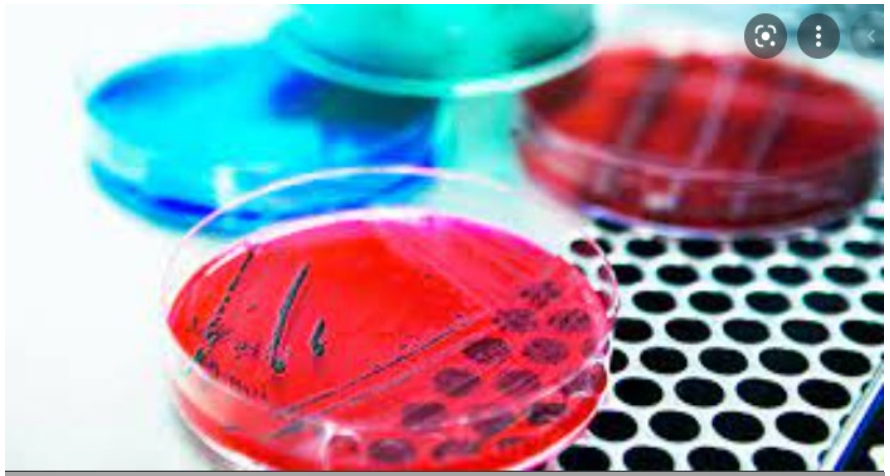
EURGen-RefLabCap Network Meeting 2021

Welcome

Wednesday, 1 December 2021

12:30 -16:00 CET



European Antimicrobial Resistance Genes Surveillane Network Reference Laboratory Capacity (EURGen-RefLabCap)
EURGen-RefLabCap supports EU networking and capacity building with-in public health reference laboratory functions for antimicrobial resistance in priority healthcare-associated infections

Funded by the European Union

Virtual Housekeeping

Please **turn off your cameras and microphones** unless you're speaking – this will help with bandwidth and maximise audibility.

Do frequently **use the chat function** to share your views, comments and challenges. Keep the chat constructive, respectful and on topic!

If you wish to make a comment for e.g. the discussion, please use the **'Raise hand'** function.

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Meeting agenda of day 1

Wednesday 1 December 2021

Introduction to the EURGen-RefLabCap project

Time		Topic	Speaker/moderator
12:30	12:40	Welcome and brush-up on the EURGen-RefLabCap project	René S. Hendriksen
12:40	12:50	Updates from HaDEA in relation to EURGen-RefLabCap	Marc Vandenbroeck Karolina Hanslik
12:50	13:00	Updates from ECDC in relation to EURGen-RefLabCap	Anke Kohlenberg
13:00	13:10	Updates from ECDC in relation to HERA Incubator	Karin Johansson
13:10	13:25	The EURGen-RefLabCap workplan incl. questions	Anders Rhod Larsen
COFFEE BREAK (20')			

Capacity of the NRLs

13:45	14:15	The 5 NRL core functions in the EURGen-RefLabCap laboratories and introduction to the break-out groups	Camilla Wiuff Coia
14:15	14:45	Break-out groups on the 5 NRL core functions	All
14:45	15:45	Feed-back from the break-out groups	Valeria Bortolaia
15:45	16:00	Questions and wrapping up the day	Anders Rhod Larsen

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René S. Hendriksen
rshe@food.dtu.dk

Welcome and brush-up on the EURGen-RefLabCap project

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Organisation of the work

Acknowledgement

Staff of the NRL for AMR at SSI
Staff of the GLO-CAB at DTU
ECDC
HaDEA
DG SANTE

Management team

Lead: Rene Hendriksen (DTU)
Deputy lead: Anders Rhod Larsen (SSI)
Project Manager: Birgitte Helwigh (DTU)



Administrative staff
at DTU

Language quality
proof-reader (DTU)

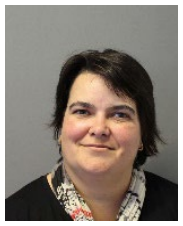
Network team

Berit Müller-Pebody (SSI)

Capacity building team

Valeria Bortolaia (SSI)
Camilla Wiuff Coia (SSI)
Lina Maria Cavaco (SSI)





Bioinformatic team

Ana Rita Rebelo (DTU)
Jette Sejer Kjeldgaard (DTU)


EQA Team

Susanne Pedersen (DTU)

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Project purpose

- **Provision of services to strengthen coordination, support and capacity in public health national microbiology reference laboratory functions for antimicrobial resistance in priority healthcare associated infections**

- Served under the Contracting Authority, the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA)
  - *From 1 April 2021, a new executive Agency with name HaDEA (Health and Digital Executive Agency) is taking over all contractual obligations from Chafea*

- The support will be implemented in coordination with the European Commission Directorate General for Health and food Safety (DG SANTE) and the European Centre for Disease Prevention and Control (ECDC)

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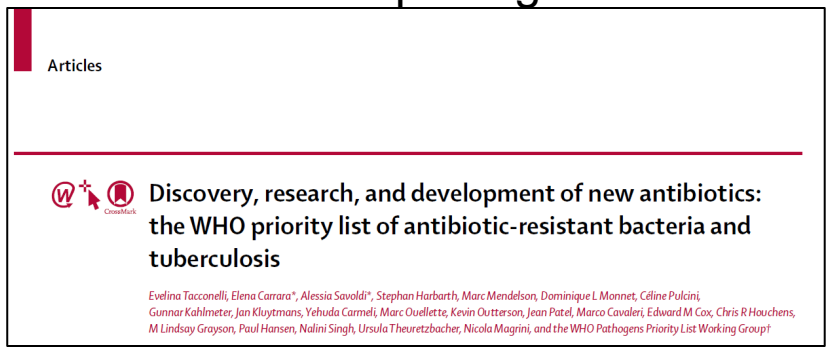
Project goals and objectives

- In a period of 4 years support will be provided to a range of training, external quality assessment (EQA) schemes and networking activities to improve public health reference laboratory functioning through improved laboratory functioning at local, regional and national levels in all countries participating in the EU health programme
  – currently EU countries plus Iceland, Norway, Bosnia Herzegovina, Serbia and Moldova

- Address antimicrobial-resistant pathogens whose predominant modes of transmission are healthcare-associated
  – carbapenem and colistin resistant *Enterobacterales*
  – two additional pathogens to be selected based on the list published in The Lancet


Articles

Discovery, research, and development of new antibiotics: the WHO priority list of antibiotic-resistant bacteria and tuberculosis

Evelina Tacconelli, Elena Carrara*, Alessia Savoldi*, Stephan Harbarth, Marc Mendelson, Dominique L Monnet, Céline Pulcini, Gunnar Kahlmeter, Jan Kluytmans, Yehuda Carmeli, Marc Ouellette, Kevin Outterson, Jean Patel, Marco Cavaleri, Edward M Cox, Chris R Houchens, M Lindsay Grayson, Paul Hansen, Nalini Singh, Ursula Theuretzbacher, Nicola Magrini, and the WHO Pathogens Priority List Working Group†

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Overall project tasks

- **Capacity building activities** provided to national reference laboratories (NRLs) for public health for the specified organisms **to improve NRLs' functions for AMR**
- **Strengthening the role of NRLs** for public health **to build capacities in regional and local laboratories** in the health systems of their countries
- **Modernisation of diagnostic and molecular typing** tests used in health systems for the specified organisms using whole genome sequencing (WGS)

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Thank you for your attention

Prof. Rene S. Hendriksen, PhD

Head of Unit, Research Group Global Capacity Building

WHO Collaborating Centre for Antimicrobial Resistance in Food borne Pathogens and Genomics

European Union Reference Laboratory for Antimicrobial Resistance

FAO Reference Laboratory for Antimicrobial Resistance

National Food Institute, Technical University of Denmark

rshe@food.dtu.dk

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Karolina Hanslik
Marc Vandenbroeck

Updates from HaDEA in relation to EURGen-RefLabCap

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EU networking and support for public health reference laboratory functions for antimicrobial resistance in priority healthcare associated infections (SC 2019 74 01)

European Health and Digital Executive Agency (HaDEA)

Marc Vandenbroeck, Project Advisor, Unit A1, Sector 002

Karolina Hanslik, Project Advisor, Unit A2, Sector 001

1 December 2021, online meeting

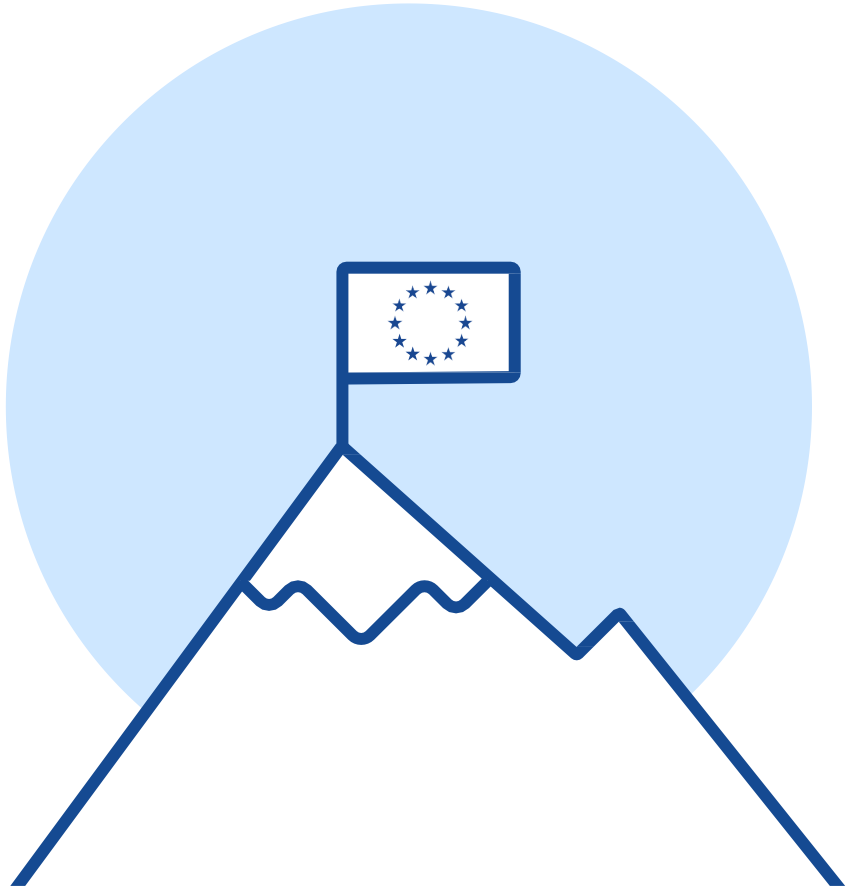
European Health and Digital Executive Agency

HaDEA is an Executive Agency

- Entrusted by the European Commission (EC) with programme implementation tasks and works that are allocated to the Agency by EC implementing decisions

- Financing instruments for funding in the form of **procurement**, **grants** and **prizes**

Our purpose



Vision

HaDEA – boosting Europe by building, from earth to space, a healthy society, a digital economy and a competitive industry.

Mission

To implement actions that strengthen Europe in the domains of **health**, food safety, digital technologies and networks, industrial capacities and space.

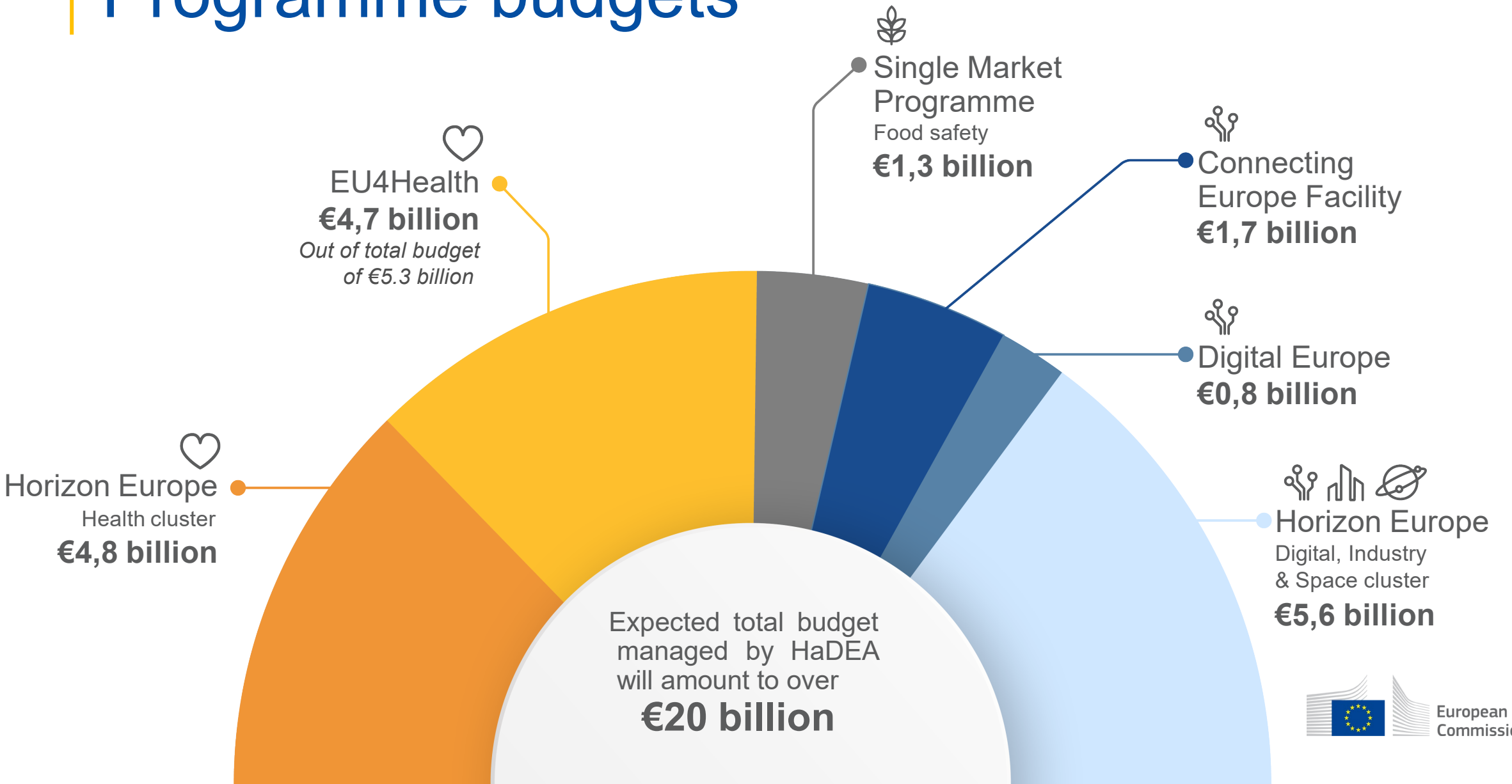
We ensure that the projects funded by the HaDEA deliver **concrete results** that benefit the lives of all EU citizens and provide the European Commission with valuable input for its policies.

European Commission

HaDEA is an Executive Agency

- Established on 16/02 /2021 to implement parts of the following Union programmes:
  - EU4 Health programme
  - Single Market Programme: Food Safety
  - Horizon Europe, Pillar II, cluster 1: Health
  - Connecting Europe Facility: Digital
  - Digital Europe Programme
  - Horizon Europe, Pillar II, cluster 4: Digital, industry and space
- Based in Brussels
- Health Staff (units at HaDEA)

Programme budgets



European Commission

EU Health Programmes

- Community action programme in the field of health **2003-2007 - EUR 312 million**
- 2nd Community action programme in the field of health **2008-2013 - EUR 321,5 million**
- 3rd Union action programme in the field of health **2014-2020 - EUR 449 million**
- **EU4Health programme 2021 – 2027 – EUR 5,3 billion**

HaDEA: the way we work with the Contractor

In this contract, a joint collaboration in place:

- **HaDEA**: contract and tasks' **execution**: contracts deliverables, timelines, meetings, finances, payments
- **DG SANTE**: policy **implementation**
- **ECDC**: content **collaboration**

AMR: an EU policy priority

- EU AMR Action Plan 2017: “EU a best practice region in the world”
  - improve AMR detection in the human health sector by providing EU support for networking collaboration and reference laboratory activities;
- Commissioner Kyriakides’s mission letter: AMR is a key priority in public health
- Decision 1082/2013: preparedness and response to serious cross-border health threats, including AMR
- EU Health Programme
- NEW: EU Health Union: proposal for EU Reference Laboratories in human health

AMR – SC 2019 74 01

- Support to MSs and other countries participating in the EU Health program / surveillance data / AMR
- Role of the PA in the **monitoring** of the **implementation** of the service contract
  - 4 years' duration
  - 2 different workstreams with specific tasks
  - Intermediate outputs and deliverables (linked to reporting / task-specific)
  - Meetings (kick-off meeting, progress and intermediate meetings, workshops, etc…)

Thank you

Your questions?

European Commission

What we expect?

- **Strengthened capacity** across the EU to detect resistant infections
  - By identifying gaps and needs for further capacity
  - By providing tailored support to priority countries in need
  - By providing training and hands-on direct support
  - By supporting whole genome sequencing analytic methods
  - By strengthening the networking of national reference labs across the EU
- High-levels of whole genome sequencing capacity across the EU
- Strengthened surveillance of antimicrobial resistance across the EU
- Strengthened preparedness to respond to outbreaks

Anke Kohlenberg

Updates from ECDC in relation to EURGen-RefLabCap

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Karin Johansson

Updates from ECDC in relation to HERA Incubator

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Genomics-based support activities implemented by ECDC under HERA Incubator action area 1: Rapid detection of SARS-CoV-2 variants

Karin Johansson, Microbiology and Molecular Surveillance Group, Public Health Functions Unit, ECDC

EURGen-RefLabCap network meeting, 1 December 2021

The EU Health Emergency Preparedness and Response Authority (HERA)

- As part of the EU Health Union proposals of 11 November 2020, the European Commission proposed to set up a EU Health Emergency Preparedness and Response Authority (HERA)
  - Goal: to enable the EU and its Member States to rapidly deploy the most advanced medical and other counter measures, to ensure capacity and readiness to respond to cross-border threats and emergencies
  - Address gaps revealed by COVID-19 and previous serious cross-border threats to health, such as the flu pandemic H1N1 in 2009
  - Complement and create synergies with the work of existing EU Agencies, in particular ECDC and EMA

- On 16 September 2021, the European Commission put forward a legislative proposal for HERA

HERA Incubator and Action Area 1

- In preparation of the formal establishment of HERA, several preparatory actions were launched in 2021 to serve as a blueprint for the EU's long term preparedness for health emergencies, and to pilot some of the aspects that will be covered by the new Authority
- On 17 February, the Commission launched 'HERA Incubator', a new EU bio-defence preparedness plan against SARS-CoV-2 variants
- HERA Incubator focuses on five specific action areas:
  1. Rapid detection of SARS-CoV-2 variants
  2. Swift adaptation of COVID-19 vaccines (investments in research and innovation)
  3. Setting up a European Clinical Trials Network (VACCELERATE)
  4. Fast tracking the regulatory approval process
  5. Ramping up industrial production of COVID-19 vaccines against variants of concern

- On 25 February, President Ursula von der Leyen announced that the EU would provide EUR 200 M to strengthen detection of variants and improve knowledge on how they are developing and spreading, under Action Area 1. More specifically, this funding would be used to invest in:
  - Whole genome sequencing (WGS), both shorter-term support for access to high-capacity WGS services, and longer-term support for national investments into WGS infrastructure for the public health laboratories as well as cross-border networking activities such as bioinformatics, standardisations, and training
  - In case of need, ensuring the swift development and deployment of specialised RT-PCR assays that are able to detect VOCs
  - Wastewater surveillance as a complementary data tool

WGS and RT-PCR support activities in 2021 under HERA Incubator action area 1

- *Shorter-term support:* **Access to high-capacity WGS services** in a commercial laboratory (external contractor)

- *Medium-term support:* Cross-border capacity-building support programme for **bioinformatics training, twinning and WGS and RT-PCR standardisation**

- *Medium-to-longer term support:* Infrastructure support programme to **develop and/or enhance national WGS and RT-PCR infrastructure**

Outsourced WGS support

- Immediate sequencing capacity is provided to EU/EEA countries and Western Balkans through access to a WGS service contract with an external contractor

- Services include shipping of RNA samples, cDNA synthesis, sequencing and basic bioinformatics

Cross-border capacity-building support programme

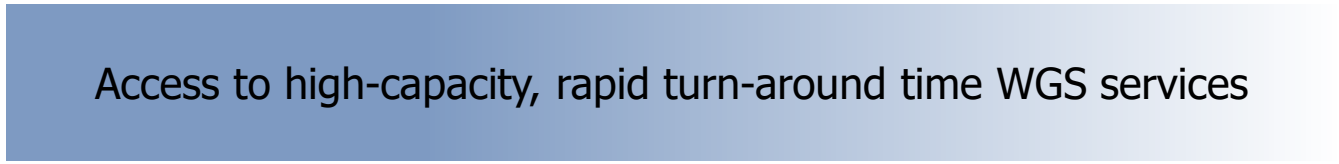
- Capacity-building activities should include:
  - Laboratory support activities
  - Laboratory and bioinformatics training activities, including support to twinning
  - WGS and RT-PCR quality assurance and standardisation activities
  - RT-PCR assay development and validation

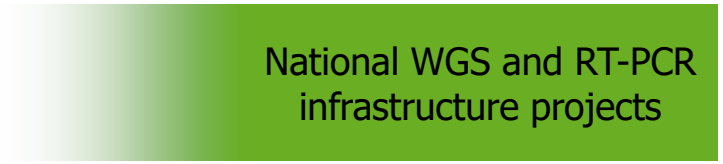
National infrastructure support programme

- Aim: Supporting activities via the award of grants for action that directly lead to enhanced and/or improved national public health WGS and/or RT-PCR capacity
  - Implemented as call for proposals to enable a bottoms-up approach where countries specify their needs and the proposed solutions at the national level
  - Reimbursement rate 90% of the eligible costs, i.e. each country needs to finance 10% of the included activities
  - Equipment purchase costs: Not normally eligible for reimbursement under such grants, but costs exceptionally fully eligible due the nature of the programme

- On 3 September 2021, ECDC allocated 77.1 M to 24 national projects

Overview of ECDC-led activities under HERA Incubator action area 1 (2021-2024)





Wastewater surveillance

- Also part of HERA Incubator Action Area 1, but responsibilities for activities delegated to Joint Research Centre (JRC) instead of ECDC

- JRC is coordinating network of national initiatives on wastewater surveillance

- Agreement to support collaboration between initiatives, initially by sharing contact information between national HERA Incubator WGS grants and national wastewater surveillance initiatives

Questions?

Anders Rhod Larsen
arl@ssi.dk

The EURGen-RefLabCap workplan

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Aims

- The work plan aims at

"extending the current ECDC networking and technical support activities to further enable: exchange of information and good practice between NRLs in participating countries on core NRL activities; and to develop and disseminate guidelines, standards, training materials; external quality assessment (EQA) exercises; and other activities to be proposed in the tender offer" (as set out in Call for Tenders Chafea/2019/Health/09, task 1.e).

..and was developed to meet the overall aim:

To strengthen laboratories' capabilities and capacities to detect and effectively prevent and control spread of CRE and CCRE in healthcare settings at local and national level, across Europe and globally

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Workplan All countries

- Engage network members
- Provide technical support
- Facilitate shared learning and exchange of best practice

- Consultation on the work plan with HADEA and ECDC
- Shared with all participants to comment on
- Feedback is very welcome – you can use the shared template

#	Country and organisation	Page no.	Comments	Proposed changes	Outcome (to be completed by the EURGen-RefLabCap contractors)
1					
2					
3					

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Priority and non-priority countries

Distribution of the 37 countries that participated in the questionnaire. Identified **Priority Countries** (n=14): --- Other countries included in the **Third EU Health Programme** (n=18): --- Countries **not included in the Third EU Health Programme** (n=5): ---

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Mapping of current phenotypic testing and molecular/genomic methods for AMR prediction and strain typing used in the NRLs for CCRE

- Review of existing evidence
  - Capacities for national surveillance and outbreak investigations
  - Guidance documents and bioinformatic initiatives for WGS based surveillance methods
- Survey on phenotypic and genotypic methods used at the NRLs for CCRE typing and the five core functions of NRLs.

- 14 countries were invited to become priority countries
  - Individual consultations with the 14 selected priority countries
  - ..meeting tomorrow afternoon

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Deliverables and overall tasks for all participating countries

	TASK DESCRIPTION	DEADLINE
T3.2	Mapping of current phenotypic testing and molecular/genomic methods for AMR prediction and strain typing used in the NRLs for CCRE.	Oct 2021
T3.3	Proposed common WGS-based genome analysis methods and standard protocols for national CCRE surveillance and integrated outbreak investigations.	Dec 2021
T3.4	Agreed common WGS-based genome analysis methods and standard protocols for national CCRE surveillance and integrated outbreak investigations.	Feb 2022
T2.1	Report of mapping and evaluation of regional and local laboratory capacity carried out by the NRLs in the network.	April 2023
T3.6	Training plan including activities for all network members.	Jun 2022
T3.7	Guidance document on 'internal QC schemes' including local quality management systems.	Jun 2022
T3.8	Plan for 'ring trials' including EQA and benchmarking of national bioinformatics pipelines for WGS-based CCRE resistome profiling and high-risk clone/plasmid identification.	Jun 2022
T4.5	Mapping of current molecular/genomic methods for AMR prediction and strain typing used in the NRLs for WS2 pathogens.	Aug 2022

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Common WGS-based genome analysis methods and standard protocols for national CCRE surveillance and integrated outbreak investigations

- Network Meeting Session tomorrow
  - Presentation of review of existing WGS initiatives and bioinformatic tools
  - Breakout rooms to discuss proposals for harmonized protocols for molecular surveillance of CRE/CCRE and outbreak detection
- Webinar to present the results of the survey on WGS-based methods January 2022
- Agreed common WGS-based genome analysis methods and standard protocols for national CCRE surveillance and integrated outbreak investigations, February 2022

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Mapping and evaluation of regional and local laboratory capacity

Aim: To identify strength and weaknesses as a basis for further national capacity building activities

- Webinar to present aims of the mapping survey and possible evaluation criteria of regional and local laboratory capacity, **March 2022**
- Online workshop for training in the use of the EUSurvey tool, **April 2022**
- Online workshop for training in interpretation and dissemination of data obtained using the EUSurvey tool
- Conduct survey and analyze the results
- Support from EURGen-RefLabCap: Know-how, activities, technical and finansial

- Report in local language + English summary, Template will be provided. **April 2023**

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Guidance document on *'internal QC schemes'* including local quality management systems

- Internal QC schemes to ensure high quality in clinical laboratories and NRLs

- Webinars to present the most critical points to develop, implement and maintain an internal quality management system
- Consultancy services on local internal quality management systems on request
- Video conference/presentation at a network meeting to share best practice on internal quality control schemes
- Sharing of experiences with QC schemes
- Guidance document on *'internal QC schemes'* including local quality management systems. **June 2022**

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Training plan including activities for all network members

- Physical technical training workshop on WGS based AMR detection
- Virtual multidisciplinary training to resolve a CCRE outbreak scenario using simulation exercises
- Webinars on scientific topics of interest and/or country presentations on CCRE
- Others….

- Finalized June 2022

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'Ring trials' , EQAs and benchmarking

- EQA/benchmarking of national bioinformatics pipelines for WGS-based CCRE resistome profiling and high-risk clone/plasmid identification

- Three EQAs are planned
  - Sequence (Dec. 2022)
  - DNA (Dec. 2023)
  - Bacterial samples (Dec. 2024)

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Selection of Workstream 2 pathogens

- Short Survey for WS2 pathogen to be decided by the NFPs
  - MRSA
  - VRE
  - Carbepenem and /or colistin resistant *P. aeruginosa*
  - Carbepenem and /or colistin resistant *Acinetobacter baumanii* complex

Discovery, research, and development of new antibiotics: the WHO priority list of antibiotic-resistant bacteria and tuberculosis

Evelina Tacconelli, Elena Carrara, Alessia Savoldi*, Stephan Harbarth, Marc Mendelson, Dominique L Monnet, Céline Pulcini, Gunnar Kahlmeter, Jan Kluytmans, Yehuda Carmeli, Marc Ouellette, Kevin Outterson, Jean Patel, Marco Cavaleri, Edward M Cox, Chris R Houchens, M Lindsay Grayson, Paul Hansen, Nalini Singh, Ursula Theuretzbacher, Nicola Magrini, and the WHO Pathogens Priority List Working Group†*

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Number of planned activities for all participating countries by type (month 9 – month 48).

TYPE OF ACTIVITY	NUMBER OF ACTIVITIES
Network meetings for all network members	3
Physical training workshops	2
Virtual training workshops	2
EQA trials	5
Virtual multidisciplinary training: outbreak simulation exercises	5
Webinars*	13 (10)
Video conference*	11 (6)
Consultation via E-mail	10
Surveys	3
Bespoke consultancy	Ad hoc

*Numbers in brackets indicate the number of webinars and video conferences supporting specific activities (e.g. EQA and simulation exercises)

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Thank you for your attention

Questions?

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Coffee break

Back at 13:45.

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Camilla Wiuff Coia
cmwi@ssi.dk

The 5 NRL core functions in the EURGen-RefLabCap laboratories and introduction to the break-out groups

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RESULTS FROM THE QUESTIONNAIRE ON PUBLIC HEALTH LABORATORY CAPACITY FOR CRE AND CCRE (SUMMER 2021)

Provision of EU networking and support for public health reference laboratory functions for

AMR in priority healthcare-associated infections

Service contract no. SC 20197401

Funded by the European Union

Camilla Wiuff Coia: cmwi@ssi.dk

BACKGROUND

- Publicly available reports (by ECDC, WHO, EC, national institutes) on National Reference Laboratory (or equivalent) functions for AMR and more specifically CRE and CCRE were reviewed by SSI/DTU (May 2021)
- Available up-to-date information differed greatly between countries
- For many indicators of capacity there was no information available at country-level

- It was concluded that there was a need to obtain **comparable and up-to-date information** on NRL capacity for CRE and CCRE in the **37 EURGen-RefLabCap countries** as:
  - Many reports dated back from 2018
  - AMR awareness is rising globally and new national policies and strategies have been developed in recent years
  - Implementation of WGS is underway across the world

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TO ALL THE COORDINATORS!

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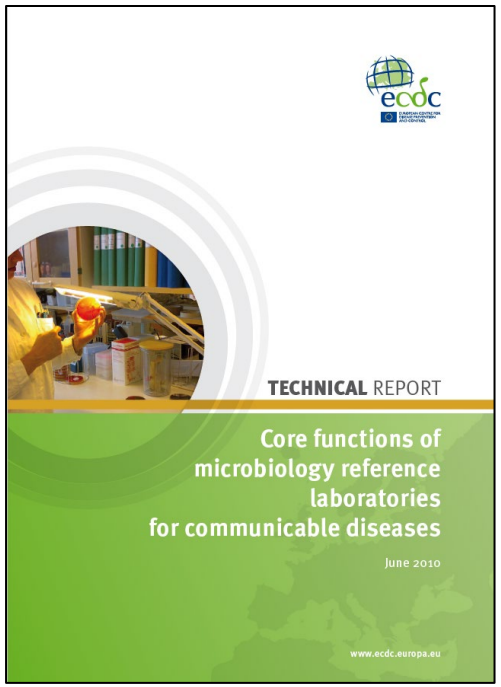
EURGEN-REFLABCAP QUESTIONNAIRE – SUMMER 2021

- The questionnaire was completed by the coordinators in all 37 countries in July-September 2021
- It addressed the **5 National Reference Laboratory** (NRL) **core functions** as defined by ECDC:



1. **Reference diagnostics***
2. **Reference material resources**
3. **Scientific advice**
4. **Collaboration and research**
5. **Monitoring, alert and response***

- Additional information was collected on: the NRL setup, epidemiological stage and rating of training activities
- Answers were analysed for each country. Particular importance was given to **i) availability of WGS for CRE/CCRE reference diagnostic functions** and ii) **CRE/CCRE monitoring, alert and response set-up in the countries**.

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CATEGORIES OF QUESTIONS

REFERENCE DIAGNOSTICS

REFERENCE MATERIAL RESOURCES

SCIENTIFIC ADVICE

COLLABORATION AND RESEARCH

MONITORING, ALERT AND RESPONSE

NRL PROVISION

EPIDEMIO-LOGICAL STAGE

RATING OF THE IMPORTANCE OF SUGGESTED ACTIVITIES

The questions were aimed at **gaining more detailed and up-to-date information on the current situation** in each of the participating countries in order to **plan the activities of the entire network** and to identify a **number of priority countries**

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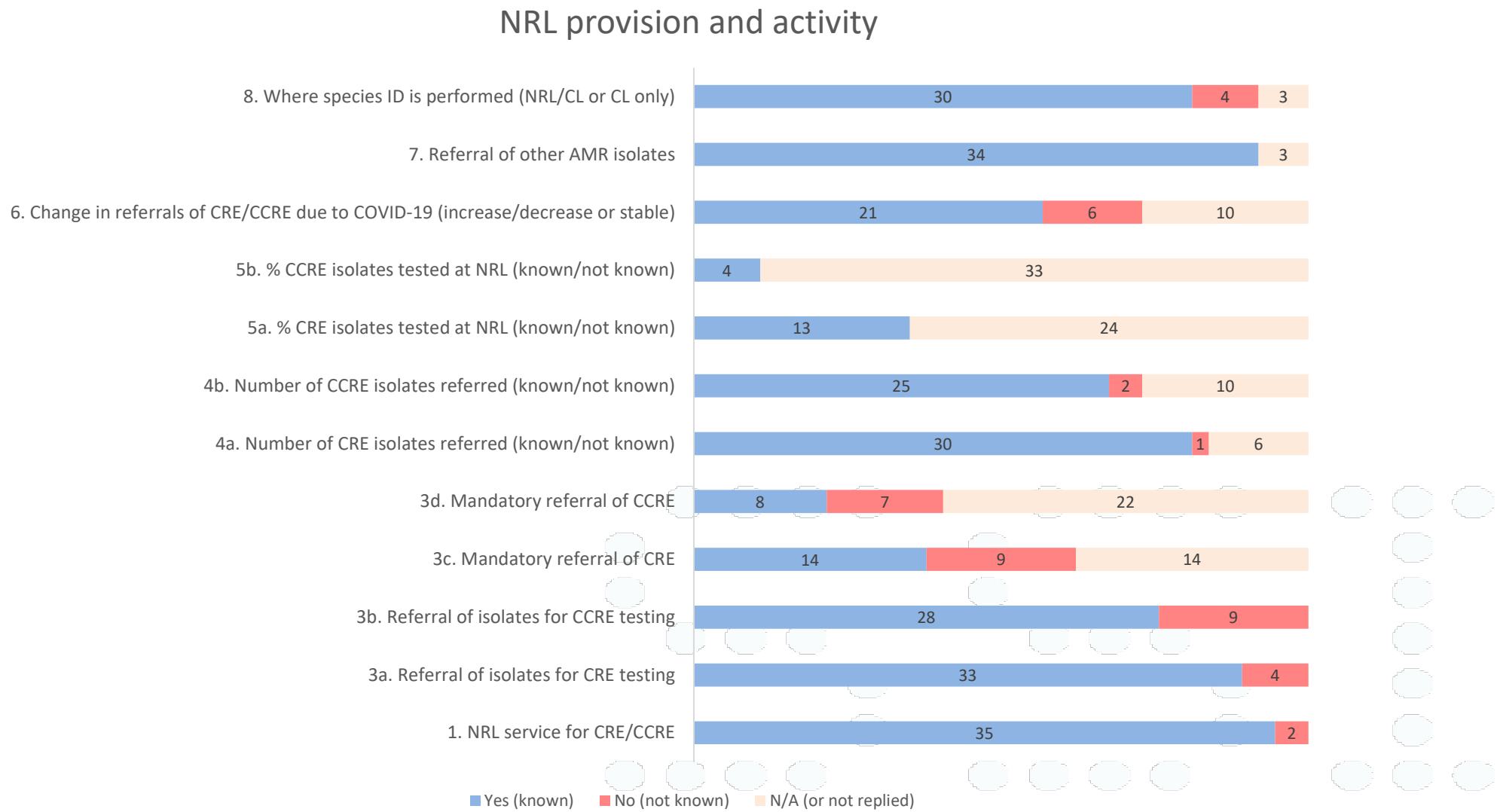
NRL PROVISION AND ACTIVITY

NRL PROVISION



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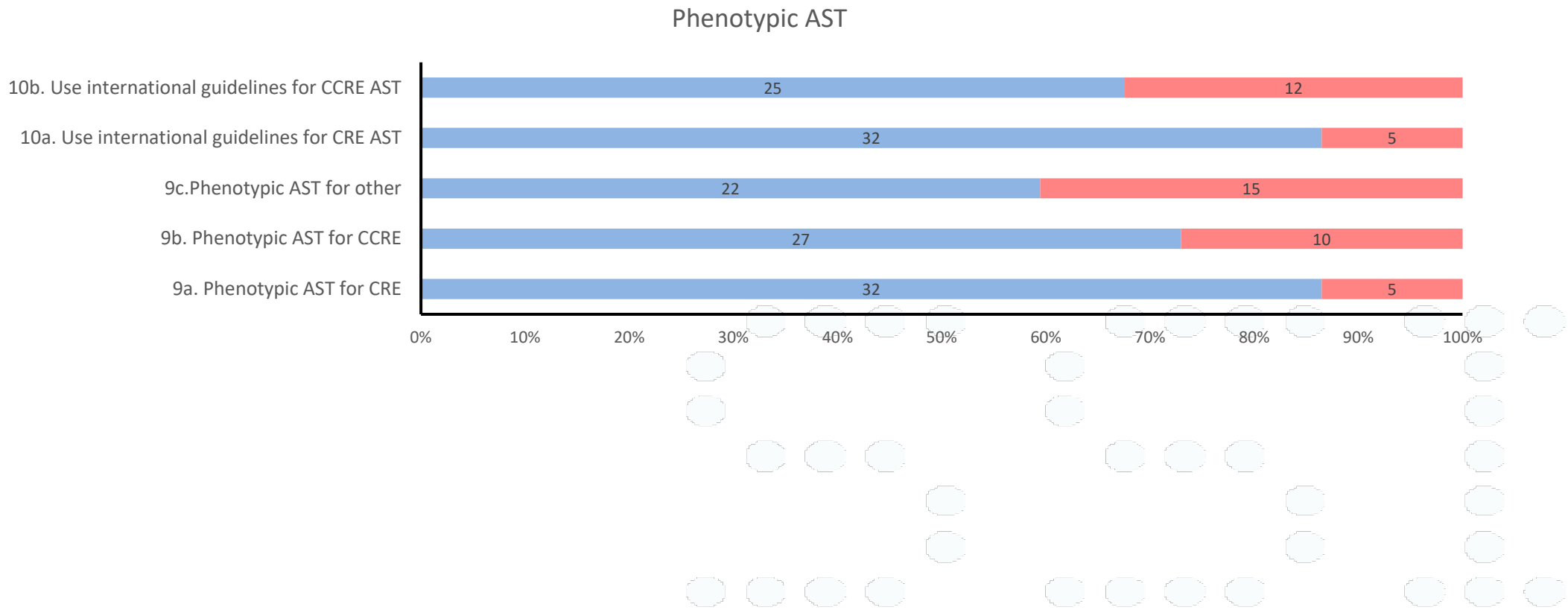
PHENOTYPIC ANTIMICROBIAL SUSCEPTIBILITY TESTING (AST)

REFERENCE DIAGNOSTICS



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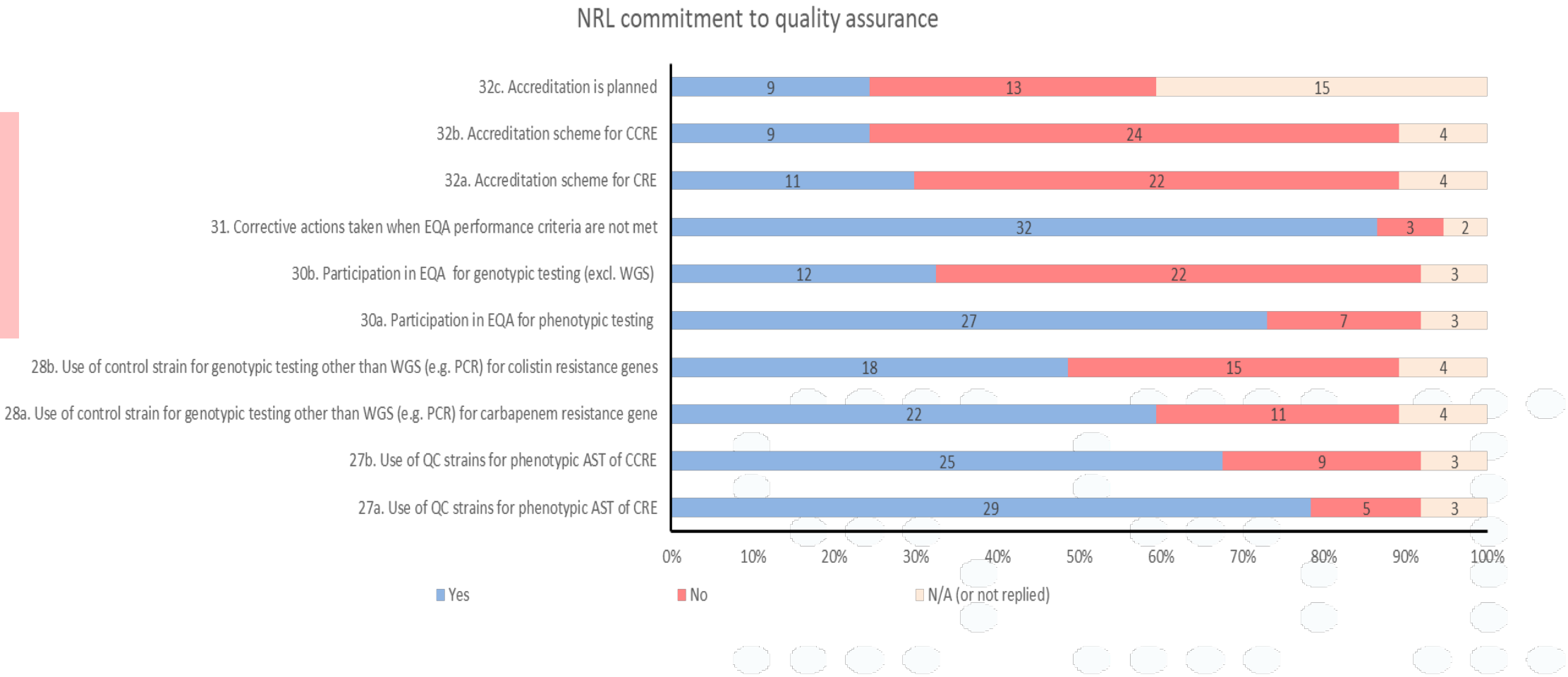
COMMITMENT TO QUALITY ASSURANCE

REFERENCE DIAGNOSTICS



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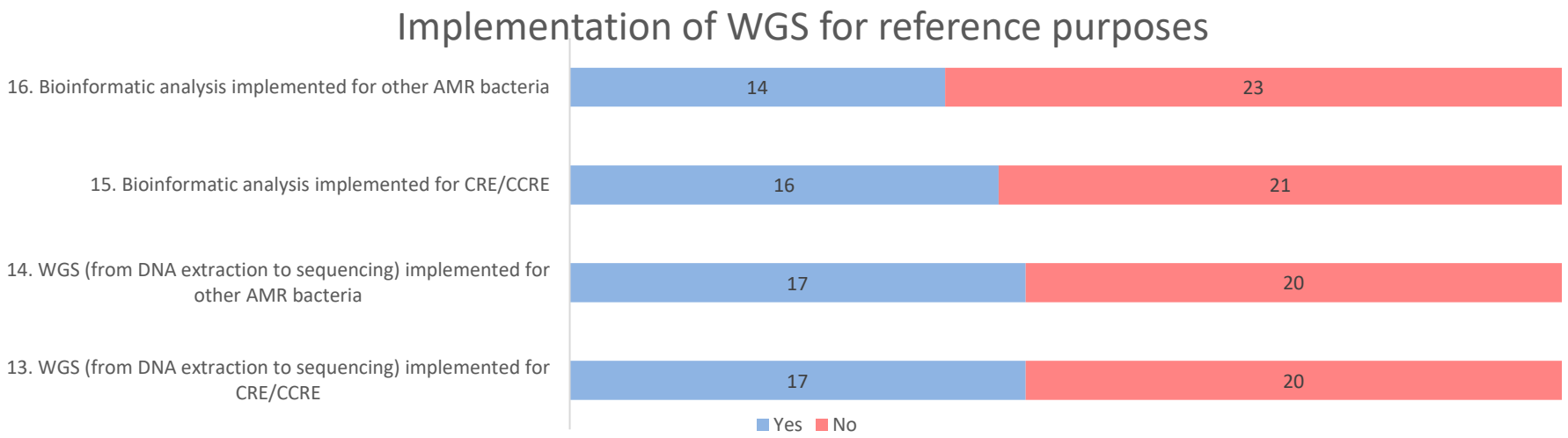
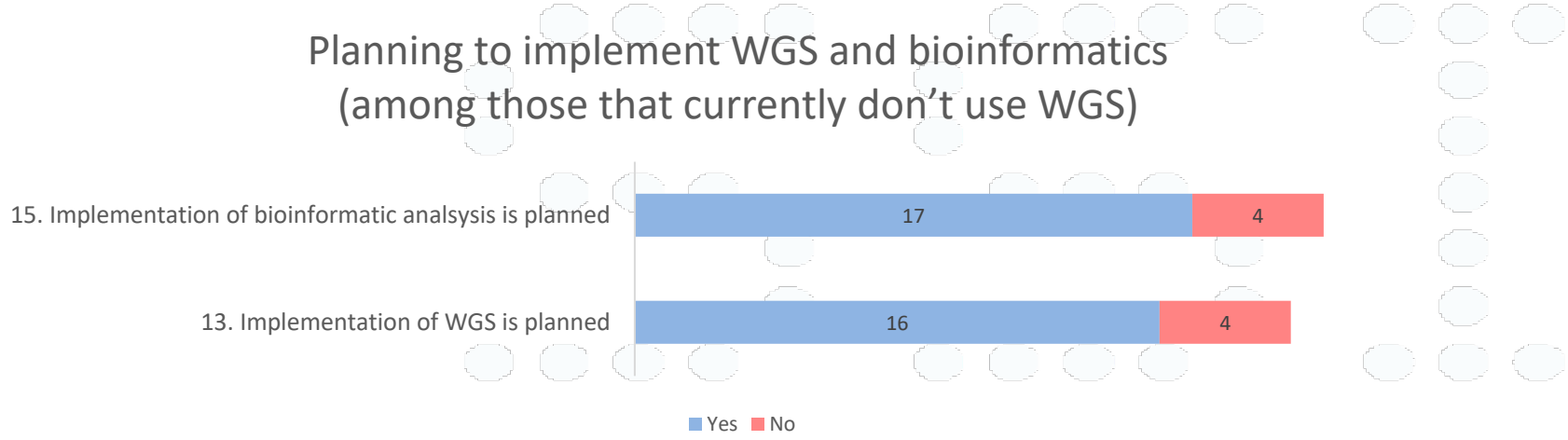
IMPLEMENTATION OF WGS FOR SURVEILLANCE AND OUTBREAK DETECTION

REFERENCE DIAGNOSTICS





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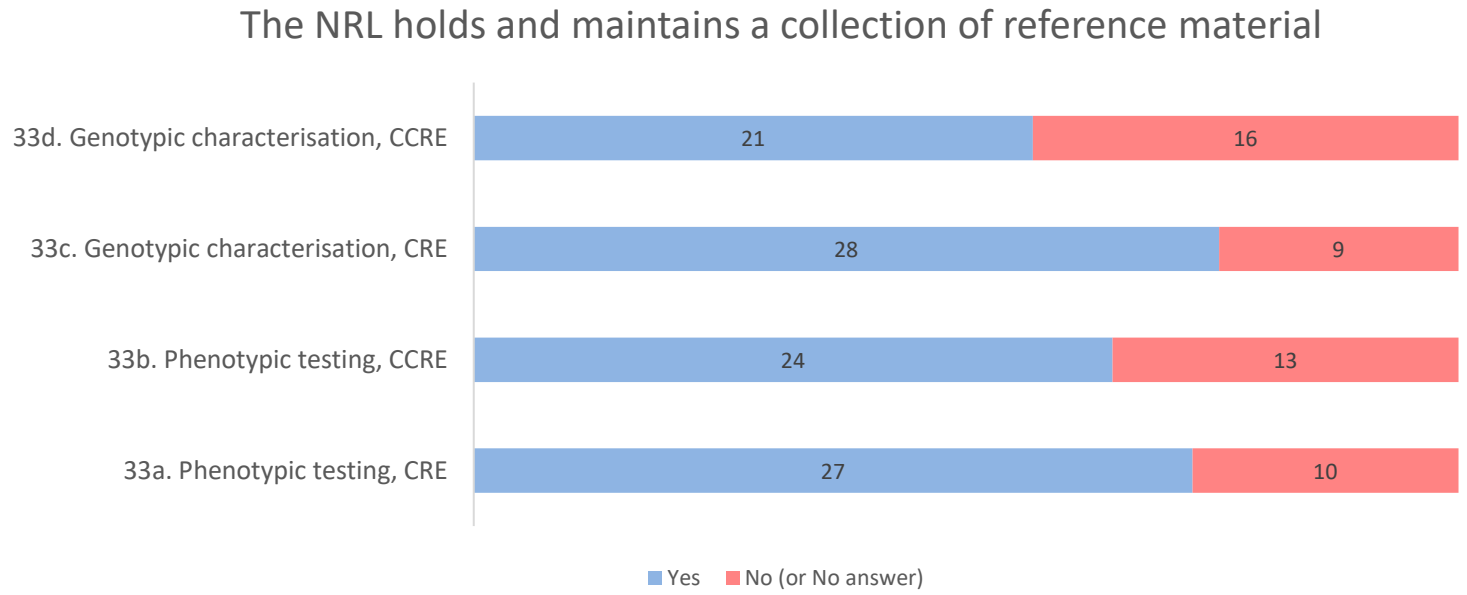
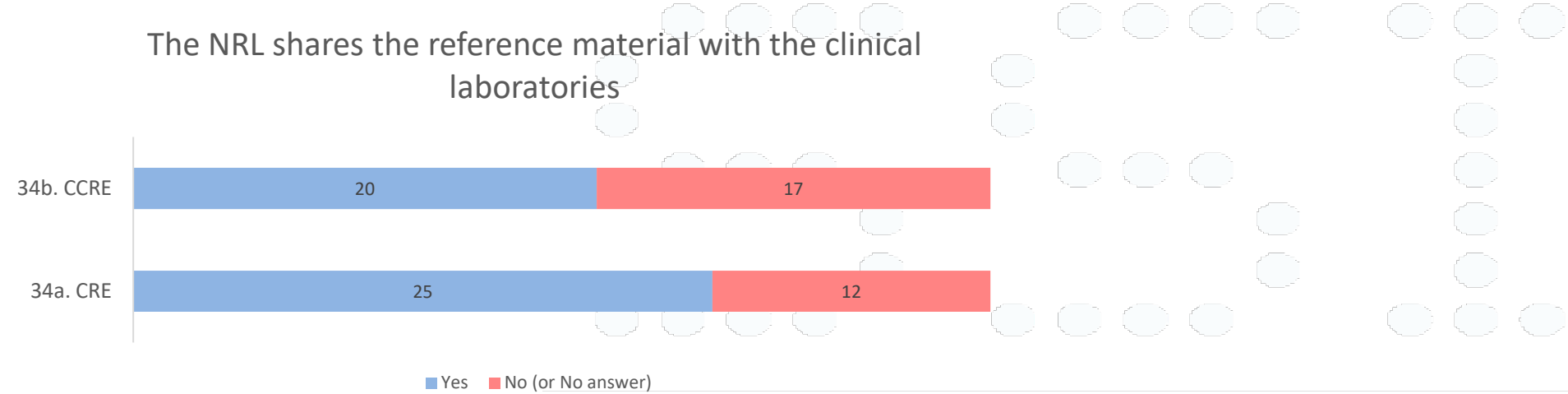
REFERENCE MATERIAL RESOURCES

REFERENCE MATERIAL RESOURCES





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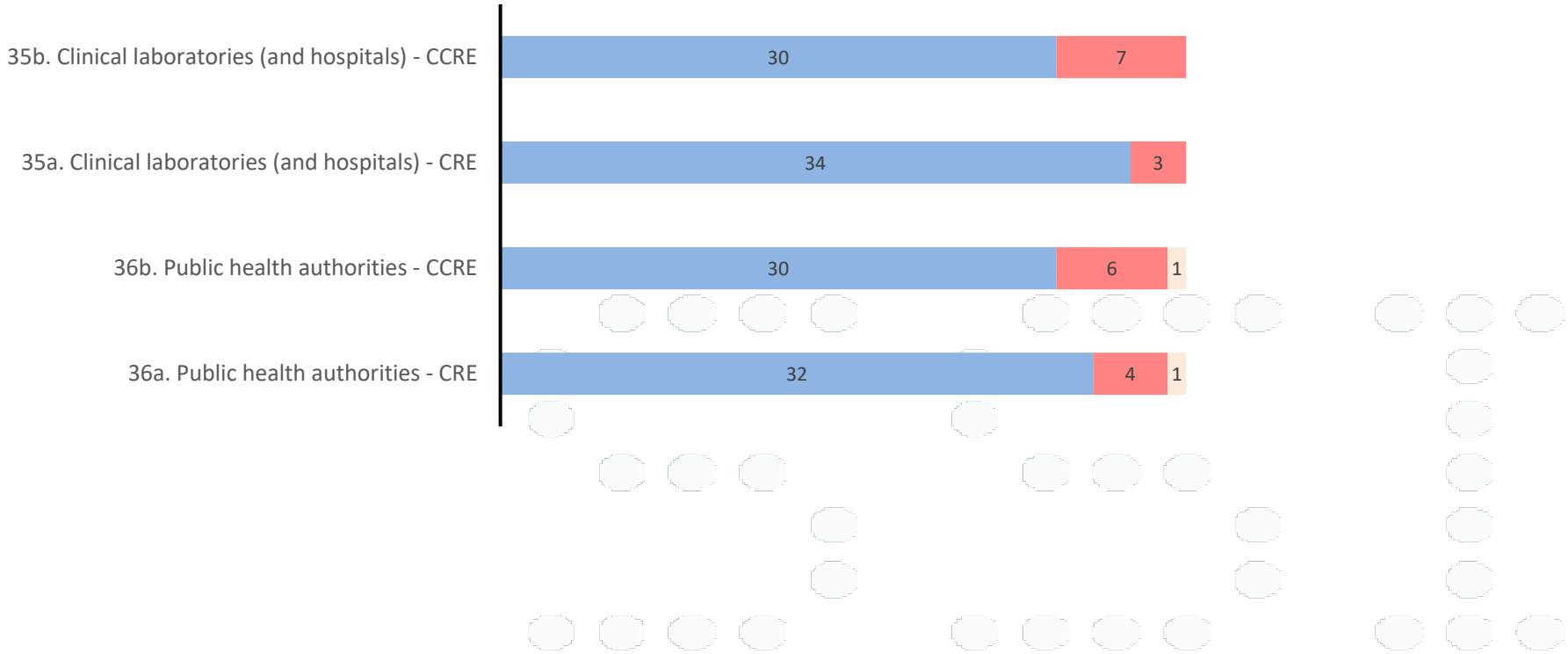
PROVISION OF SCIENTIFIC ADVICE

SCIENTIFIC ADVICE

The NRL provides scientific advice for interpretation and relevance of laboratory findings to:



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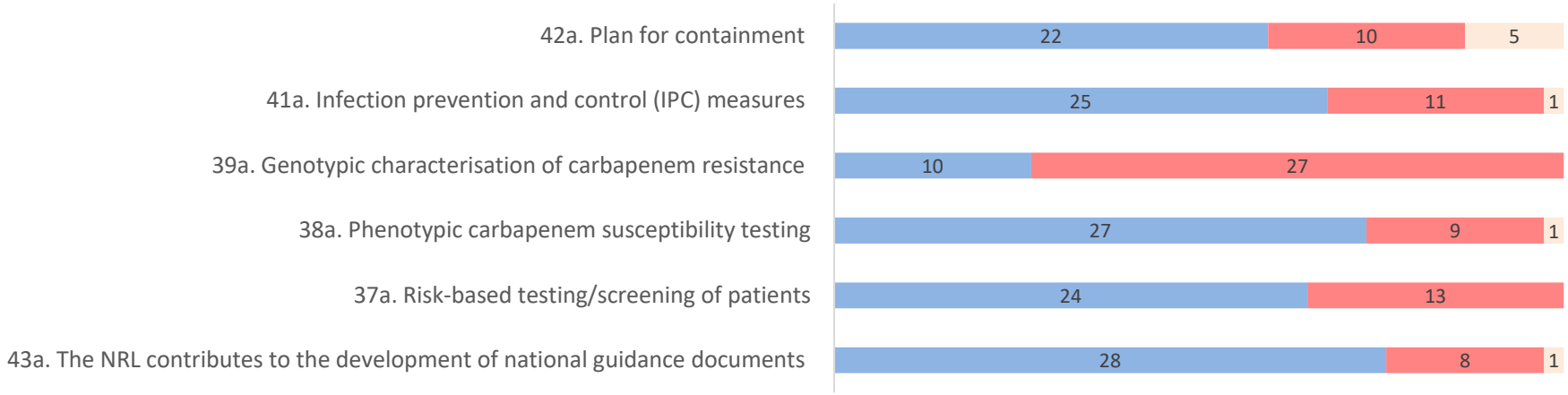
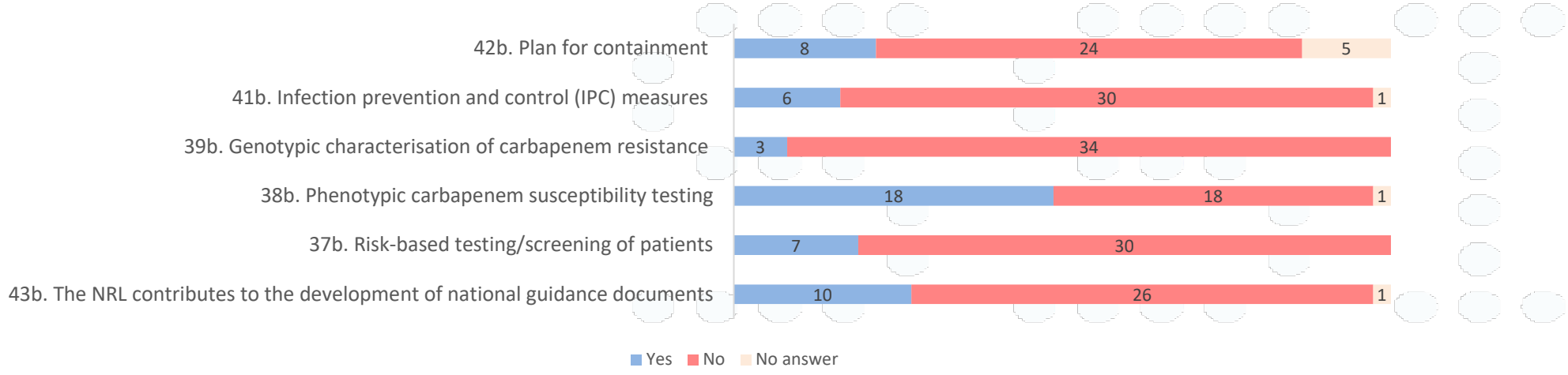
AVAILABILITY OF NATIONAL GUIDANCE DOCUMENTS

SCIENTIFIC ADVICE

Availability of national guidance documents for CRE



Availability of national guidance documents for CCRE



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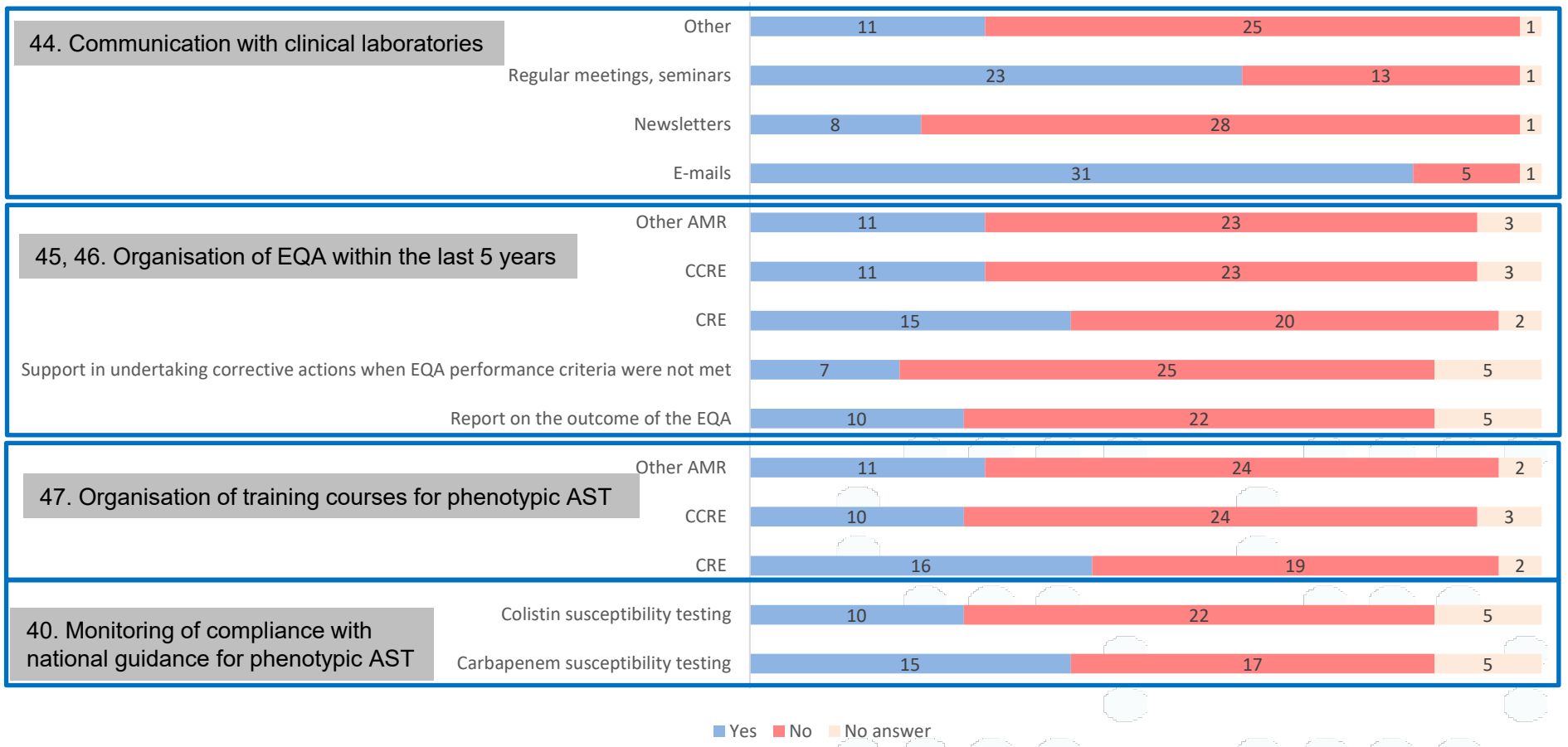
COMMUNICATION OF ADVICE, ORGANISATION OF EQA AND TRAINING OF COLLEAGUES IN CLINICAL LABORATORIES

SCIENTIFIC ADVICE

Activities organised by the NRL for clinical laboratories in the national network



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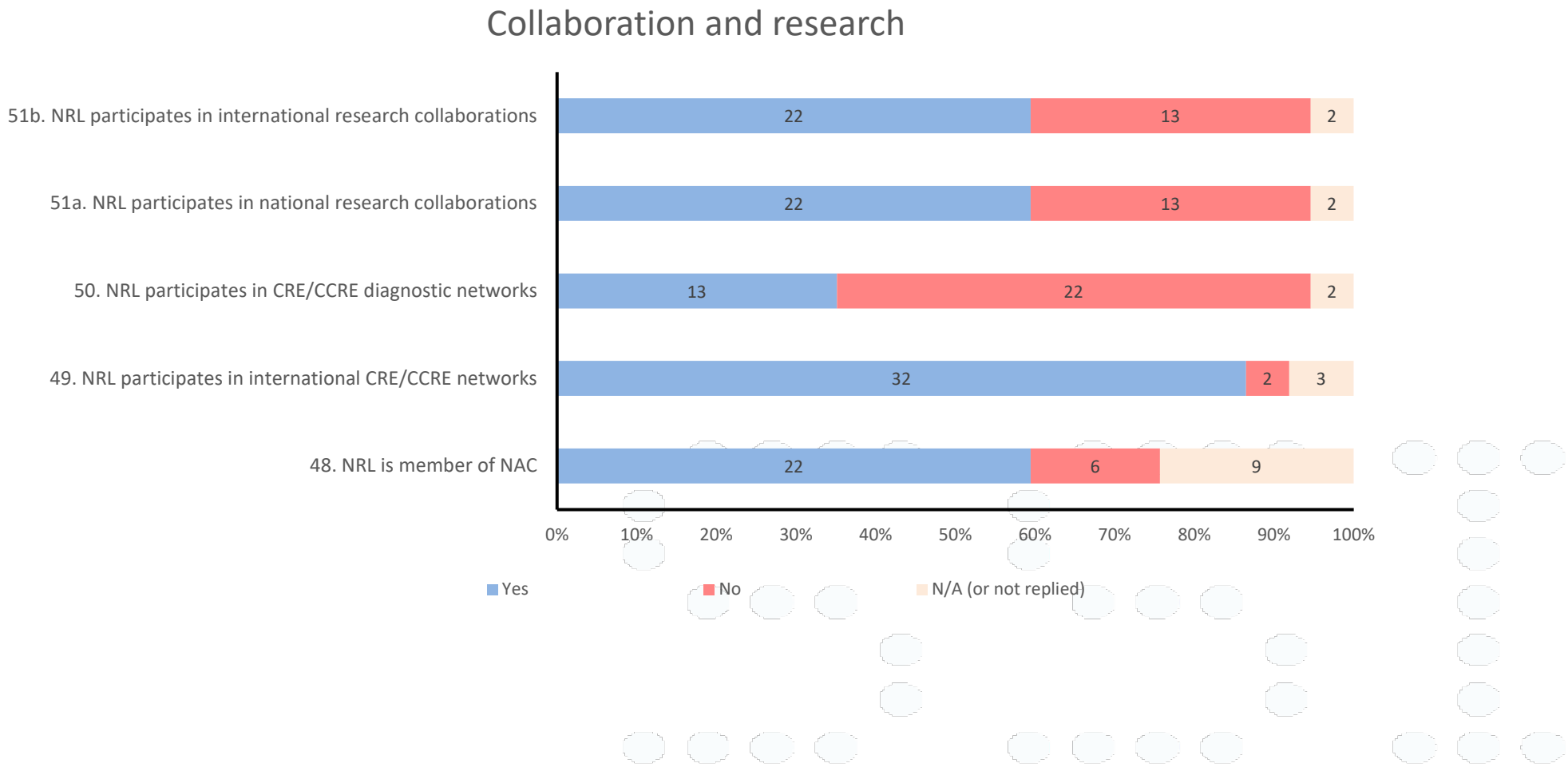
COLLABORATION AND RESEARCH

COLLABORATION AND RESEARCH



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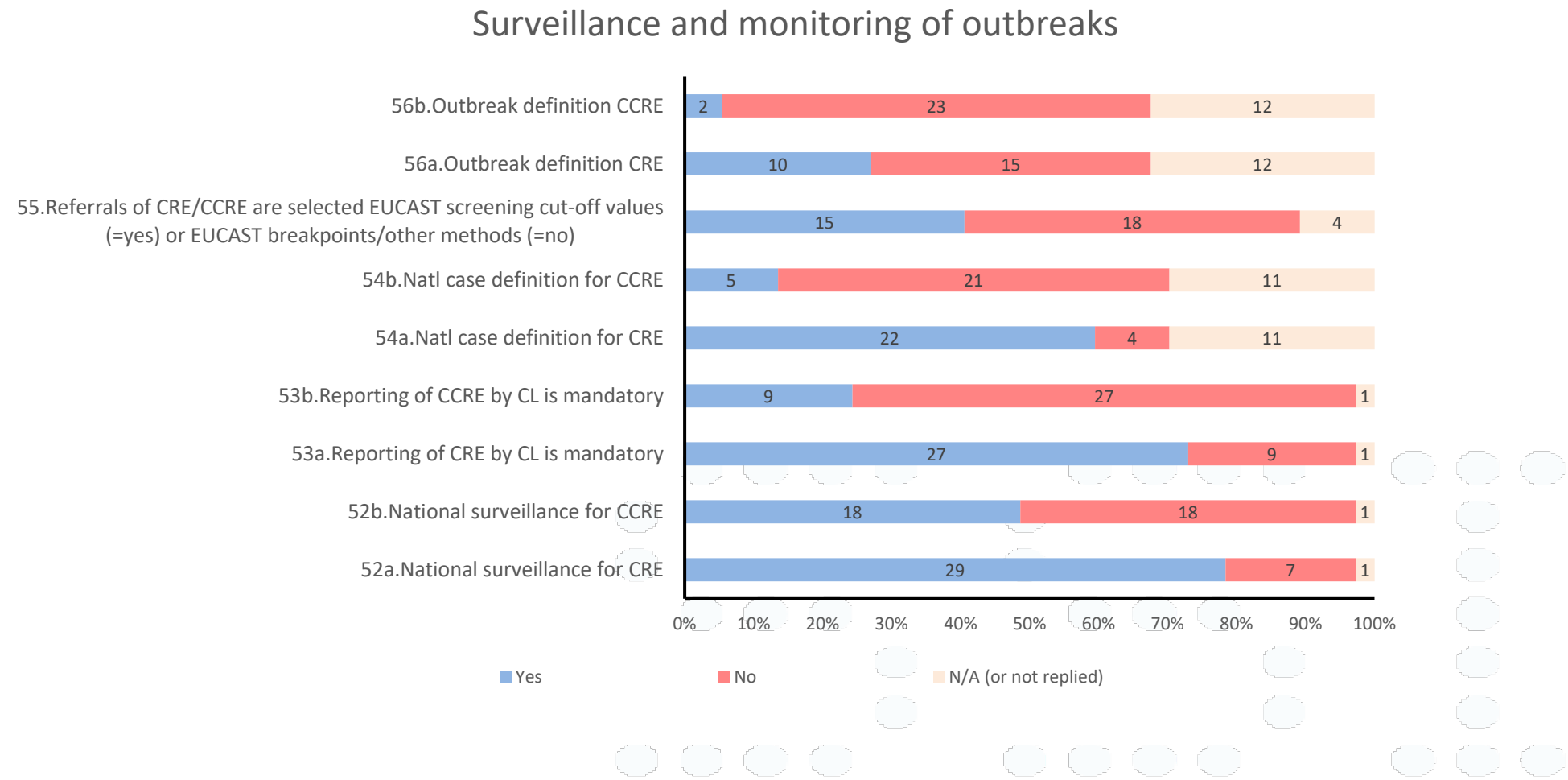
MONITORING, ALERT AND RESPONSE

MONITORING, ALERT AND RESPONSE



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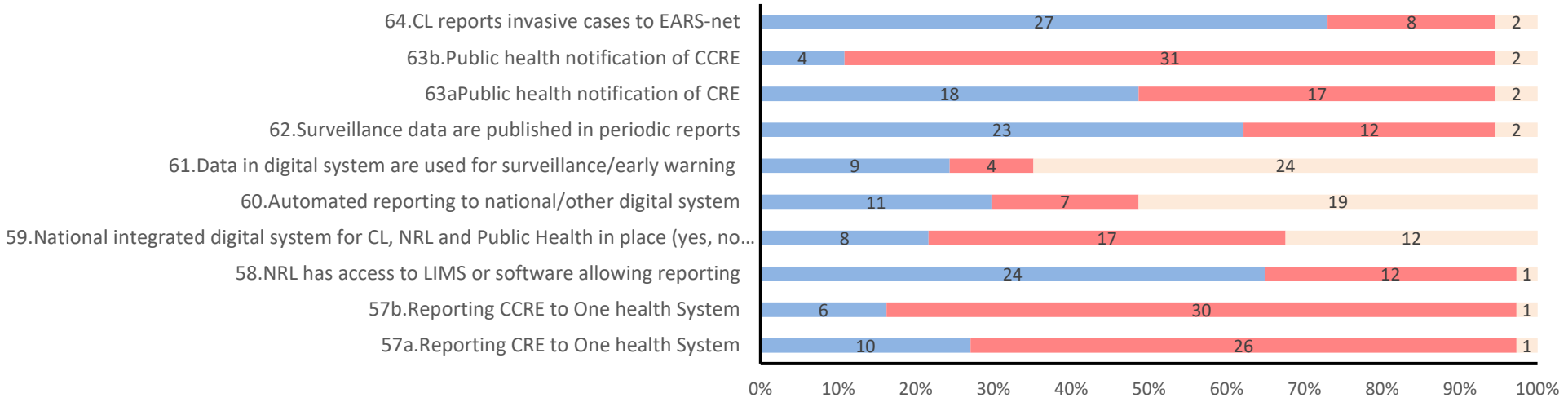
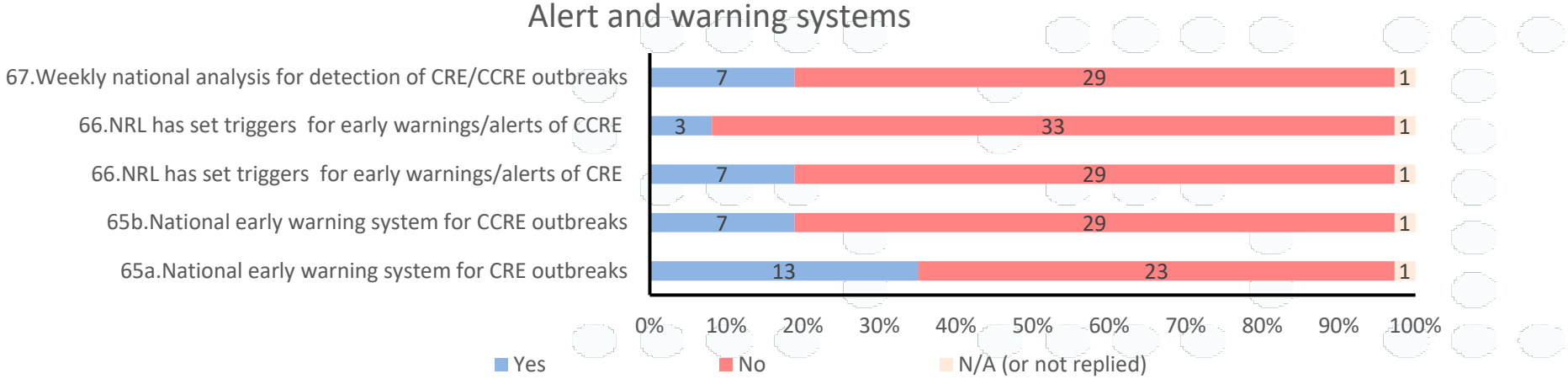
MONITORING, ALERT AND RESPONSE

MONITORING, ALERT AND RESPONSE

Surveillance data collection and reporting



Alert and warning systems



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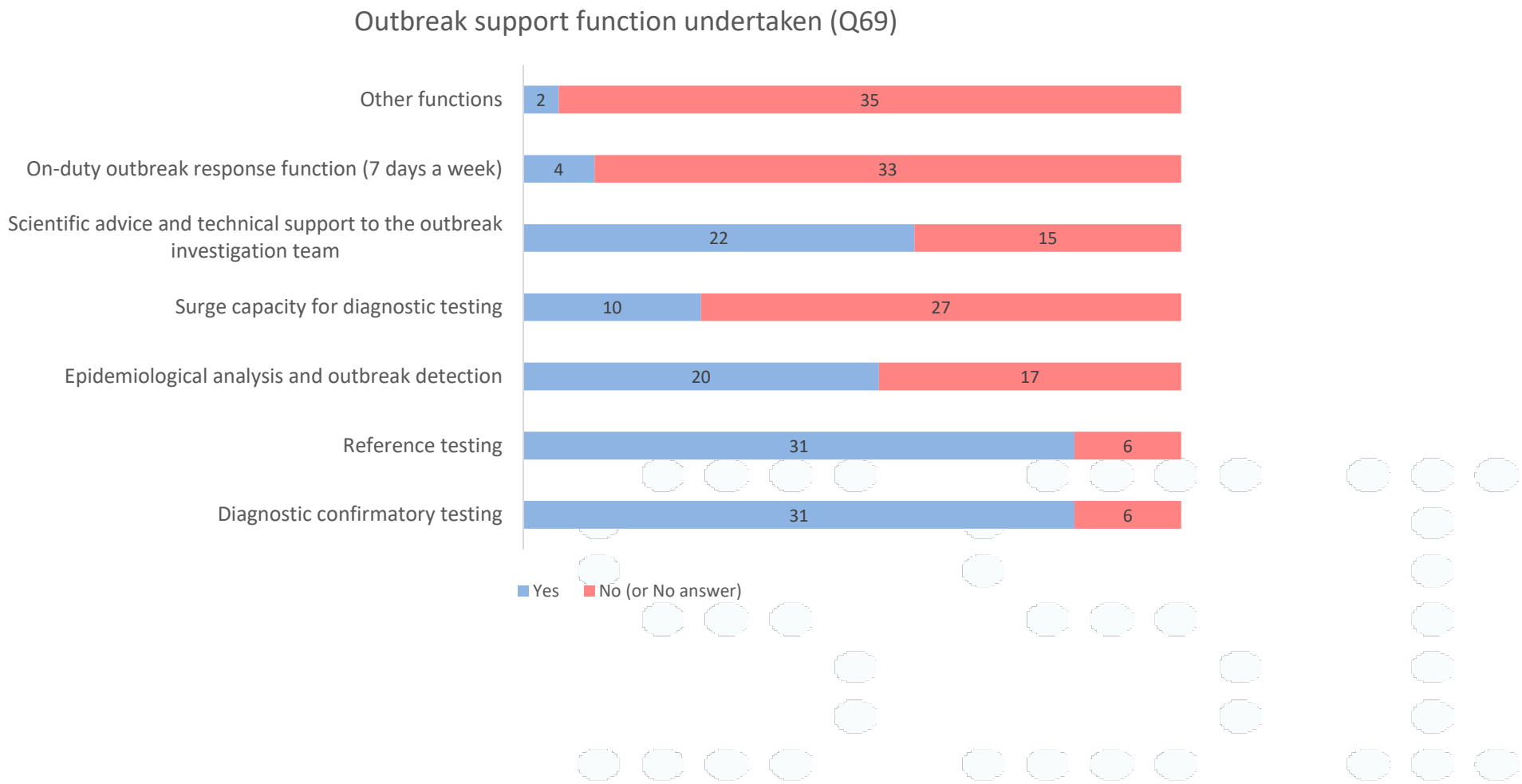
OUTBREAK SUPPORT FUNCTIONS PROVIDED BY THE NRL

MONITORING, ALERT AND RESPONSE



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EPIDEMIOLOGICAL STAGE: CRE

EPIDEMIO-LOGICAL STAGE

Epidemiological stage - CRE	Number of countries	Countries
Stage 0 – no cases reported	0	---
Stage 1 – sporadic occurence	3	---
Stage 2a – single hospital outbreak	3	---
Stage 2b – sporadic hospital outbreaks	2	---
Stage 3 – regional spread	5	---
Stage 4 – inter-regional spread	9	---
Stage 5 – endemic situation	7	---
Information not available	8	---

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EPIDEMIOLOGICAL STAGE: CCRE

EPIDEMIO-LOGICAL STAGE

Epidemiological stage - CCRE	Number of countries	Countries
Stage 0 – no cases reported	1	---
Stage 1 – sporadic occurence	12	---
Stage 2a – single hospital outbreak	0	---
Stage 2b – sporadic hospital outbreaks	0	---
Stage 3 – regional spread	1	---
Stage 4 – inter-regional spread	2	---
Stage 5 – endemic situation	2	---
Information not available	19	---

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SUMMARY OF THE QUESTIONNAIRE RESULTS

REFERENCE DIAGNOSTICS

- All but two countries had ”NRL/expert” services set up for CRE/CCRE (referrals systems varied).
- There was variation in the **commitment to quality assurance** for phenotypic and genotypic methods.
- **20 countries had not yet implemented WGS-based NRL services** – 16 countries had plans of implementing WGS in the near future.

SCIENTIFIC ADVICE

- Scientific advice on the interpretation of laboratory results was frequently provided by the NRLs, **but there were gaps in the availability of national guidance on laboratory testing, IPC measures, containment plans** etc.
- **Gaps in NRLs outgoing/outreaching expert functions** towards the clinical labs in their countries (e.g. organisation of EQA, training activities on methodologies, proactive communication, compliance monitoring on AST).

MONITORING, ALERT AND RESPONSE

- National surveillance and public health notification of CRE/CCRE were in place in many countries - but more often for CRE than for CCRE.
- NRLs in 12 countries did not report their data periodically in reports to their users – **surveillance data are for action!**
- **Gaps in NRLs having national ”early warning systems”** and **weekly analysis of national data** - This leads to a risk of outbreaks developing without being detected nor controlled.
- **Gaps in public health response functions** (NRL preparedness, outbreak investigation and support, response duty)

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INTRODUCTION TO THE VIRTUAL BREAK-OUT SESSION 1
WEDNESDAY 1 DECEMBER

https://opensource.christmas/2019/24

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BREAK-OUT SESSIONS

- **Purpose**
- The breakout sessions have been designed to give the participants an opportunity to interact, inspire each other in overcoming challenges and share best practice.

- **Instructions**
- Participants have been divided in **groups** and assigned **specific topics for breakout session 1** on 1 December **and breakout session 2** on 2 December.

- Each group has also been assigned a **moderato**r, who will facilitate the active contribution of all participants in the group and clarify questions, if needed.
- Each group has been assigned a **reporter,** who will summarize the content of the discussion within their group during the session in plenary (in front of the other groups) in maximum 5 minutes.

- The discussion within each group will be captured in a written **summary**, **which will be shared with the EURGen-RefLabCap network** after the meeting. This document will be important to identify common challenges and solutions and share good practice between the participating countries.

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BREAK-OUT GROUPS

	Countries	Reporters (from the national coordinators' group)	Moderators (from the contractors' group)
Group 1	---	---	Jette Kjeldgaard
Group 2	---	---	Ana Rita Rebelo
Group 3	---	---	Camilla Wiuff Coia
Group 4	---	---	Berit Müller-Pebody
Group 5	---	---	René S. Hendriksen
Group 6	---	---	Anders Rhod Larsen
Group 7	---	---	Valeria Bortolaia
Group 8	---	---	Lina Cavaco

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GROUP WORK - SCHEDULE

- You will now join the ”**break-out virtual room”** with the group you have been assigned to (approx 45 minutes),
- At 15:00 you will be transferred back to the ”**virtual plenary session”** with all the participants,
- The Reporters will give a summary of the key points discussed in their groups (maximum 5 minutes per group),
- After the two Reporters (on the same set of questions) have presented their key points. The discussion will be opened up to everybody in the ”room”.

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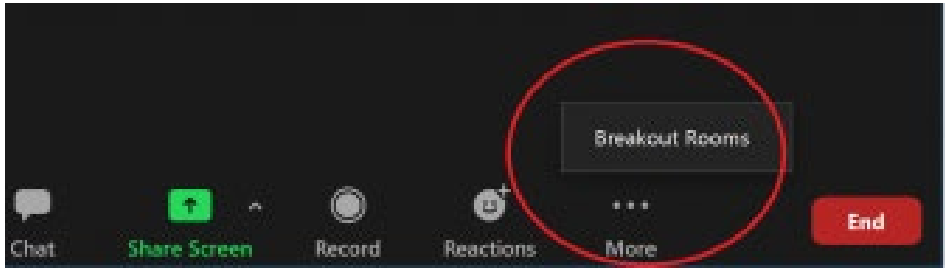
Break-out session 1



Please join your respective break-out session room now.

The session ends at 15:00.

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Valeria Bortolaia
vabo@ssi.dk

Feedback from the break-out groups

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The Reporters are presenting the key points from their groups

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THE QUESTIONS – GROUP 2 AND 5
IMPLEMENTATION OF WGS-BASED NRL SERVICE – AIMS AND BENEFITS

Implementation of WGS-based NRL service – aims and benefits – GROUP 2 and 5

- **1. Please outline a <u>strategic aim</u> to the provision of WGS-based reference laboratory services.**
  - Describe "WHY" we need to implement WGS at the NRL.
  - What are the service needs?
  - What are the desired outputs and impacts?
    - *For example: improve quality in reference testing, provide timely and accurate outbreak detection, etc*.

- **2. Please describe your experiences with WGS in the NRL so far, including benefits and challenges.**
  - What works well?
  - What does not work so well?
  - What would you have done differently if you were to implement WGS today?

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THE QUESTIONS – GROUP 3 AND 4
IMPLEMENTATION OF WGS-BASED NRL SERVICE – AIMS AND BENEFITS

- **1. Please list the benefits and desired impacts of implementing WGS in the national reference laboratory (NRL or equivalent) services?**
  - Describe benefits in a measurable way in terms of quality of service, health benefits, financial/operational benefits.

- **2. Please list the options and the respective pros and cons for implementation of WGS in the NRL services in your countries.**
  - In broad terms, options are:
    - Do nothing
    - Do limited amount (add on limited range of cases)
    - Do large amount (major part of core activities)
  - Describe 2 or more alternative options of WGS-based reference laboratory service setup
  - And then describe the possible organizational setups of WGS-based reference laboratory services

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THE QUESTIONS – GROUP 7 AND 8
NRL CAPACITY FOR MONITORING, ALERT AND RESPONSE

NRL role preparedness
NRL has defined roles and responsibilities described and tested in exercises as part of the national preparedness and response plan for health threats due to epidemic prone/high consequence pathogens
Roles and responsibilities may be described in relation to clinical laboratories, hospitals, community settings, etc.

NRL role in outbreak investigation
Functions such as diagnostic confirmatory testing, reference testing, epidemiological analysis and outbreak detection, surge capacity for diagnostic testing, scientific advice and technical support
Percentage of outbreaks investigated at the national level for which NRL personnel participated as a member of the outbreak investigation team and undertook

NRL 24/7 response duty
NRL has trained personnel available for assistance in outbreak teams at national level

1. How would you describe the capacity of your NRL in relation to the above-mentioned indicators?

2. What are the obstacles that prevent your NRL in fulfilling some of the roles in outbreak investigation as listed above?

3. What is needed to overcome these obstacles?

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THE QUESTIONS – GROUP 1 AND 6
NRL CAPACITY FOR SCIENTIFIC ADVICE

1. Please indicate if the NRL in your country has actively contributed to the development of any of the following guidelines, and if not, please explain the reasons :

- National guidance on testing/screening of patients for CRE
- National guidance on phenotypic antibiotic susceptibility testing (AST) of CRE
- National guidance on molecular characterisation of CRE
- National guidance on infection prevention and control measures for patients with confirmed CRE in healthcare settings
- National plan for containment of CRE
- Other areas

2. Risk-based testing/screening of patients for CRE/CCRE could be done in different situations. Which situations are included in the national guidance in your country?

Situations included in the national guidance could, for example, be: admission to hospital, same-day surgery, outpatient investigations and treatments, outbreak in healthcare facilities, outbreak in other facilities, etc.

- **Does the NRL also test isolates from situations not included in the national guidance and/or referred without specific criteria but based, for example, on clinical laboratory decision?**

3. What are the reasons for inclusion and/or exclusion of any of the situations mentioned above?

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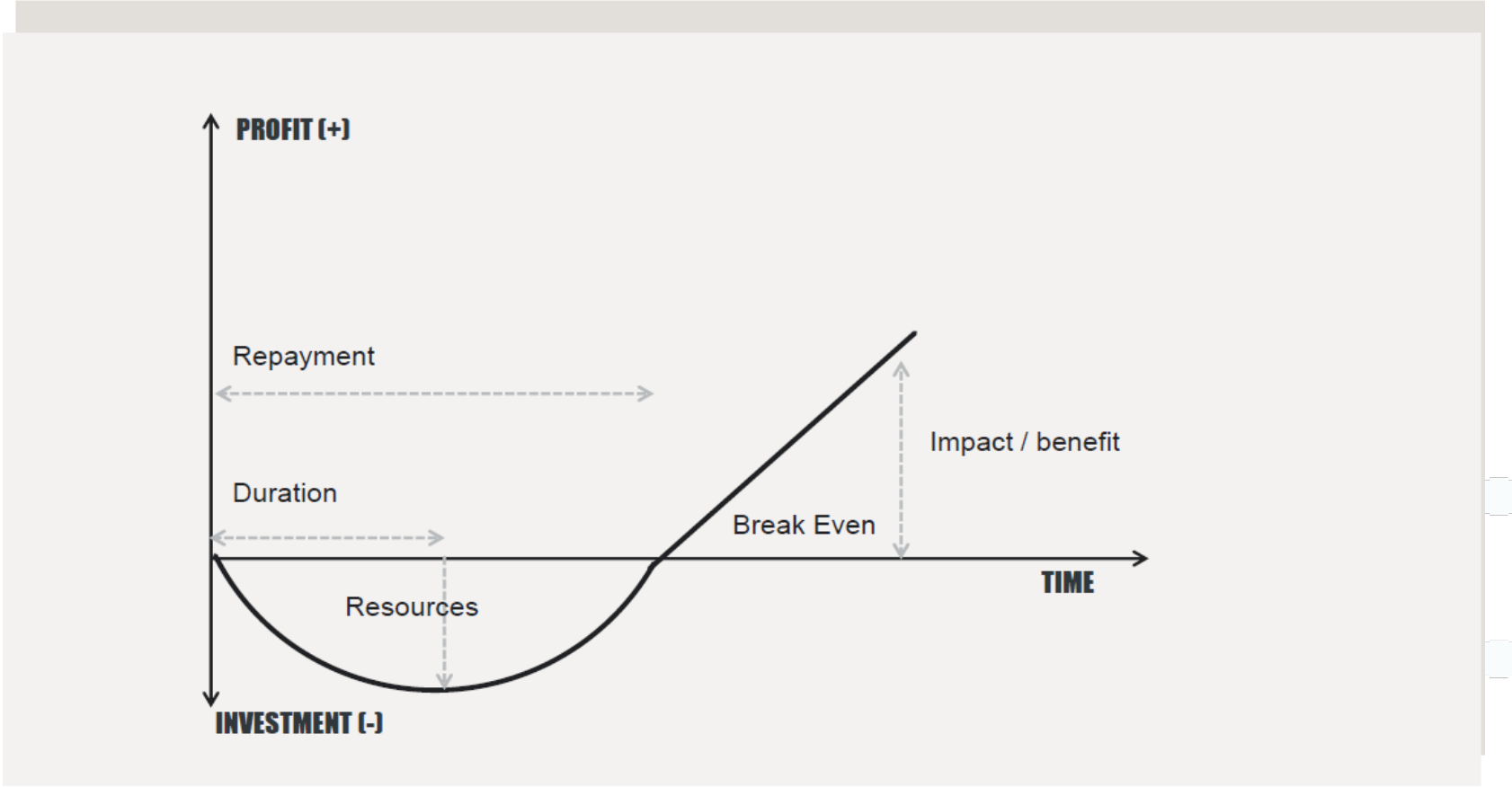
END OF TODAY'S GROUP WORK SESSION: IMPLEMENTATION OF WGS-BASED NRL SERVICES



Group 2, 3, 4 and 5

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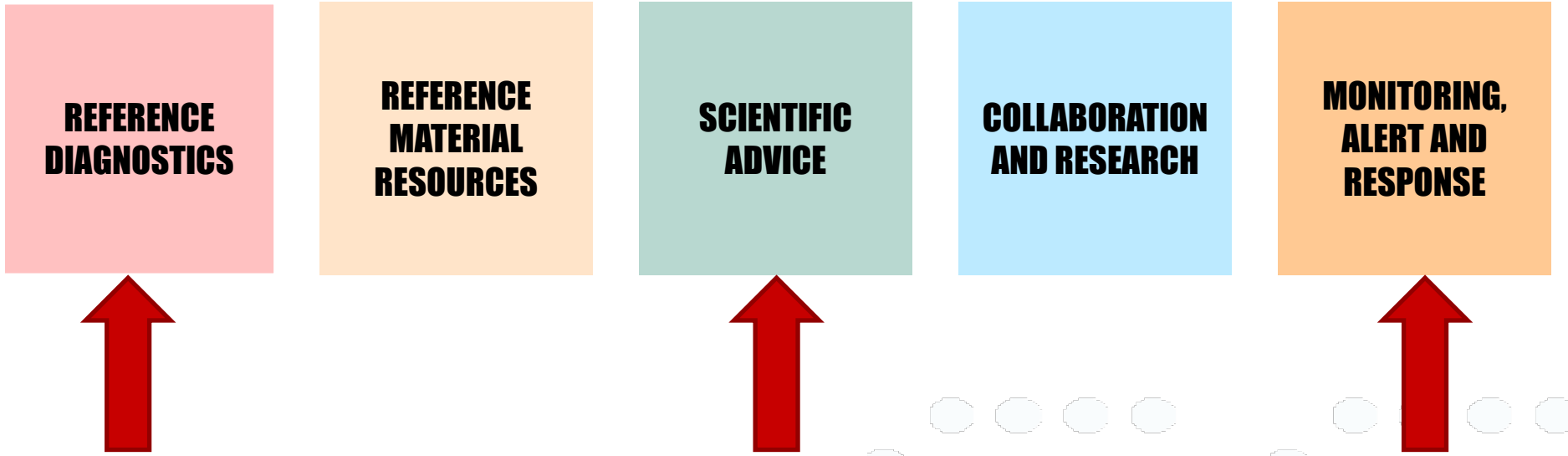
END OF TODAY'S GROUP WORK SESSION: NRL CORE FUNCTIONS



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Anders Rhod Larsen
arl@ssi.dk

Questions and wrapping up the day

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EURGen-RefLabCap@food.dtu.dk

Thank you on behalf of the EURGen-RefLabCap team

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