

Ecraid

European Clinical Research
Alliance on Infectious Diseases

Evelina Tacconelli
CSO Ecraid


ecraid



Purpose-driven, people-centred

www.ecraid.eu

 @ecraid

 Ecraid

Building on COMBACTE and PREPARE

COMBACTE – Combatting Bacterial Resistance in Europe – is an Innovative Medicines Initiative funded project focusing on improving the clinical development of antibacterial treatment programmes

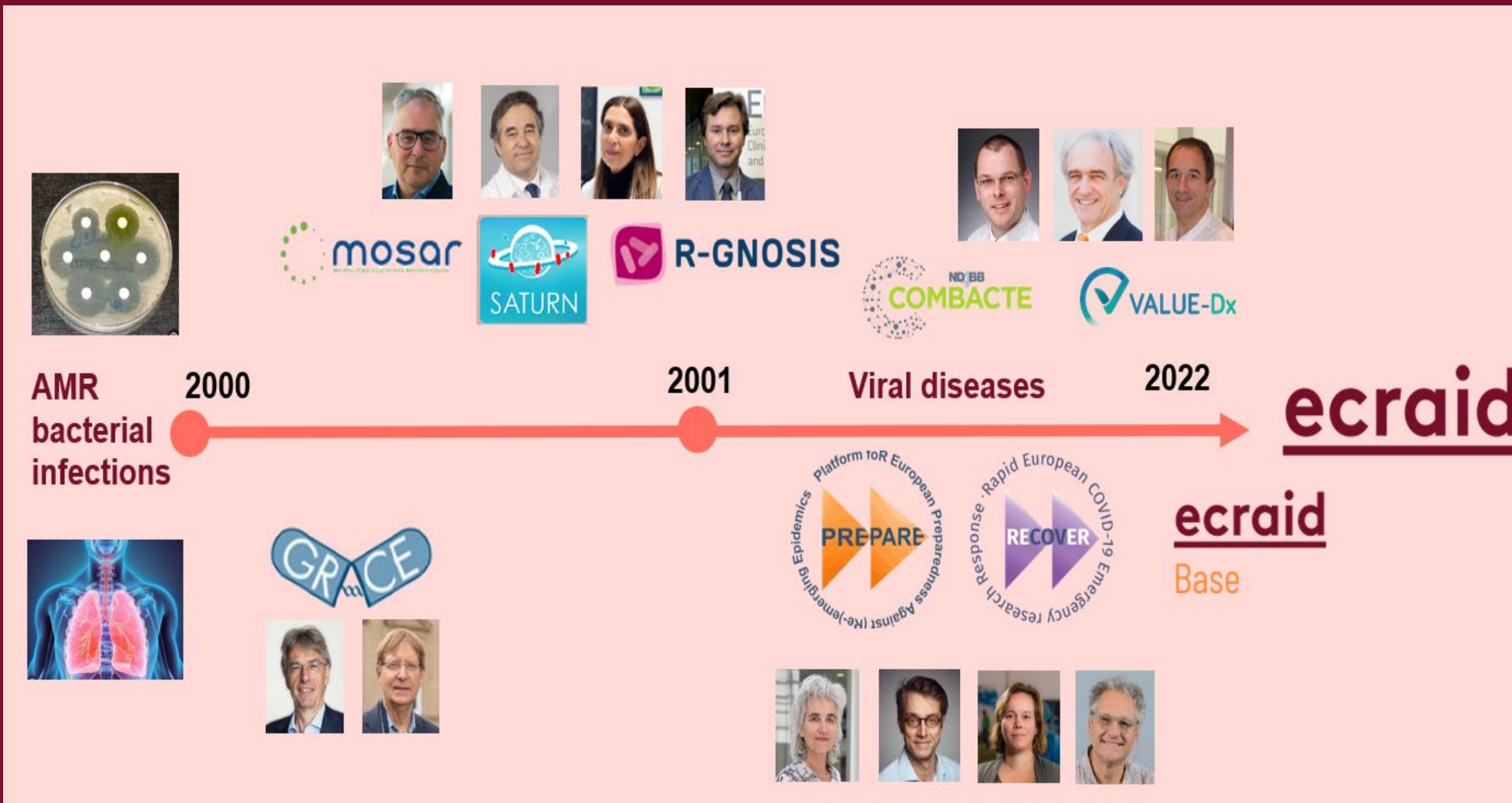
The result is a comprehensive clinical research infrastructure consisting of four high-quality networks:



PREPARE – Platform for European Preparedness Against (Re-)emerging Epidemics – is a large-scale European network funded by the Framework Programme 7 aimed at building operational readiness for rapid deployment of harmonised European clinical studies for any infectious disease outbreak

Network of experts in clinical management, epidemiology of infectious diseases and in the design of clinical studies, statistical methods and analyses

History



Achievements in Antimicrobial Resistance

Project	New antimicrobial drug	Study name	Study design	Publications	Drug's faith
COMBACTE-NET	DAV132 (Clostridium difficile)	ANTICIPATE	Observational	Nature Comm Nature Comm	
		MICROCARE	Phase 3	-	Program stopped: operational futility
	Suvratoxumab (S. aureus)	ASPIRE-ICU	Observational	JAMA Network Open	
		SAATELLITE	Phase 2	Lancet Infect Dis	
		SAATELLITE-2	Phase 3	-	Program stopped: operational futility
E. coli vaccine	EXPECT1-2	Observational	CID	Phase 3 study ongoing (E.mbrace)	
COMBACTE-MAGNET	Gremubamab (P. aeruginosa)	ASPIRE-ICU	Observational	Nature Comm	
		EVADE	Phase 2	Crit Care	Program stopped: Lack of efficacy
COMBACTE-CARE	Emblaveo (Aztreonam-Avibactam) (Multi-drug resistant Gram-negative bacteria)	EURECA	Observational	Eclinical Med	
		REJUVENATE	Phase 2	JAC	
		REVISIT	Phase 3	Submitted	Approved by EMA



Achievements in Acute Respiratory Infections and COVID-19

Patient Domain	Study	Study design	Intervention	Publications	Conclusion
Primary Care	ALIC ⁴ E	APT	Oseltamivir	Lancet 2020	Benefit
ICU	REMAP-CAP	APT	Corticosteroids	JAMA Sep 2020	Benefit
			Lopinavir/ritonavir	ICM Jul 2021	Likely harm
			Hydroxychloroquine	Nature Comm Apr 2021	Harm
			Tocilizumab/Sarilumab	NEJM Jan 2021	Benefit
			Anakinra	JAMA Mar 2022	Futile
			Interferon beta-1a		Operationally futile
			Heparin – moderate	NEJM Aug 2021	Benefit
			Heparin – severe	NEJM Aug 2021	Futile
			Convalescent plasma	JAMA Oct 2021	Futile
			ACEi and ARB	JAMA Apr 2023	Likely harm
continued TAC - severe	ICM May 2023	Likely harm			
Vitamin C	JAMA Oct 2023	Likely harm			
Simvastatin	NEJM Oct 2023	Benefit			
Healthcare workers	BRACE	RCT	BCG vaccine	NEJM Apr 2022	Futile

Coordinating Committee



Marc Bonten
Chair, COMBACTE
& CLIN-Net,
Ecraid CEO



Herman Goossens
LAB-Net



Chris Butler
POS-ARI-PC,
PRUDENCE,
ECRAID-Prime



Oliver Cornely
VACCELERATE



**Jacques Demotes-
Mainard**
ECRIN
Data Management



Lennie Derde
REMAP-CAP



Carlo Giaquinto
PENTA-ID
VERDI



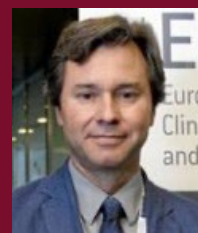
Peter Horby
POS-ARI -ER
MERMAIDS 2.0



Thomas Jaenisch
RECODID
Data Sharing



Marion Koopmans
Outbreak
Preparedness &
Response, POS-
Disease-X, VEO



**Jesús Rodríguez
Baño**
POS-cUTI



Stephan Harbarth
STAT-Net



Bruno François
POS-VAP



Evelina Tacconelli
EPI-Net, LOTTA-
Net, ORCHESTRA,
Ecraid CSO



**Arjana Tambić
Andrašević**
Capacity building
Eastern Europe



**Yazdan
Yazdanpanah**
EU-RESPONSE,
MPX-RESPONSE



Roger Brüggemann
P3-Net



Oana Sandulescu
Chair of Ecraid
Clinical Liaison
Council



Sibyl Antherens
Public Engagement



Governance

A not-for-profit foundation NGO status since 2023 with 80 employees

The Management Board performs overall coordination and is supervised by a Supervisory Board

MANAGEMENT BOARD



Marc Bonten
Chief Executive Officer



Evelina Tacconelli
Chief Scientific Officer



Nils Visser
Chief Operating Officer

SUPERVISORY BOARD



Prof. Arno Hoes
Executive Board member & Dean, UMC Utrecht



Prof. Juan E. Echevarria
Laboratory Head, Instituto de Salud Carlos III



Bernard Pécoul, PhD
Former Executive Dir. Drugs for Neglected Diseases initiative



Prof. Deborah Cook
Professor of Health Research Methods, Evidence and Impact, McMaster University



Annie Van Broekhoven
former CEO Q-Biologics, Antwerp

Operational service/country level management

Ecraid HQ

Ecraid Chief Offices (ECHOs)

Coordination units
Local support units

Ecraid Country Offices

Ecraid Clinical Liaisons Council

Objectives

Ecraid is a warm-base academic clinical research network for infectious diseases

The network has the capacity and capabilities to:

- Directly enrol patients for **generating evidence** to support, through **RCT design**, testing, development and validation of new anti-infective therapies, diagnostics, and preventive strategies of infectious diseases
- Provide active, prospective cohorts continuously enrolling patients with infectious diseases
- Function as a platform for a rapid research response in the face of serious infectious diseases with epidemic and pandemic scenarios



900 labs
42
countries



300 primary care sites
18
countries
GRACE



90 sites
18
countries
PENTA



45 sites
11
countries
LOTTA-Net



1216 hospitals



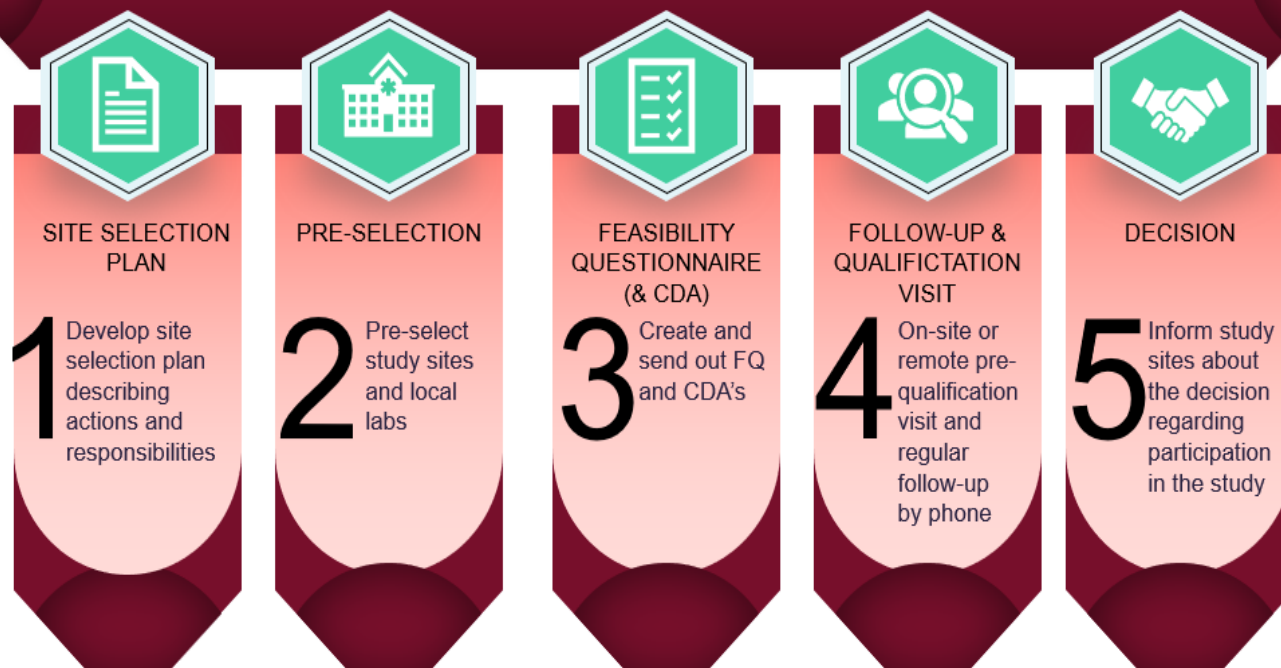
42
countries






























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Ecraid
Clinical
Liaisons

The Network: Ecraid built bridges for the future

Site Selection



Ecraid Clinical Liaison Council

- | | | | |
|---|--|--|---|
| 
Prof. Slavica Kvolik
Anaesthesiology, ICM
J.J. Strossmayer University
Croatia | 
A/Prof. Zoi Dorothea Pana
Paediatrics, ID
European University of Cyprus
Cyprus | 
Dr Kadri Tamme
ICM
Tartu University Hospital
Estonia | 
Dr Piret Mitt
ID
Tartu University Hospital
Estonia |
| 
Dr Ana Hernandez
PC
University Hospital of Limoges
France | 
Prof. Oliver Cornely
ID, IM
University of Cologne
Germany | 
Prof. Sotirios Tsiodras
ID, IM
Attikon University Hospital
Greece | 
Dr Despoina Koulenti
ICM, IM
Attikon University Hospital
Greece |
| 
Prof. Akos Csomos
ICM
National Institute of Hematology and Infectious Diseases
Hungary | 
Dr Botond Lakatos
ID
Hungarian Defense Forces Medical Centre
Hungary | 
Prof. Alistair Nichol
ICM
St Vincent's University Hospital ²
Ireland | 
Prof. Mical Paul
ID
Rambam Health Care Campus ²
Israel |
| 
Dr Diletta Pezzani
ID
University of Verona
Italy | 
A/Prof. Gennaro de Pascale
ICM
Agostino Gemelli University Policlinic ⁴
Italy | 
Dr Jose Pedro Cidade
ICM
St. Francis Xavier Hospital ⁶
Portugal | 
Dr Mariana Guedes
ID
University Hospital Center of São João
Portugal |
| 
Dr Raquel Duro
ID
Tâmega e Sousa Hospital Center
Portugal | 
Prof. Oana Sândulescu
ICM
University of Medicine and Pharmacy "Carol Davila"
Bucharest
Romania | 
Prof. Elena Copaciu
Anaesthesiology, ICM
National Institute of Infectious Diseases "Prof. Dr. Matei Bals"
Romania | 
Dr Biljana Carevic
Epidemiology
Oslo University Hospital
Serbia |
| 
Dr Jose Bravo-Ferrer
ID
University Hospital Virgen Macarena
Spain | 
A/Prof. Pontus Nauciler
ID
Karolinska University Hospital ⁸
Sweden | 
A/Prof. Thomas Tängden
ID
Uppsala University
Sweden | 
Prof. Arzu Topeli
ICM, IM
Hacettepe University
Turkey |
| 
Dr Jake Dunning
ID
University of Oxford ⁹
United Kingdom | 
Prof. Paul Dark
ICM
University of Manchester
United Kingdom | 
Prof. Philip Evans
PC
University of Exeter
United Kingdom | |

Trials and Cohorts: the Ecraid Portfolio

REMAP-CAP	CAP/COVID-19 in ICU	SUNRISE-3	Early treatment COVID-19 MPOX
PNEUMO	S pneumoniae Acute Respiratory Infections (ARI) in ER	Epoxi	
POS-VAP	VAP in ICU	RECOVERY	ARI
POS-cUTI	cUTI	POS-DisX	Undiagnosed infection in immunocompromised
POS-ARI-ER	ARI in ER	Neo-IPC	Sepsis in NICU
SAATELLITE2	Mabs S. aureus carriers in ICU	ECRAID-Prime	ARI in PC
COVACC	SARS-CoV-2 vaccination in children (5-12 yrs)	RECLAIM	Long COVID
POS-ARI-PC	ARI in PC	E.Mbrace	Vaccine to prevent UTI
SNAP	Staph aureus bacteremia		

ECRAID-Base POS studies

 173 unique sites

 20 countries

- Albania
- Belgium
- Bulgaria
- Croatia
- Cyprus
- Czech Republic
- Denmark
- France
- Germany
- Greece
- Italy
- Netherlands
- Portugal
- Romania
- Serbia
- Spain
- Sweden
- Switzerland
- Turkey
- United Kingdom



Perpetual observational studies

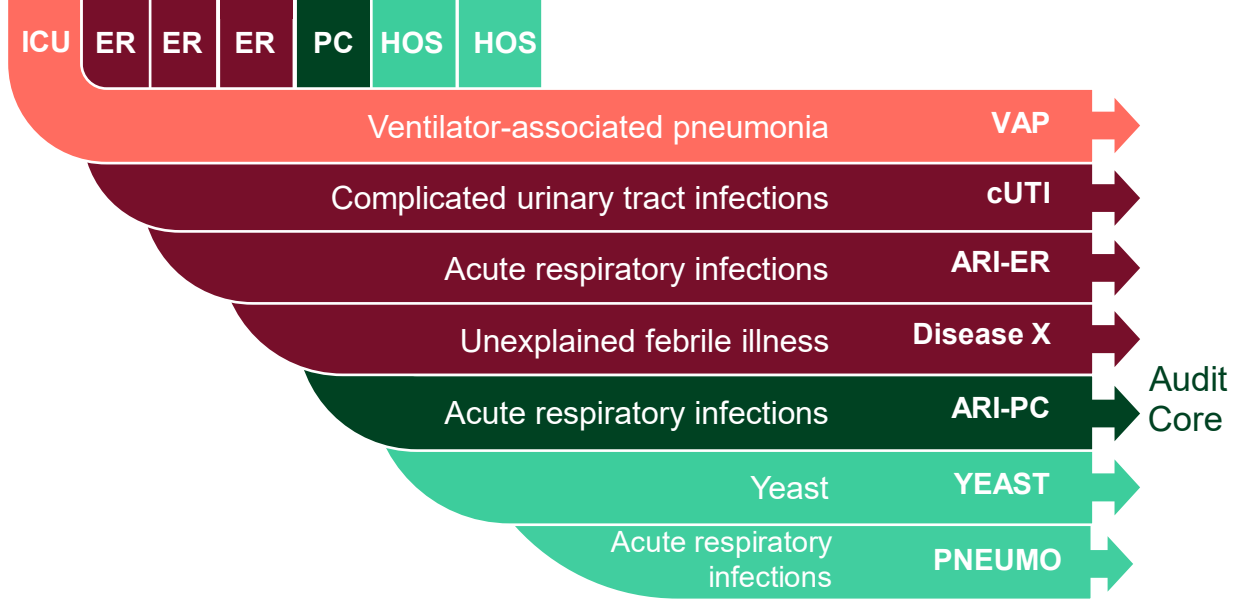
VAP = Ventilator Associated Pneumonia

cUTI = Complicated Urinary tract Infections

ARI = Acute Respiratory Infections

1 protocol, 1 infection, multiple sites in multiple countries

Perpetual Observational Studies

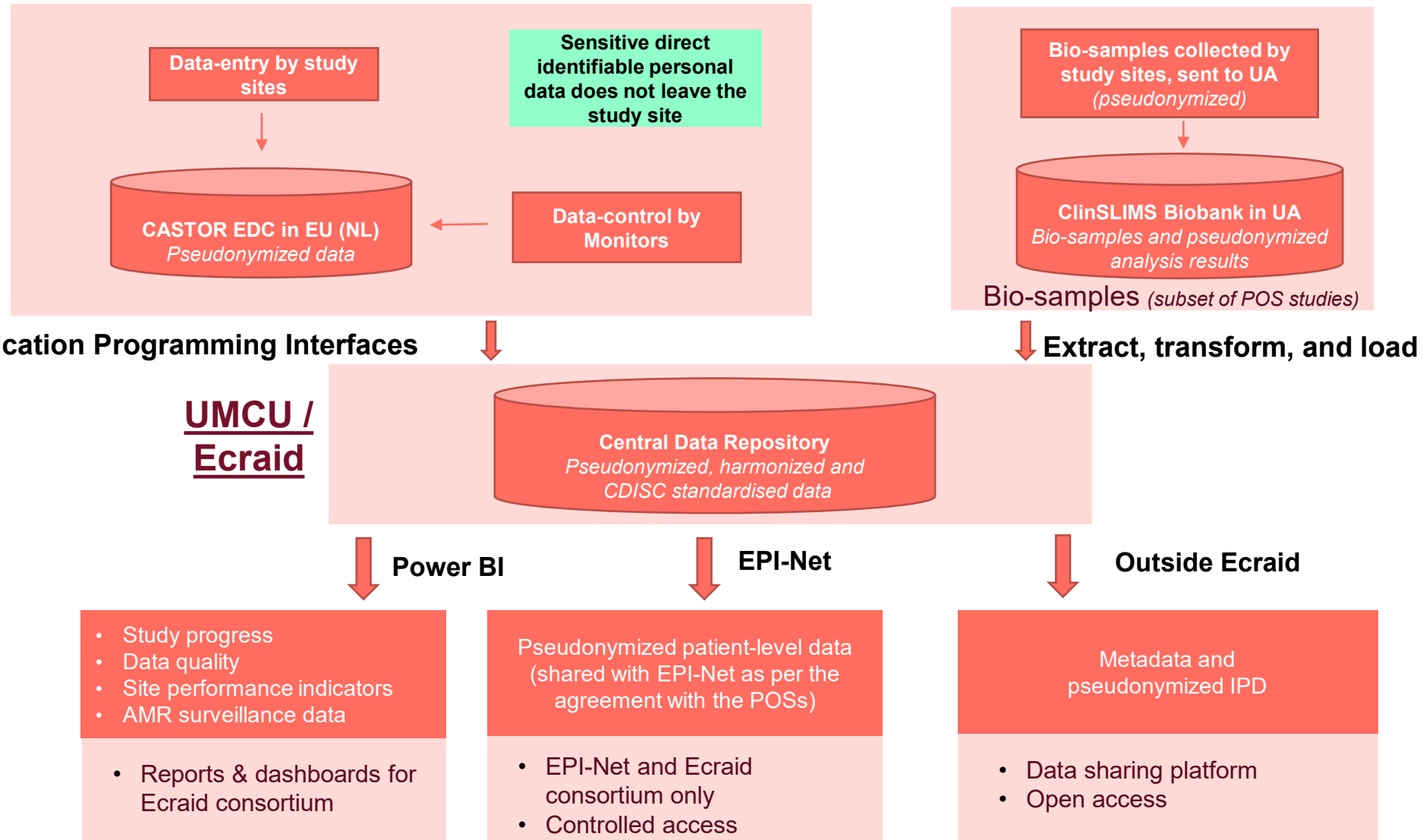


ICU = Intensive Care Unit
 ER = Emergency Room
 PC = Primary Care
 HOS = Hospital wards

No. of sites activated	No. of countries	Enrolled as at 1 Jan 24	Enrolled as at 2 May 24
23	9	1,882	2,828
34	14	1,480	2,230
13	5	334	700
1	1	1	10
95	18	4,324	6,752
7	1	0	48
Pending funding			
42	6	4,719	5,800
173	24	12,740	18,368 (+5,628)

Perpetual observational studies: data flow

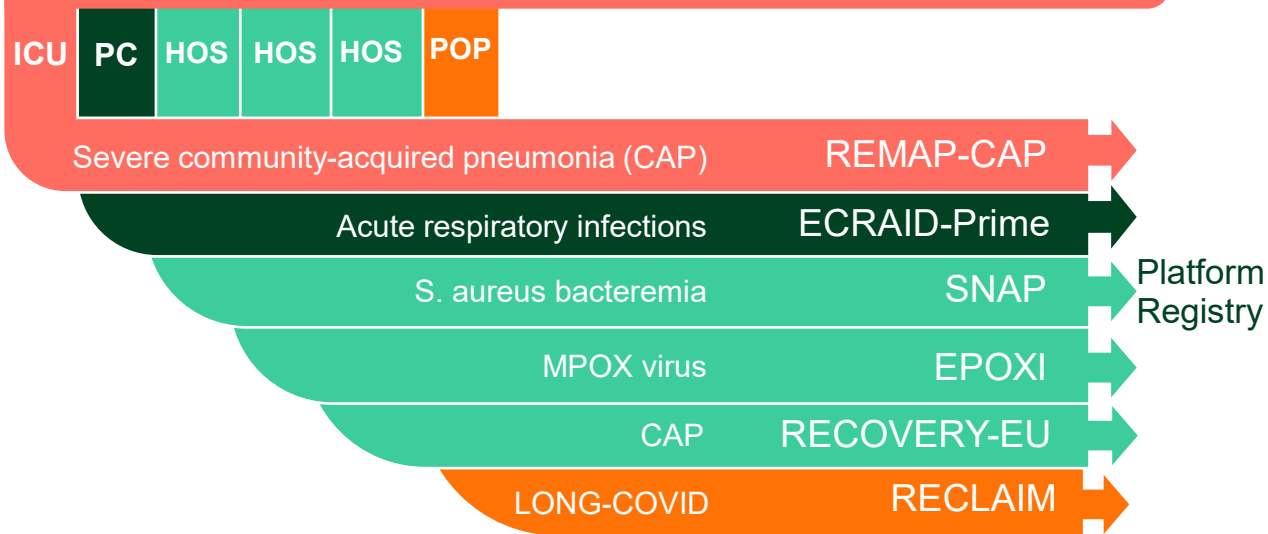
eCRF data



Platform Trials



(Adaptive) Platform Trials

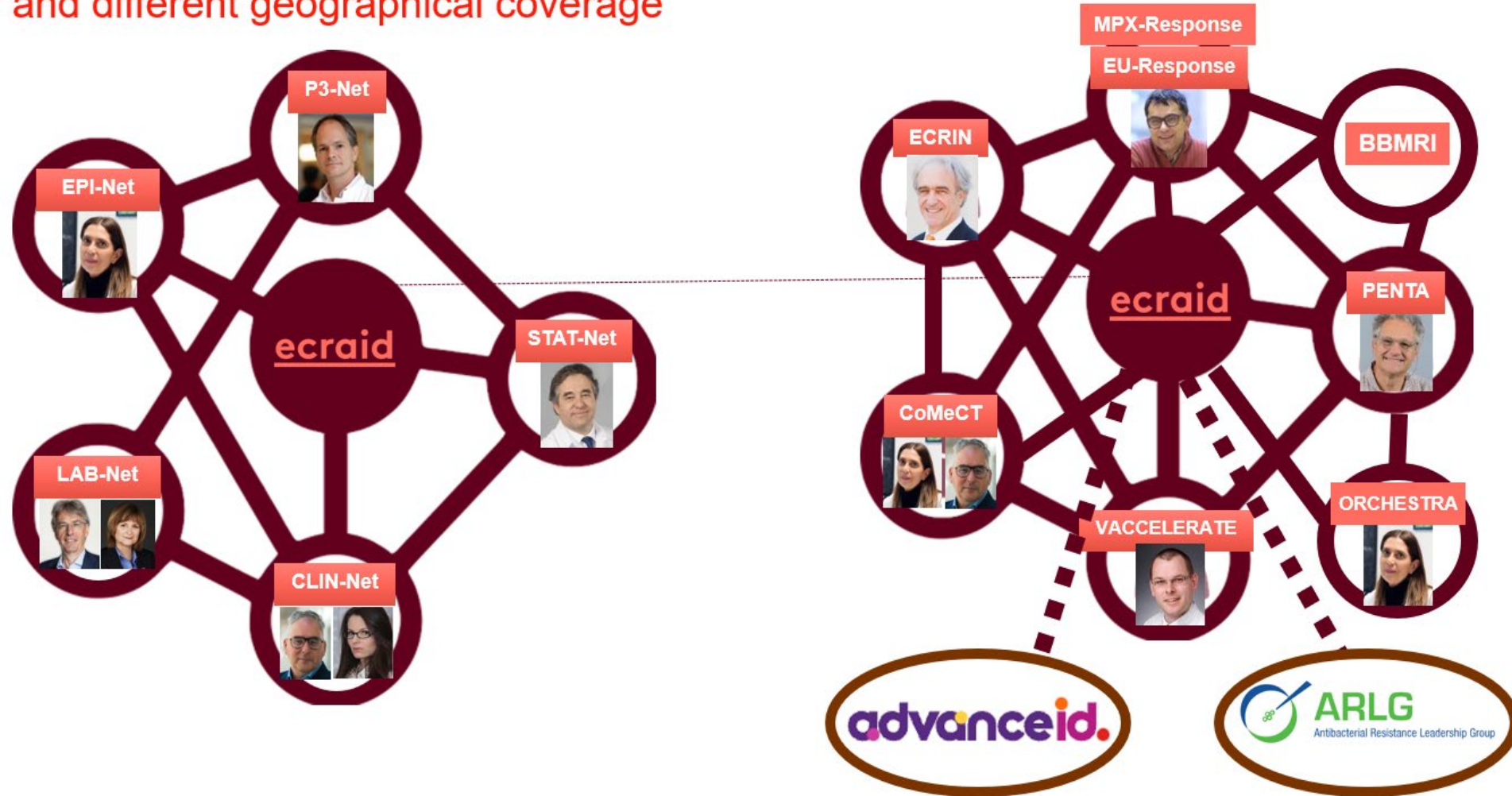


No. of sites activated	No. of countries	Enrolled as at 1 Jan 2024	Enrolled as at 2 May 2024
131 (265)	12 (19)	7,606	7,902
Pending regulatory approval			
6	1	1	28
6	1	1	44
Pending regulatory approval			
6	2	0	4
Pending regulatory approval			
149	12	7,608	7,978 (+370)

ICU = Intensive Care Unit
 ER = Emergency Room
 PC = Primary Care
 HOS = Hospital wards

CAP = Community-Acquired Pneumonia
 ARI = Acute Respiratory Infections
 SAB = Staph aureus bacteremia

and..a network of networks including different study designs (from Phase 2 to cohort studies), different diseases targets (from mpx to post COVID syndrome), and different geographical coverage



Outbreak Preparedness & Response

'Inter-epidemic' mode

The Ecraid warm-base network is operationally prepared to rapidly initiate a clinical research response addressing key questions in the event of an infectious disease **outbreak** or changing in epidemiology due to the **climate change**

What if a viral pandemic scenario (pneumonia as a primary infection site) would start tomorrow:

REMAP-CAP

130 active sites in 11 countries active with 8 domains operational (embedded in global network of 298 sites)

RECOVERY-EU

- 5 sites in 2 countries active with for randomisation to oseltamivir, baloxavir or standard care
- 188 study sites.
- End of 2024: 65 new sites in 8 EU countries

POS-ARI-ER

- 13 sites in 5 countries active
- End of 2024: 30 active sites in 10 countries

POS-ARI-PC

- 7 sites in 1 country active
- End of 2024: 60 active sites in 8 countries

ORCHESTRA

- 82 active cohorts (500000 enrol.)
- Children/ adult
- Underserved populations
- HCWs
- Centralised infrastructures
- Federated learning
- Acute disease
- 24-month follow-up

A patient-centred network Transferability

IMI-supported treatment against multidrug-resistant bacteria approved by European Commission

The Commission's green light means this new treatment will soon be available for adult patients with serious infections caused by multidrug-resistant Gram-negative bacteria where treatment options are limited.

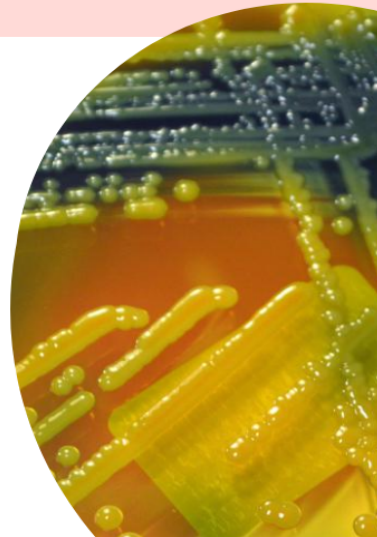
Two of the EMBLAVEO® clinical studies were conducted with the support of the Innovative Medicines Initiative project COMBACTE-CARE – the first was a Phase II study (REJUVENATE) which investigated its potential as a treatment for hospitalised patients with complicated intra-abdominal infections. The second was a Phase III study (REVISIT) which compared the aztreonam-avibactam treatment with meropenem and colistin – a commonly used treatment – to treat complicated intra-abdominal infections, hospital-acquired pneumonia and ventilator-associated pneumonia. The REVISIT study was also supported by the Biomedical Advanced Research and Development Authority (BARDA). Data from the studies showed that the treatment is effective and well-tolerated.

22 April 2024

A patient-centred network Support to public health

Ecraid network responds to hypervirulent *Klebsiella* *pneumoniae* warning

The ECDC cautions that hypervirulent *Klebsiella pneumoniae* may be causing untreatable infections in Europe. The teams behind Ecraid's platform studies on ventilator-associated pneumonia and complicated urinary tract infections swiftly analysed their data to quantify the prevalence of carbapenem-resistant *Klebsiella*.



POScUTI

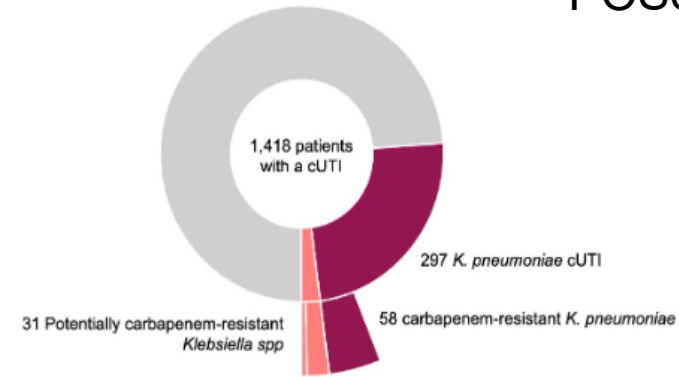


Figure 1. Prevalence of carbapenem-resistant *Klebsiella* in patients with a cUTI

POSVap

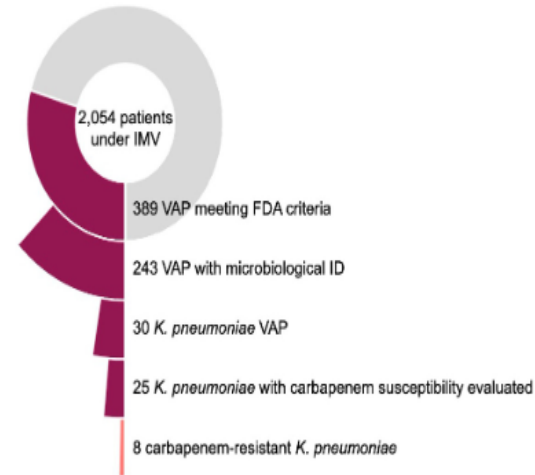


Figure 2. Prevalence of carbapenem-resistant *Klebsiella* in patients with microbiologically confirmed VAP

A patient-centred network Education

Free webinar on complicated urinary tract infections

Experts will explore definitions, microbiological challenges and novel randomised trials of two-hour webinar on Registration is now

Webinar good practice laboratory

In an effort to help tract infection diagnosis team responsible for work in the ECRAI hosting a practical February 14, 2024. address the microbiological clinical nuances of offering know-how done for the POS- These good laboratories are included in a n

Young Investigator Workshop returns to ESCMID in 2024

Conducting international clinical research is not easy, even for the most experienced trialists. How can it be made easier for young investigators? On the heels of two fully booked Young Investigator Workshops held in 2022 and 2023, the team behind this series is returning to ESCMID Global (formerly known as ECCMID) for a third, hybrid edition.

Six-part course introduces the future of clinical research: adaptive designs

Traditional clinical research designs are not sufficiently equipped to tackle infectious disease threats. Adaptive designs, on the other hand, *are*. This free online training course will introduce the distinct types of adaptive designs and explain their advantages and limitations.



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