has demonstrated to be a powerful tool to **escalate/resolve issues and to share knowledge**

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## MOFINA - Lessons learned

- Finalization of the project despite time delays
- Underestimation of development, verification and validation burden for industry partners
- Hard to explain rationale for product development with no existing market
- More detailed planning from the legal *manufacturer point of view*
- Access to banked samples from Ebola-infected patients was tightly held by a few institutions at the front line of the epidemic, while hundreds of groups sought well-characterized samples for test development. This led to unforeseen, and at times lengthy delays in conduct field trials.
- Regular meetings, establishing direct communication lines: Despite the moderate additional cost and logistical challenges, regular face-to-face meetings were critical to maintaining progress and understanding timelines between partners.

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## MOFINA - Questions

Thank-you for your time



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