



CNR-MyRMA  
Centre National de  
Référence des  
Mycobactéries  
et de la Résistance  
des Mycobactéries  
aux Antituberculeux



## Présentation d'outils des CNR pour communiquer avec les homologues européens

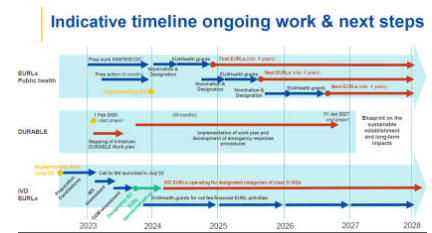
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Université Paris cité, APHP-Nord Hôpital Bichat,  
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Laboratoire associé du Centre National de Référence des Mycobactéries et résistance  
des mycobactéries aux antituberculeux

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Attention il y a 3 définitions de  
laboratoires européens de référence (EURL)



1. Réseau DURABLE de DG HERA
2. Règlementation IVDR pour les tests diagnostiques
3. Nouvelle règlementation sur  
"serious cross-border threats to health" menée  
par DG Santé de la commission européenne en  
lien avec l'ECDC



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## Projet EU4Health Delivering a Unified Research Alliance of Biomedical and public health Laboratories against Epidemics

### DG HERA – Lab Network DURABLE



## Laboratoires européens de référence pour la réglementation «IVDR »

Article 100 de la réglementation (EU) 2017/746

- Laboratoires de référence pour les tests de classe D (infectieux et transfusion)
  - Vérifier les performances des tests et les spécifications du fabricant
  - Tester des lots
- Appel d'offres 2022-2023 => 5 sont en liste
  - Hépatites et rétrovirus
  - Herpesvirus
  - Agents bactériens (?)
  - Virus respiratoires d'infections graves
- Prochain calls pour autres sujets à suivre sur [https://health.ec.europa.eu/vitro-diagnostics/eu-reference-laboratories-eurls\\_en](https://health.ec.europa.eu/vitro-diagnostics/eu-reference-laboratories-eurls_en) )

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# Nouvelle réglementation DG Santé - ECDC

## EURLs for public health: Legal base



### • 23 November 2022



• REGULATION (EU) 2022/2371 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 23 November 2022 on **serious cross-border threats to health** and repealing Decision No 1082/2013/EU

• Published in the OJ on 6 December 2022, entry into force 26 December 2022

• **Article 15 – EU reference laboratories**

2023

Voir la présentation  
de  
Daniel Palm ECDC

Antimicrobial Resistance in bacteria ;  
Vector-borne viral pathogens ;  
Emerging, rodent-borne and zoonotic viral pathogens ;  
High risk emerging and zoonotic bacterial pathogens ;  
Legionella ;  
Diphtheria and Pertussis

## Starting point: List of current ECDC disease and laboratory networks, or projects with laboratory components



| Network or project | Pathogens covered   |
|--------------------|---|
| EARS-Net           | <i>Streptococcus pneumoniae</i> , <i>Staphylococcus aureus</i> , <i>Enterococcus faecalis</i> , <i>Enterococcus faecium</i> , <i>Escherichia coli</i> , <i>Klebsiella pneumoniae</i> , <i>Pseudomonas aeruginosa</i> and <i>Acinetobacter baumannii</i> complex |
| HAI-Net CDI module | <i>Clostridium difficile</i>  |
| EURGen-Net         | Carbapenem- and/or colistin-resistant <i>Escherichia coli</i> and <i>Klebsiella pneumoniae</i>  |
| EVD-LabNet         | Emerging viral pathogens  |
| FWD-Net            | <i>Salmonella enterica</i> , Shiga toxin-producing <i>Escherichia coli</i> , <i>Listeria monocytogenes</i> and <i>Campylobacter jejuni</i>   <i>coli</i>  |
| ERLI-Net           | Influenza virus   |
| Euro-GASP          | <i>Neisseria gonorrhoeae</i>  |
| Diphtheria-LabNet  | <i>Corynebacterium diphtheriae</i>  |
| EUPert-LabNet      | <i>Bordetella pertussis</i>   |
| IBD-LabNet         | <i>Neisseria meningitidis</i> , <i>Streptococcus pneumoniae</i> , <i>Haemophilus influenzae</i>   |
| ERLTB-Net          | <i>Mycobacterium tuberculosis</i> complex   |
| ELDSNet            | <i>Legionella pneumophila</i>   |
| ECOVID-LabNet      | SARS-CoV-2  |

## Réseau des laboratoires nationaux de référence pour la tuberculose des pays de l'Union Européenne Réseau ERLTB-Net

- Grant de 4 ans avec l'ECDC, débuté en 2009 et 3ème grant 2023-2026
- Consortium de 5 pays (UK, Italie, Allemagne, Danemark, Suède)
- Coordonnateur: Public Health UK (CNR Londres) puis Institut San Raffaele (Milan, Italie)
- Chaque pays est représenté par une ou deux personnes (OFP): Jérôme Robert et Emmanuelle Cambau pour la France

### Research articles

#### THE ADDED VALUE OF A EUROPEAN UNION TUBERCULOSIS REFERENCE LABORATORY NETWORK – ANALYSIS OF THE NATIONAL REFERENCE LABORATORY ACTIVITIES

F A Drobniewski<sup>1</sup>, V Nikolayevskiy<sup>2</sup>, S Hoffner<sup>2</sup>, O Pagorylova<sup>2</sup>, D Mantssero<sup>3</sup>, A J Ozin (amanda.ozin@ecdc.europa.eu)<sup>1</sup>  
<sup>1</sup>Health Sciences Research and Health Protection Agency, London, United Kingdom  
<sup>2</sup>Department of Bacteriology, Smittskyddsinstitutet/Swedish Institute for Infectious Disease Control, SMI, Solna, Sweden  
<sup>3</sup>European Centre for Disease Prevention and Control, Stockholm, Sweden

- Expertise
- Alertes
- Conseils
- surveillance

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### EUROPEAN REFERENCE LABORATORY NETWORK FOR TUBERCULOSIS (ERLTB-Net-3)

1<sup>st</sup> Annual Meeting and Large Capacity Building Workshop  
 Madrid – 09<sup>th</sup> – 11<sup>th</sup> October 2023

## Activités professionnelles

- Réunions annuelle des directeurs de CNR
  - Présentation des données de surveillance nationale
  - Biobook pour les membres
- Partage du cahier des charges et listes d'examens
  - chaque CNR décrit ce qu'il fait comme techniques, organisation etc...
  - => Action de soutien entre CNRs si besoin
- Échanges avec le groupe Tuberculose de l'ECDC et de OMS Europe
  - Délégués
  - Réunions ponctuelles

Bulgaria  
 Elizabeta Bachytska



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**EUROPEAN REFERENCE LABORATORY NETWORK FOR TUBERCULOSIS (ERLTB-Net-3)**  
**1<sup>st</sup> Annual Meeting and Large Capacity Building Workshop**  
**Madrid – 09<sup>th</sup> – 11<sup>th</sup> October 2023**

# Activités d'expertise technique

- Ecriture de référentiels
  - Handbook 2010, et mises à jour en 2015, 2022, prévu 2025
- Recommandations et état des lieux => articles multicentriques dans revues internationales



## Impact of the COVID-19 pandemic on tuberculosis laboratory services in Europe

Utility of the Whole Genome Sequencing based methodologies in routine European tuberculosis reference laboratory network setting  
 Yen Heidecker<sup>1</sup>, Ellen Tagliani<sup>2</sup>, Daniela Maria Cirillo<sup>3</sup>, Vlad Nikolayevskiy<sup>4</sup>

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# Activités de formation et qualité

- Contrôle externe de qualité pour techniques de routine (EM, culture, PCR, AST phénotype et génotype): environ 200 tests
- Contrôle externe de qualité pour NGS (RFLP, MIRU-VNTR, WGS) : 10 à 30 ADNs
- Actions de formation : ex. tests de sensibilité phénotypique et génotypique, WGS pour résistance et pour comparaison génotypique, Accréditation
- Formation d'auditeurs experts pour visiter les labos du réseau

## First Worldwide Proficiency Study on Variable-Number Tandem-Repeat Typing of *Mycobacterium tuberculosis* Complex Strains

Jessica L. de Beer,<sup>1</sup> Kristin Kremer,<sup>2</sup> Cuaba Kidmisi,<sup>3</sup> Philip Supply,<sup>4</sup> Dick van Soolingen,<sup>5</sup> and the Global Network for the Molecular Surveillance of Tuberculosis 2009

## External Quality Assessment for Tuberculosis Diagnosis and Drug Resistance in the European Union: A Five Year Multicentre Implementation Study

Vladislav Nikolayevskiy,<sup>1,2,3,4</sup> Doris Hillemann,<sup>5</sup> Ekina Richter,<sup>6</sup> Hoda Anwer,<sup>7</sup> Marika J. van der Werf,<sup>8</sup> Cuaba Kidmisi,<sup>9</sup> Francis D'Armenant,<sup>10</sup> Sabine Rosenzweig,<sup>11</sup> ERLTB Net members

<sup>1</sup> IFR Tuberculeux Reference Laboratory, London, United Kingdom; <sup>2</sup> National Reference Laboratory for Tuberculosis, Friedrich-Loeffler-Institut, Berlin, Germany; <sup>3</sup> European Centre for Disease Prevention and Control, Stockholm, Sweden; <sup>4</sup> Imperial College London, London, United Kingdom



## Experiences from 4 Years of Organization of an External Quality Assessment for *Mycobacterium tuberculosis* Whole-Genome Sequencing in the European Union/European Economic Area

Ekina Richter,<sup>1</sup> Ellen Tagliani,<sup>2</sup> Vladislav Nikolayevskiy,<sup>3</sup> A. de Craen,<sup>4</sup> A. Wabbe,<sup>5</sup> M. Kawanishi,<sup>6</sup> C. Kridinos,<sup>7</sup> M. J. van der Werf,<sup>8</sup> D. Cirillo,<sup>9</sup> D. van Soolingen,<sup>10</sup> E. Tagliani,<sup>11</sup> Nikolayevskiy,<sup>12</sup> Kremer,<sup>13</sup> Supply,<sup>14</sup> van Soolingen,<sup>15</sup> and the Tuberculosis Reference Laboratory Network

<sup>1</sup> IFR Tuberculeux Reference Laboratory, London, United Kingdom; <sup>2</sup> National Reference Laboratory for Tuberculosis, Friedrich-Loeffler-Institut, Berlin, Germany; <sup>3</sup> European Centre for Disease Prevention and Control, Stockholm, Sweden; <sup>4</sup> Imperial College London, London, United Kingdom; <sup>5</sup> National Reference Laboratory for Tuberculosis, Friedrich-Loeffler-Institut, Berlin, Germany; <sup>6</sup> European Centre for Disease Prevention and Control, Stockholm, Sweden; <sup>7</sup> National Reference Laboratory for Tuberculosis, Friedrich-Loeffler-Institut, Berlin, Germany; <sup>8</sup> National Reference Laboratory for Tuberculosis, Friedrich-Loeffler-Institut, Berlin, Germany; <sup>9</sup> European Centre for Disease Prevention and Control, Stockholm, Sweden; <sup>10</sup> National Reference Laboratory for Tuberculosis, Friedrich-Loeffler-Institut, Berlin, Germany; <sup>11</sup> National Reference Laboratory for Tuberculosis, Friedrich-Loeffler-Institut, Berlin, Germany; <sup>12</sup> National Reference Laboratory for Tuberculosis, Friedrich-Loeffler-Institut, Berlin, Germany; <sup>13</sup> National Reference Laboratory for Tuberculosis, Friedrich-Loeffler-Institut, Berlin, Germany; <sup>14</sup> National Reference Laboratory for Tuberculosis, Friedrich-Loeffler-Institut, Berlin, Germany; <sup>15</sup> National Reference Laboratory for Tuberculosis, Friedrich-Loeffler-Institut, Berlin, Germany

J. Antimicrob. Chemother. 2019; 74: 1188–1194. doi:10.1093/acids/kry277 Advance Access publication 11 February 2019

## Novel external quality assurance scheme for drug susceptibility testing of non-tuberculous mycobacteria: a multicentre pilot study

Vladislav Nikolayevskiy,<sup>1</sup> Florian P. Maurer,<sup>2</sup> Yen Heidecker,<sup>3</sup> Lucy Taylor,<sup>4</sup> Helen Lloyd,<sup>5</sup> and Katharina Krieger<sup>6</sup>



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## Echanges de données entre CNR européens?

- En cas d'épidémies « cross boarder »
- En cas d'études ou travaux multicentriques
- Pas systématique, pas d'open data en dehors de EPIPULSE
- Besoin de se donner des règles de publication

### A cluster of multidrug-resistant *Mycobacterium tuberculosis* among patients arriving in Europe from the Horn of Africa: a molecular epidemiological study

Tamotsy M. Wabara<sup>1</sup>, Matthias Meeker<sup>2</sup>, Astrid M. Kneiblich<sup>3</sup>, Peter Hebling, Otto D. Schoch, Mawardi van der Werf, Katharina Krenze, Lena Fink, Stefan Brügel, Walter Hain, Harald Hoffmann, Alexander Isakov, Anker Jørg, Daniela M. Colla, Johannes Böhler, Thomas P. Rieger, Ramona Groenhet, Anne T. Mengshoel, Vanessa Machys, Marjo Haazepoel, Dick van Soelingen, Sofjen Niemann<sup>4</sup>, Erik C. Böttiger<sup>5</sup>, Peter M. Keller<sup>6</sup>, and the MDR-TB Cluster Consortium

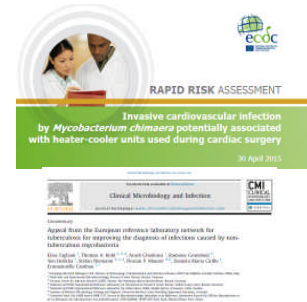
### SURVEILLANCE AND OUTBREAK REPORTS

### Molecular surveillance of multi- and extensively drug-resistant tuberculosis transmission in the European Union from 2003 to 2011

J. L. De Beer (jessica.de.beer@rivm.nl), C. Kibimbi<sup>1</sup>, M. J. van der Werf<sup>2</sup>, J. van Ingen<sup>3</sup>, D. van Soolingen<sup>4,5</sup>, the ECDC MDR-TB molecular surveillance project participants<sup>6</sup>

1. National Tuberculosis Reference Laboratory, Laboratory for Infectious Diseases and Perinatal Screening (LIS), Centre for Infectious Disease Control (CI), National Institute for Public Health and the Environment (RIVM), Bilthoven, The Netherlands
2. European Centre for Disease Prevention and Control (ECDC), Stockholm, Sweden
3. Department of Medical Microbiology, Department of Medical Microbiology Nijmegen, The Netherlands
4. Department of Pulmonary Diseases, Radboud University Nijmegen Medical Centre, Nijmegen, The Netherlands
5. The participants are listed at the end of the article

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## Collaboration ERLTB net et ESCMID



- Création en 2016 du sous groupe EUCAST-AMST spécialisé dans les tests de sensibilité pour les mycobactéries (tuberculose et mycobactéries non tuberculeuses)
  - Chair: Emmanuelle Cambau
  - Scientific Secretary: Thomas Schön
  - ESGMYC members: Miguel Santin and Miguel Viveiros
  - ERLTB-net members: Daniella Cirillo and Sven Hoffner/Jim Werngren
  - EUCAST members: Gerard Lina and Johan Mouton, Christian Giske and Gunnar Kahlmeter

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European Society of Clinical  
Microbiology  
and Infectious Diseases

ESCMID  
study  
groups

<https://www.escmid.org/research-projects/study-groups>

Communication  
avec les  
homologues  
européens

| Field   | Acronym                 | Full Name  |
|---|-------------------------|--|
| Anaerobic Infections                          | <a href="#">ESGAI</a>   | ESCMID Study Group for Anaerobic Infections                            |
| Antimicrobial Stewardship                     | <a href="#">ESGAP</a>   | ESCMID Study Group for Antimicrobial stewardship                       |
| Biofilms                                      | <a href="#">ESGB</a>    | ESCMID Study Group for Biofilms  |
| Bloodstream Infections, Endocarditis & Sepsis | <a href="#">ESGBIES</a> | ESCMID Study Group for Bloodstream Infections, Endocarditis and Sepsis |
| Brain Infections                              | <a href="#">ESGBI</a>   | ESCMID Study Group for Infectious Diseases of the Brain                |
| Clinical Parasitology                         | <a href="#">ESGCP</a>   | ESCMID Study Group for Clinical Parasitology                           |
| Clostridioides difficile                      | <a href="#">ESGCD</a>   | ESCMID Study Group for Clostridioides difficile                        |
| Critically Ill Patients                       | <a href="#">ESGCI</a>   | ESCMID Study Group for Critically Ill Patients                         |
| Elderly Infections                            | <a href="#">ESGIE</a>   | ESCMID Study Group for Infections in the Elderly                       |
| Epidemiological Markers                       | <a href="#">ESGEM</a>   | ESCMID Study Group for Epidemiological Markers                         |
| Food/Water Infections                         | <a href="#">EPWISG</a>  | ESCMID Food- and Water-borne Infections Study Group                    |
| Forensic/Postmortem Microbio                  | <a href="#">ESGFDR</a>  | ESCMID Study Group for Forensic and Postmortem Microbiology            |
| Fungal Infection                              | <a href="#">EFISG</a>   | ESCMID Fungal Infection Study Group                                    |
| Genomic & Molecular Diagnostics               | <a href="#">ESGMD</a>   | ESCMID Study Group for Genomic and Molecular Diagnostics               |
| Host and microbiota interaction               | <a href="#">ESGHAM</a>  | ESCMID Study Group for Host and Microbiota Interaction                 |
| Immunocompromised Hosts                       | <a href="#">ESGICH</a>  | ESCMID Study Group for Infections in Compromised Hosts                 |
| Implant Infections                            | <a href="#">ESGIAI</a>  | ESCMID Study Group for Implant-associated Infections                   |
| Legionella Infections                         | <a href="#">ESGLI</a>   | ESCMID Study Group for Legionella Infections                           |
| Lyme Borreliosis                              | <a href="#">ESGBOR</a>  | ESCMID Study Group for Lyme Borreliosis                                |
| Mycobacterial Infections                      | <a href="#">ESGMVC</a>  | ESCMID Study Group for Mycobacterial Infections                        |
| Mycoplasma & Chlamydia Infections             | <a href="#">ESGMAC</a>  | ESCMID Study Group for Mycoplasma and Chlamydia Infections             |
| Non-traditional Antibacterial Therapies       | <a href="#">ESGNTA</a>  | ESCMID Study Group for Non-traditional Antibacterial Therapy           |
| Nosocomial Infections                         | <a href="#">ESGNI</a>   | ESCMID Study Group for Nosocomial Infections                           |
| PK/PD fo Anti-Infectives                      | <a href="#">EPASG</a>   | ESCMID PK/PD of Anti-Infectives Study Group                            |
| Public Health Microbiology                    | <a href="#">ESGPHM</a>  | ESCMID Study Group for Public Health Microbiology                      |
| Resistance Surveillance                       | <a href="#">ESGARS</a>  | ESCMID Study Group for Antimicrobial Resistance Surveillance           |
| Respiratory Viruses                           | <a href="#">ESGREV</a>  | ESCMID Study Group for Respiratory Viruses                             |
| Staphylococci                                 | <a href="#">ESGS</a>    | ESCMID Study Group for Staphylococci and Staphylococcal Diseases       |
| Travel & Migration                            | <a href="#">ESGITM</a>  | ESCMID Study Group for Infections in Travellers and Migrants           |
| Vaccines                                      | <a href="#">EVASG</a>   | ESCMID Vaccine Study Group   |
| Veterinary Microbiology                       | <a href="#">ESGVV</a>   | ESCMID Study Group for Veterinary Microbiology                         |
| Viral Hepatitis                               | <a href="#">ESGVH</a>   | ESCMID Study Group for Viral Hepatitis                                 |

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