VALUE-Dx

Setting the scene for public-private collaborations in diagnostics

10th Advanced Course on Diagnostics, 15th – 20th September 2019

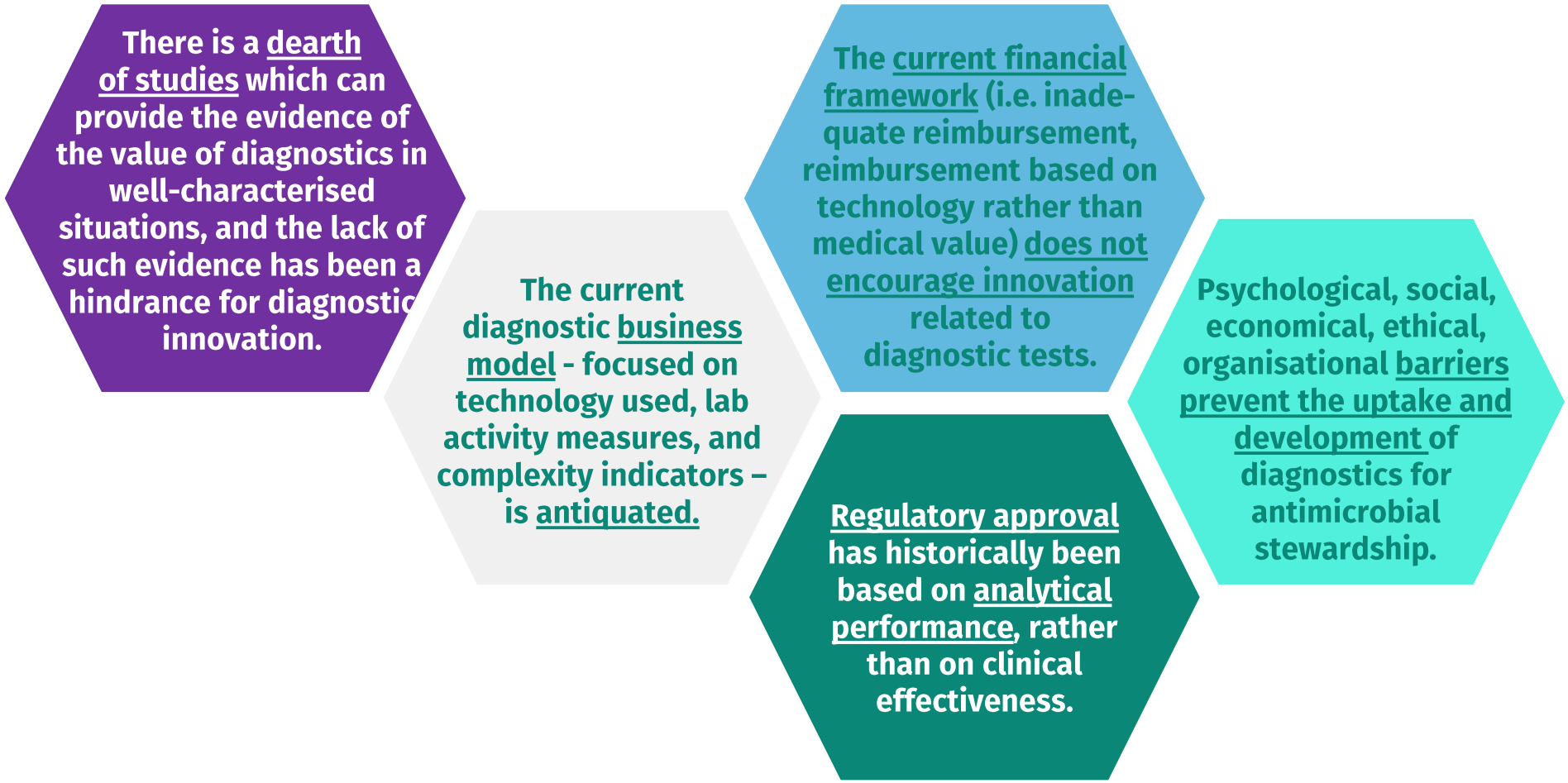
Annecy, France

Herman Goossens

Project Leader

University of Antwerp, Belgium

Challenges of diagnostics



Vision & Purpose

Our **vision** is to transform clinical practice, improve patient outcomes, and combat AMR, through the widespread use of clinical and cost-effective innovative diagnostics strategies to achieve more personalised, evidence-based antibiotic prescription and use in community care settings.

Our **purpose** is to facilitate and accelerate the rigorous assessment and implementation of (new) diagnostic technologies into healthcare settings, by establishing the infrastructure, methods, processes and approaches needed to understand, evaluate, assess, and demonstrate the multi-faceted value of diagnostics and overcome the associated barriers to their widespread adoption and use.

Our **focus** is on realising its vision and purpose on community-acquired acute respiratory tract infections (CA-ARTI).

Therefore, VALUE-Dx will focus on diagnostic strategies relevant to reducing AMR in CA-ARTI in community care settings, referred to as “CA-ARTI-Dx”

Community Care Settings

- As required by the call topic, VALUE-Dx will focus its research on community care, which is defined as the first point of contact with health services.
- This includes both in and out of office hours care.
- **Settings**: general practice, urgent care centres, accident and emergency rooms and other acute services in hospitals, paediatric care centres, and rehabilitation and long-term care facilities.

Objectives of VALUE-Dx

Helping to build the economic case for rapid diagnostics as a public good in the fight against AMR

1. To **design a health-economic framework (HEF)** to assess and demonstrate the value of diagnostics both for individual patients and for public health impact by reducing antibiotic use and subsequent antibiotic resistance among patients.

2. To **establish a sustainable European Standardised Care Network** adequately trained and resourced to conduct clinical trials evaluating the value of diagnostics.

3. To **design and implement clinical studies to demonstrate the value of diagnostics** in the optimal management of Community-Acquired Acute Respiratory Tract Infections (CA-ARTIs)

4. To **explore, define and attempt to resolve the psychological, ethical and social barriers** which prevent the more widespread adoption of diagnostics delivering healthcare to the population.

The VALUE-Dx Consortium

Contribution from European Commission, Wellcome, and IVD Companies

Budget overview

Total budget VALUE-Dx:
€ 13,643,431

European Commission:
€ 6,799,100

Wellcome:
€ 3,400,000

IVD companies:
€ 3,444,331
In kind contribution:
€ 2,939,331
In cash contribution:
€ 505,000

GOVERNANCE

GENERAL ASSEMBLY (VALUE-Dx Partners)
EFPIA partners, IMI-JU Associated Partners, Beneficiaries

Executive Board (VALUE-Dx WP Co-Leads)

Coordination Team (= WP7 Co-Leads)

Herman Goossens
Coordinator and Project Leader
University of Antwerp

Philippe Cleuziat
Industry Leader
bioMérieux

Tim Jinks
Wellcome

Project Management Office

David De Pooter
Project Manager
University of Antwerp

Christine Lammens
Budget Officer
University of Antwerp

Joyce Jacobs
Administrative Officer
University of Antwerp

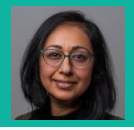
Academic and Industry WP Co-Leads

WP1

Evelina Tacconelli
University of Verona

Jorge Villacian
Janssen Pharmaceutica

WP2



Surbhi Malhotra-Kumar
University of Antwerp

Carine Malcus
bioMérieux

WP3

Frank Leus
University Medical Center Utrecht

Jean-François Gorse
bioMérieux

WP4

Christopher Butler
University of Oxford

Susanne Emmerich
Abbott

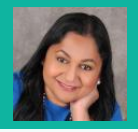
WP5

Maarten Postma
University Medical Center Groningen

Isabelle Tongio
bioMérieux

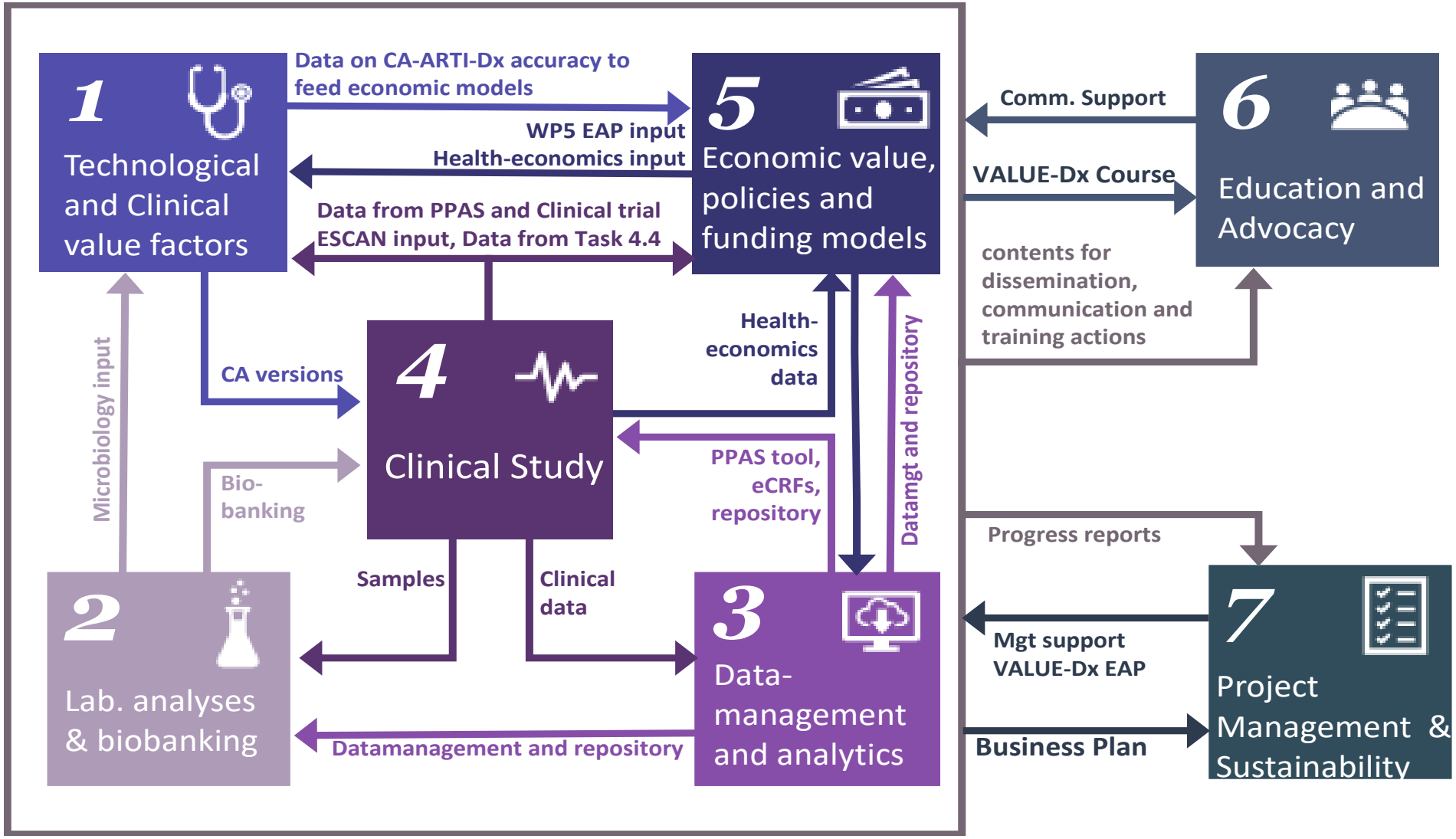
WP6

Murat Akova
ESCMID



Renuka Gadde
Becton Dickinson

Interaction between the Work Packages



Category	Characteristic	Content
General Information	Test	Name of the test
	Manufacturer	Name of the company that manufactures the product, not the selling company
	Intended use	What is the purpose of using the test?
	Setting	Location where the test will be performed (e.g. diagnostic lab, primary care, long-term care facilities, ICU, ED)
	Suitable for POC testing	Is the test suitable to be performed as Point of Care testing?
	Performer	Professional who will perform the test
	Patient type	Symptoms/characteristics of the patient for which the test should be applied
	Method	Method on which the test is based
	Targets	Molecule or molecules targeted by the method (i.e., antigen, specific gene,...)
	Analysis	Qualitative/quantitative/semi-quantitative
	Detection	Method by which the result is generated
	Detected pathogen	Organisms that the test can detect
	Detected AMR	Antimicrobial resistances directly detected by the test, both genotypic and phenotypic

Category	Characteristic	Content
Specifications	Storage conditions	Conditions of storage of the kit (i.e., temperature, humidity)
	Shelf life	Maximum storage time
	Kit components	What is included in the kit?
	Specimen	Type of sample for which the test is used
	Volume/amount required	Volume of sample required to start the test
	Test preparation	Steps to carry out before beginning to work with the sample
	Sample processing	Brief description of the steps that are needed to perform on the sample
	Controls	Internal test controls (i.e., controls that confirm the test is yielding a correct result)
	Calibration	Calibration requirements (i.e., frequency, material used…)
	Maintenance	Maintenance required for the instrument
	Hands on time	Estimated time that a trained performer has to be directly working (incubation times and analysis not included)
	Result readout	How the result is presented to the user
	Time to result	Estimated time required since the start of sample processing to result obtention (i.e., hands on time + instrument running)
	Instrumentation	Instruments required for test (i.e., detector, thermocycler)

Category	Characteristic	Content
Specifications	Instrument specifications	Specifications of the required instrument (i.e., size, zeight, warm up time, etc.)
	Connectivity	Possibility to connect the care devices remotely and transfer test data to a central hub/lab
	Waste disposal	Way to dispose of the materials used (i.e., additional requirements apart from standard guidelines)
	Samples per run	Number of samples that can be tested in one run (i.e., single or multiple testing)

Category	Characteristic	Content
Validation	Patient population	Characteristics and number of the population in which the test has been validated. Please provide a dedicated table when possible
	Sensitivity	Analytic sensitivity of the test described by the manufacturer
	Specificity	Analytic specificity of the test described by the manufacturer
	PPV	Positive Predictive Value derived from the validation study
	NPV	Negative Predictive Value derived from the validation study
	Reproducibility	% of agreement between independent sites tested by the manufacturer
	Limit of detection	Minimal concentration of the organism/target required for the test to detect it
	Cross-reactivity	Organisms that can interfere in the result
	Interference	Compounds or sample characteristics that can interfere in the result

Category	Characteristic	Content
Company Capacity	Training required	Is training required for the user to perform the test?
	On-site training	Does the company offer the possibility to train the users?
	Cost of kit (€)	
	Instrument availability in Europe	Can the instrument be purchased in Europe and how many instruments can be made available per site?
	Cost of instrument (€)/leasing possibility	
	Calibration	Service offered by the company in order to set up the instrument in the setting
	Maintenance/Support	Support offered by the company to maintain the instrument
	Stage of development	Complete, in development, prototype
	Market region	Areas where the test can be purchased

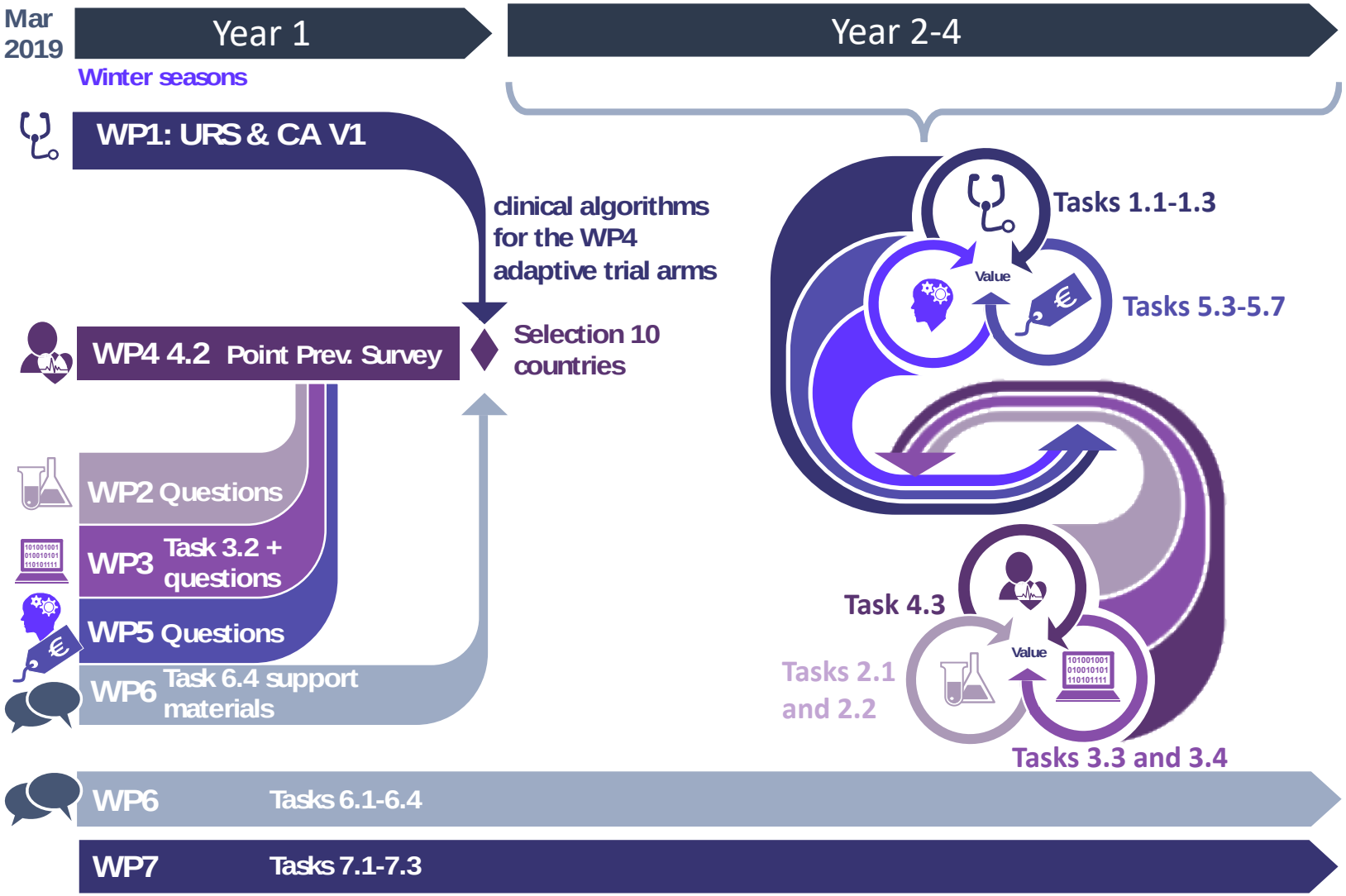
Category	Characteristic	Content
Regulation	Regulatory approval	CE marked, FDA clearance
	CLIA complexity	Waived, moderate, high

Characteristic	Content
Clinical studies	List of references in which the test has been used (clinical studies, posters, etc.)
Website	

Diagnostic Landscaping: Summary (15 September 2019)

- Includes information on 284 diagnostic tests from 69 companies
- 22 (7.7%) are under development
- 107 (37.7%) suitable for POC
- Most common methods are immunoassays (37.7%) and nucleic acid amplification tests (NAAT, 35.9%)
- Promising technologies for POCT: isothermal amplification, biochips and microfluidics

Gantt Chart


Mar 2019
Year 1
Year 2-4
Winter seasons
WP1: URS & CA V1
clinical algorithms for the WP4 adaptive trial arms
WP4 4.2 Point Prev. Survey
Selection 10 countries
WP2 Questions
WP3 Task 3.2 + questions
WP5 Questions
WP6 Task 6.4 support materials
Tasks 1.1-1.3
Value
Tasks 5.3-5.7
Task 4.3
Value
Tasks 2.1 and 2.2
Tasks 3.3 and 3.4
WP6 Tasks 6.1-6.4
WP7 Tasks 7.1-7.3

Access to Clinical Trial Networks

Primary care

>200 primary care practises in >20 European countries

- ✓ Recruited over 20,000 patients into clinical studies on ARTI in GRACE and other studies.
- ✓ Randomised 3,268 participants in a response-adaptive platform trial of a drug for a CA-ARTI in PREPARE.

Chris Butler

Hospital care + Labs

>900 hospitals and >800 labs in >40 European countries

- ✓ COMBACTE projects are managing >20 trials, including phase I – III trials for many new compounds against multi-resistant bacteria, and recruited over 20,000 patients.

Marc Bonten (CLIN-Net)
Herman Goossens (LAB-Net)

Paediatric care

90 paediatric clinical sites in 18 countries

- ✓ Network of hospital sites of neonates and chrilden.
- ✓ Active a.o in ZIKACTION, PREPARE, C4C (IMI-2)

Carlo Giaquinto

Long Term Care

Nursing homes and rehabilitation centres in 11 countries in Europe and Israel with more than 14,000 LTCF beds

- ✓ Experience in clinical trials on antibiotic use, influenza epidemiology and vaccines, microbiome and more.

Evelina Tacconelli
Mical Paul

Selection of Countries and Healthcare settings

NOT FINAL !

	Income Classification	AB use	Primary Care	Paediatrics	Long-term Care	Hospital
The Netherlands	High	10.4	Yes			Yes
Sweden	High	12				
Slovenia	High	13.9				
Germany	High	14.1	Yes	Yes		
Norway	High	15.2	Yes			
Hungary	High	15.4	Yes		Yes	Yes
Denmark	High	15.9				
Lithuania	High	16.9				
UK	High	19.6	Yes	Yes		
Czech Republic	High	20				
Poland	High	24	Yes			
Ireland	High	24.2	Yes		Yes (confirmed)	Yes
Belgium	High	27.5	Yes		Yes (confirmed)	Yes
France	High	30.3	Yes		Yes (confirmed)	
Greece	High	36.3	Yes	Yes		
Spain	High	23 plus	Yes	Yes	Yes (confirmed)	Yes
Italy	High		Yes	Yes	Yes (confirmed)	

	Income Classification	AB Use	Primary Care	Paediatrics	Long-term Care	Hospital
Bulgaria	Upper Middle	19.8				
Croatia	Upper Middle	20.7	Yes			Yes
Romania	Upper Middle	29.5 minus	Yes			Yes
Turkey	Upper Middle	35 (2014)				
Armenia	Lower Middle	13 (2014)	Yes			
Moldova	Lower Middle	14 (2014)	Yes			
Kosovo	Lower Middle	17 (2014)				
Switzerland	High	Nd				
Macedonia	Upper Middle	Nd				
Georgia	Lower Middle	Nd	Yes			
Ukraine	Lower Middle	Nd	Yes			

ECRAID

European Clinical Research Alliance on Infectious Diseases

ECRAID ENVISAGES A EUROPEAN-WIDE, SUSTAINABLE CLINICAL TRIAL ORGANIZATION FOR INFECTIOUS DISEASES, INCLUDING ANTIMICROBIAL RESISTANCE, BY LEVERAGING PAST SUCCESSES, BUILDING PUBLIC AND PRIVATE ALLIANCES, AND CREATING GLOBAL SYNERGIES

PURPOSE

To reduce the impact of infectious diseases on individual and population health

VISION

To efficiently generate rigorous evidence for new or improved diagnosis, prevention and treatment of infections and to better respond to infectious disease threats. This is facilitated by a European multidisciplinary clinical trial network and innovative research approaches

CONCEPT

ECRAID is looking to create a 'warm-base' network in all healthcare settings to increase efficiency and quality of clinical trials. This network can act as a "warm-base" for studies that evaluate multiple new drugs, other therapeutics, vaccines & diagnostics for infectious diseases. In order to create an active "warm-base" network, ECRAID will conduct several types of clinical trials, allowing to build a network of well-trained sites. ECRAID will build a platform to conduct a series of perpetual observational studies, with a master protocol, where a selection of sites will continuously enroll patients and collect outcomes for specific infectious diseases or infectious disease syndromes.

CURRENT STAGE OF THE ECRAID PLAN

The Consortium Partners of ECRAID *(see below)* are, with the support of Monitor Deloitte, currently developing a business plan to setup a sustainable Clinical Trial Network infrastructure in Europe. In light of its design and setup, ECRAID also wants to engage with different stakeholders to ensure feedback is considered

Platform foR European Preparedness Against (Re-)emerging Epidemics PREPARE
ND/BB COMBACTE
ECRIN European Clinical Research Infrastructure Network
conect 4children Collaborative Network for European Clinical Trials for Children
compare
EVD-LabNet
erinha European Research Infrastructure on Highly Pathogenic Agents
EVAg
ZIKAction
ZIKAlliance
ZikaPLAN
EMERGE Efficient response to highly dangerous and emerging pathogens at EU level
PANDORA Pan-African Network For Rapid Research, Response and Preparedness for Infectious Diseases Epidemics
ALERRT African coalition for Epidemic Research, Response and Training

- Work in progress -

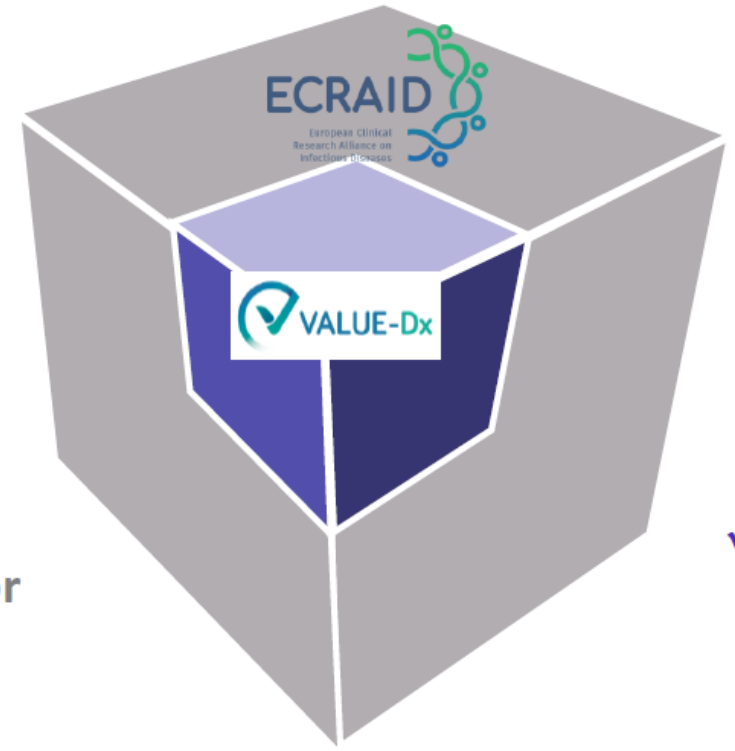
ECRAID-Plan

Kick-off 17 January 2019

"We expect the ECRAID-Plan to come up with a business plan that offers concrete solutions and prepares Europe to better deal with antimicrobial resistance and large infectious diseases outbreaks"
–EU commissioner Carlos Moedas,

"an inspiring vision of a pan-European infrastructure for patients and communities, bringing public health, clinical and laboratory, science, innovation and society together." – Sir Jeremy Farrar.

ECRAID-Plan is funded by the European Commission under Grant Agreement 825715



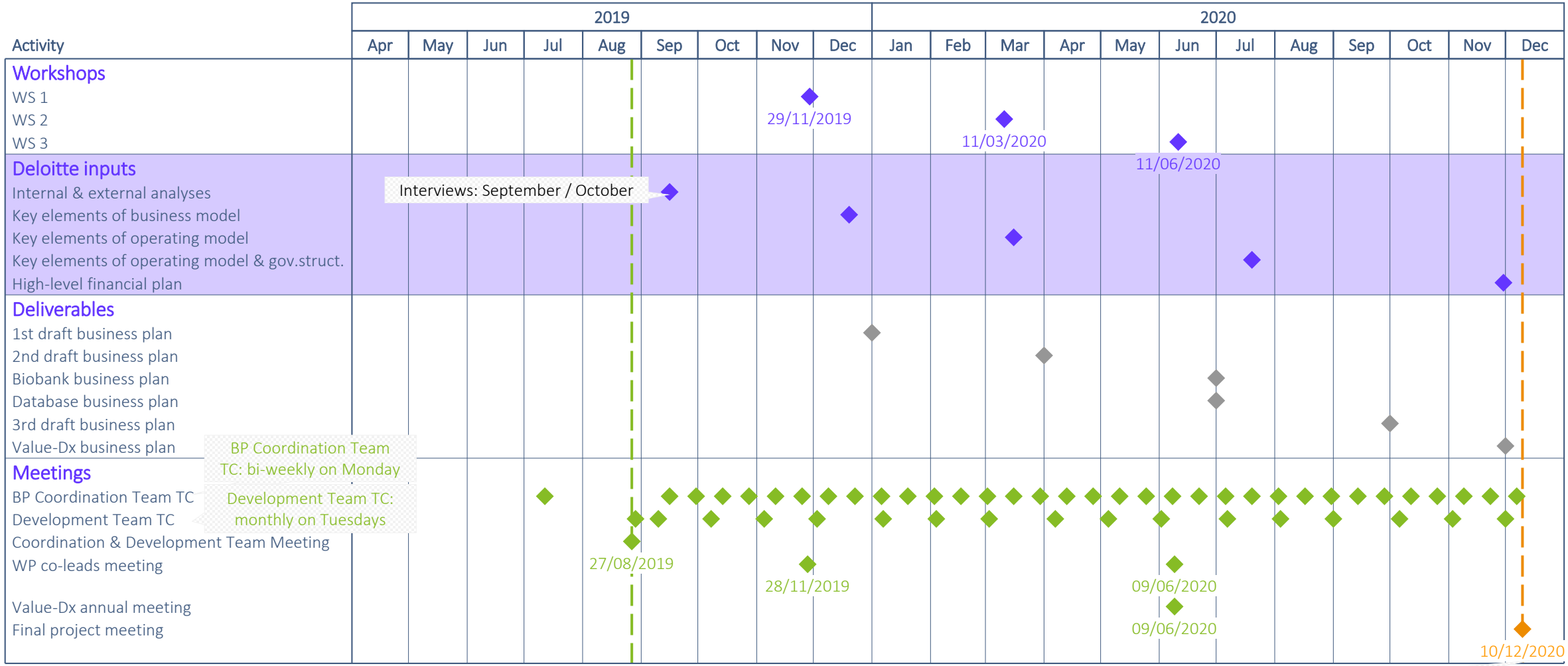
ECRAID sustainability plan

- ✓ Building an infrastructure for clinical trials of Infectious Diseases in all clinical care settings

VALUE-Dx sustainability plan

- ✓ Building an infrastructure for clinical trials and labs on diagnostics of Infectious Diseases in all clinical care settings
- ✓ Building biobank
- ✓ Building database

PROJECT TIMELINE & STATUS UPDATE



- Work in progress -

VALUE-Dx

This project has received funding from the Innovative Medicines Initiative 2 Joint Undertaking under grant agreement No 820755. This Joint Undertaking receives support from the European Union's Horizon 2020 research and innovation programme and EFPIA and bioMérieux SA, Janssen Pharmaceutica NV, Accelerate Diagnostics S.L., Abbott, Bio-Rad Laboratories, BD Switzerland Sàrl, and The Wellcome Trust Limited.

www.imi.europa.eu

www.value-dx.eu

Back-up slides

Lessons learned in COMBACTE on role of diagnostics

to aid patient enrolment in COMBACTE clinical trials with narrow spectrum drugs (4/9 intervention trials)

Unclear function and performance characteristics	How will test be used? What are required performance characteristics to aid patient enrolment?
Schism between pharma and diagnostic companies	Pharma: rapid triage test targeting limited number of organisms in a specific sample Diagnostic companies: broad range tests
Unclear exploitation	How is the test developed into labeled product? Who will pay for the test?
Regulatory blind-spots	Potential regulatory needs discussed too late and/or conflicting feed-back
Demand of pharma to perform test outside of microbiology lab	Purchasing and logistical challenges Challenges to organise, track and train Healthcare Workers Maintenance, Q-controls and test support Miscommunication between pharma, diagnostic company, micro lab, and CRO

INTERVIEWEES [1/3]

- Aim: 20 interviews max., covering **broad spectrum of interviewees that can bring different insights**
- Currently 27 interviewees selected, including:

INDUSTRY

Organisation	Interviewee name	Function	Type	Part of Value-Dx consortium?	Perspective
Abbott Diagnostics	Felicia Longobardi	EMEA Marketing Director (point of care)	Diagnostics	Yes	European
Becton Dickinson	Adam Zerda	Director, Antimicrobial Resistance Strategy and Program Development	Medical devices	Yes	Outside Europe
bioMérieux	Philippe Cleuziat	Innovation Program Senior Director; VALUE-Dx industry lead	Biotechnology	Yes	European
GlaxoSmithKline	David Payne	VP Infectious Diseases & Senior Site Leader Upper Providence (US R&D Hub)	Pharmaceutical	No	Global
Janssen Diagnostics	Jorge Villacian	Chief Medical Officer	Medical devices	Yes	Global
MedImmune (AstraZeneca)	Hasan Jafri	Clinical Lead, Serious Bacterial Infections; IMI; COMBACTE	Biotechnology	No	Outside Europe
Pfizer	Rienk Pypstra	VP GPD Anti Infectives; COMBACTE	Pharmaceutical	No	Global
Qiagen	Uwe Oelmueller	Vice President MDx Development EU Sample Technologies	Biotechnology	No	European
Roche Diagnostics	Michael Hombach	Director, Senior Global Clinical Leader Infectious Diseases, Centralised and Point of Care Solutions	Pharmaceutical	No	European
Thermo Fisher Diagnostics	Verena Murer-Waser	POC Specialist	Pharmaceutical	No	European

INTERVIEWEES [2/3]

NON-INDUSTRY

Organisation	Interviewee name	Function	Type	Part of Value-Dx consortium?	Perspective
BEAM Alliance	Marc Gitzinger	VP of the Board	Biotechnology	No	European
BBMRI-ERIC	Francesco Florindi	Strategy & Partnership Manager	Research	No	European
British In Vitro Diagnostics Association (BIVDA)	Doris-Ann Williams	Chief Executive	Hospital & healthcare	No	European
EORTC	Denis Lacombe	Director General	Clinical research	No	European
ESCMID	Evelina Tacconelli	Education Officer for Infectious Diseases and Clinical Microbiology	Hospital & healthcare	No	European
ESCMID	Jesús Rodríguez Baño	President	Hospital & healthcare	Yes	European
Foundation for Innovative New Diagnostics (FIND)	Stefano Ongarello	Head of Data Services and Biobanking	Research	Yes	European
Integrated BioBank of Luxembourg (IBBL)	Fay Betsou	Chief Biospecimen Science; Biobank database business plan task lead	Biobank	Yes	European
JPIAMR	Laura Marin	Head of Secretariat	AMR Research	No	European
London School of Hygiene and Tropical Medicine	Rosanna Peeling	Professor and Chair of Diagnostic Research	Public health	No	Global
Swiss Biobanking Platform	Sabine Bavamian	Governance Manager	Biobank	No	European
UK Biobank	Chris Boultwood	Chief Information Officer	Biobank	No	European

INTERVIEWEES [3/3]

Organisation	Interviewee name	Function	Type	Part of Value-Dx consortium?	Perspective
UMC Utrecht	Marc Bonten	Professor; COMBACTE-Net coordinator	Hospital & healthcare	Yes	European
University of Antwerp (UA) and University Hospital (UZA)	Herman Goossens	Professor; PREPARE; ECRAID-Plan and VALUE-Dx project leader	Hospital & healthcare	Yes	European
University Hospital Antwerp	Manon Huizing	Director of biobank UA-UZA	Biobank	Yes	European
Wellcome Trust	Tim Jinks	Head of Drug Resistant Infections Program; VALUE-Dx Wellcome lead	Public health	Yes	European
WHO	Francis Moussy	Leader, Diagnostics & Other Health Technologies & Focal Point for New Ebola Diagnostics	Public health	No	Global

› *Regulatory bodies will be added later on*

INTERVIEW QUESTIONNAIRE [1/2]

- Objective of interviews is to **validate infectious diseases diagnostics market characteristics and gain insights into appetite & expectations regarding Value Dx's business plan development** (especially concerning potential services to be offered)
- Interviews of 1-2 hrs. face-to-face or by TC
- Selection of questions to be asked depending on background & experience of interviewee

A. General	
A. 01	What is your role in the (infectious diseases) diagnostics market space/ecosystem?
A. 02	What are your vision, mission and strategic priorities within this space?

B. Infectious diseases diagnostics market & trends	
B. 01	Looking at the infectious diseases diagnostics market: what are its characteristics?
B. 02	What is the size of the market?
B. 03	What are market drivers and barriers? How could we overcome potential barriers?
B. 04	Who are the key players in the market? Would you say the market is rather fragmented (i.e. many small players vs. few large players)?
B. 05	What are the innovations? Anything in particular that you observe when looking at company pipelines? Do you think there is an increasing/decreasing interest to develop new diagnostics for infectious diseases?
B. 06	What are characteristics of successful diagnostics?
B. 07	What differentiates a diagnostic device or platform with broad adoption/usage from one that has a more niche application?
B. 08	Where is most added value (e.g. regulation, clinical aspect, reimbursements) created today? Do you believe that this will change towards the future?
B. 09	For which indications are most new diagnostics created? Is there an unmet need? Infections without sufficient diagnostics? Why is that the case according to you?

C. Development & commercialisation of new diagnostics	
C. 01	What would you consider as today's most important challenges (e.g. financing, market adoption, regulation) in the development of new diagnostics?
C. 02	What are the trends regarding the placement of diagnostics in other settings than today (e.g. pharmacy, supermarket, online via apps)? What is the (potential) impact of such trends on the value chain? How fast do you believe that we will see this phenomenon in Europe?
C. 03	What is the added value of the WHO pre-qualified list of diagnostics *(essential list of diagnostics vs. specific list on AMR)* relative to the CE-marking? Is there an impact on commercialisation?

D. Biobanks	
D. 01	How would you define a biobank? (e.g. infrastructure that provides service and holds collections vs. the collection itself)
D. 02	What are the challenges - if any - in finding samples of the necessary quantities and characteristics today? How do you deal with this?
D. 03	How should/can samples be shared? Who should have access? Under which conditions? What would it take for you to be willing to share 'your' samples?

INTERVIEW QUESTIONNAIRE [2/2]

D. 04	What types of interactions do you have with biobanks?
D. 05	Which services are already offered in the market to ease this process?
D. 06	Do you have any fixed contracts in place with specific biobanks?
D. 07	How would you describe the dynamic between different biobanks?
D. 08	*For the owners of databases & biobanks:* what are some of the challenges (e.g. funding, quality control, maintenance) that you face? How can these potentially be overcome?

E. Data	
E. 01	What type of data (e.g. clinical, economical) do you collect? How do you deal with this data? Which data management systems do you use?
E. 02	Openness of data: what does this mean for you? Which data should be transparent vs. be kept confidential?
E. 03	Is there a need to have access to data collected by others? Why?
E. 04	How should/can data be shared? Who should have access? What are the most important hurdles for data sharing (e.g. privacy, data quality)? What would it take for you to be willing to share 'your' data?
E. 05	How can increased use of data improve or enhance the role of diagnostics in infectious disease management?
E. 06	What is important in the governance (e.g. capturing, management, sharing) of data? What power will different stakeholders (incl. patients) have here?

F. Regulation	
F. 01	Which impact does regulation have on the development of new diagnostics? What is the regulatory process linked to the development of new diagnostics? Would you perceive it as a market barrier?
F. 02	What are the challenges with regards to regulatory aspects? (Incl. ethical issues) How do you believe these might evolve towards the future?
F. 03	To which extent do the regulatory agencies take up an active/passive role?

G. VALUE-Dx	
G. 01	To which extent are you aware of the existence of the VALUE-Dx project?
G. 02	In your understanding, which market need(s) should VALUE-Dx aim to address/provide an answer to? How could VALUE-Dx help organisations active in the ecosystem to overcome the aforementioned barriers?
G. 03	What do you see as the (potential) role for VALUE-Dx in terms of services offering? (Role as a biobank or link between biobanks? Role in data management?) Are there 'no-go' areas?
G. 04	What should Value-Dx offer in order to have researchers use its services?
G. 05	Are there unmet needs or specific indications VALUE-Dx should focus on?
G. 06	What should its geographical scope be? Is Europe broad enough?
G. 07	With this scope in mind, how would you see your interaction and role linked to VALUE-Dx?
G. 08	What are important (operational) implications for Value-Dx in its set up?

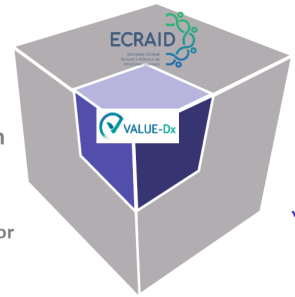
H. Miscellaneous	
H. 01	Are there any other items you would like to mention/stress that we did not discuss yet in the questions so far?
H. 02	Thinking about the scope of this project, are there any other people you would recommend us to interview?

VALUE-Dx

VALUE OF DIAGNOSTICS TO COMBAT ANTIMICROBIAL RESISTANCE & IMPROVE PATIENT OUTCOMES BY OPTIMISING ANTIBIOTIC USE, STARTING COMMUNITY-ACQUIRED ACUTE RESPIRATORY TRACT INFECTIONS

ECRAID sustainability plan

- ✓ Building an infrastructure for clinical trials of Infectious Diseases in all clinical care settings



VALUE-Dx sustainability plan

- ✓ Building an infrastructure for clinical trials and labs on diagnostics of Infectious Diseases in all clinical care settings
- ✓ Building biobank
- ✓ Building database

PURPOSE

To facilitate and accelerate the rigorous assessment and implementation of (new) diagnostic technologies into healthcare settings, by establishing the infrastructure, methods, processes and approaches needed to understand, evaluate, assess, and demonstrate the multi-faceted value of diagnostics and overcome the associated barriers to their widespread adoption and use

VISION

To transform clinical practice, improve patient outcomes, and combat AMR, through the widespread use of clinical and cost-effective innovative diagnostics strategies to achieve more personalised, evidence-based antibiotic prescription and use in community care settings, starting with CA-ARTI

OBJECTIVES

- To design a health-economic framework to assess & demonstrate the value of diagnostics
- To establish a sustainable European Standardised Care Network adequately trained and resourced to conduct clinical trials evaluating the value of diagnostics
- To design & implement clinical studies to demonstrate the value of diagnostics
- To explore, define & attempt to resolve the psychological, ethical and social barriers which prevent the more widespread adoption of diagnostics delivering healthcare to the population

CONSORTIUM PARTNERS

The Consortium Partners of VALUE-Dx *(see below)* consist of 6 in vitro diagnostic companies and 20 non-industry partners. In light of its business plan design and setup, VALUE-Dx also wants to engage with different stakeholders to ensure feedback is considered