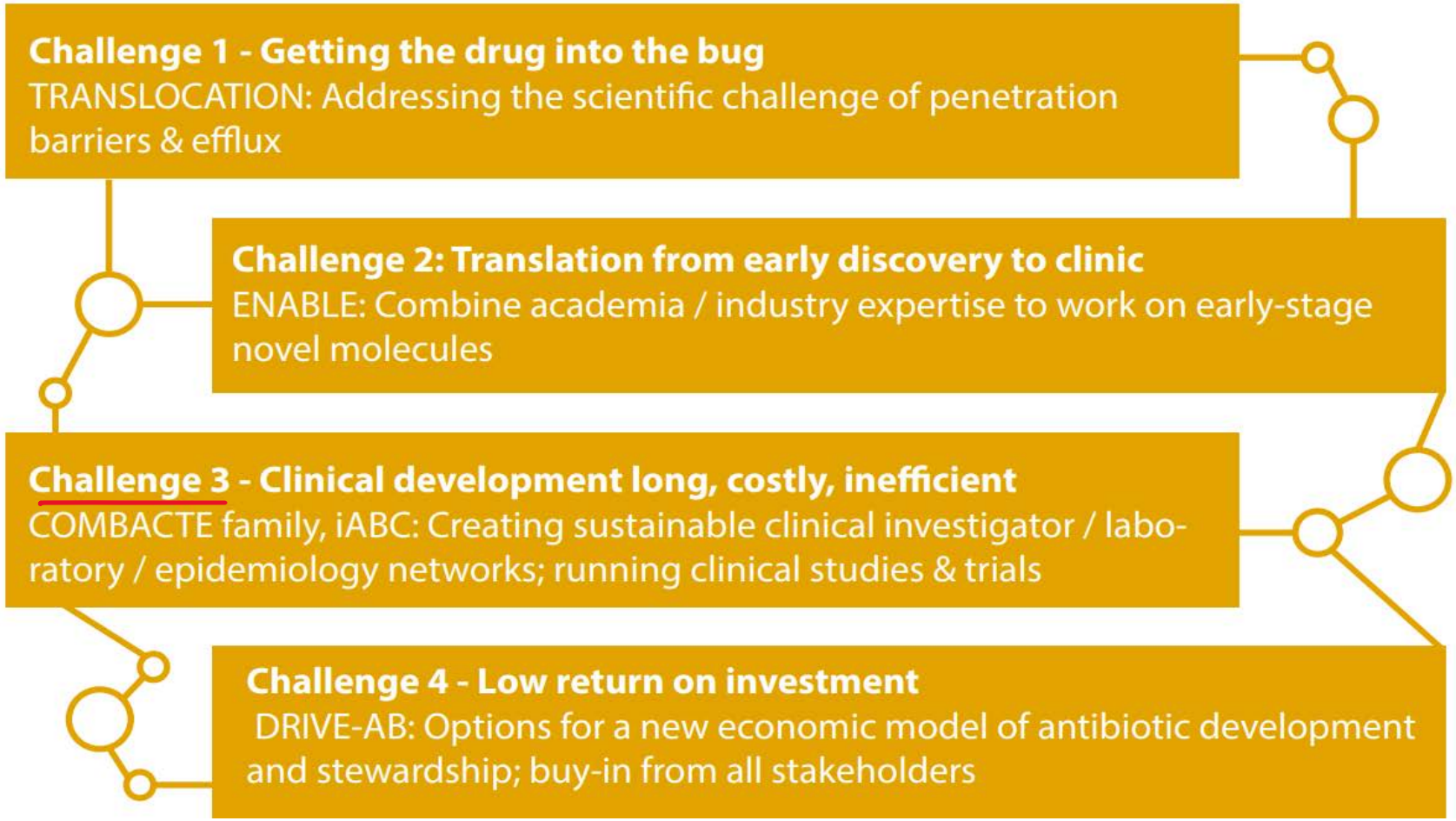
IMI impact on:

Antimicrobial Resistance: Legacy of IMI COMBACTE projects

31 May 2024

New Drug for Bad Bugs (ND4BB)

Large public private collaboration programme launched under IMI in response to the 2011 EC ‘s Action Plan against the rising threats from AMR



innovative health initiative

innovative health initiative

IMI impact on: AMR

31.05.2024

Meet the speakers:

Marc Bonten
UMC Utrecht & Ecraid

Hasan Jafri
Aridis Pharmaceuticals

Bruno François
CHU Limoges

Halley Rogers
Pfizer

Jesús Rodríguez Baño
Hospital Universitario Virgen Macarena, University of Sevilla and Instituto of Biomedicine of Sevilla

Nathalie Seigneuret
IHI, Event Moderator

COCIR efpia EuropaBio MedTech Europe from diagnosis to cure Vaccines Europe

Co-funded by the European Union

innovative health initiative

Use the chat below

Ask questions and interact with the speakers
(bottom of your screen)

The session is being **recorded.**
The recording will be posted on IHI's website and Youtube channel.

COCIR · efpia · EuropaBio · MedTech Europe from diagnosis to cure · Vaccines Europe · Co-funded by the European Union

Network building in COMBACTE

Marc Bonten

University Medical Center Utrecht

Antimicrobial resistance: the perfect storm

- Associated with worse outcomes and costs
- Jeopardizing modern medicine
- Increasing worldwide
- Slow development of new antibiotics

2012: Objectives of COMBACTE

- Increase efficiency of antibiotic development
  - Align clinical trials with cutting edge molecular methodologies and trial design

- Create a self-sustaining premier antibacterial development network
  - Expanding research and laboratory networks
  - Optimal alignment of clinical trials with investigator sites
  - Clinical and epidemiologic data also supports stewardship

What makes studies in antibiotic resistance inefficient?

- EARL hurdles: Ethical, Administrative, Regulatory and Legal
- Lack of appropriate expertise training for executing studies in acute infectious diseases (inverse relation between capacity and prevalence of resistance!)
- Lack of laboratory support for study execution
- Incomplete understanding of antibiotic resistance epidemiology
- Lack of innovation in clinical trial methodology

2024: The network of networks created by COMBACTE

1. CLIN-Net
   - The network of study sites; hospitals and primary care sites
2. LAB-Net
   - The network of laboratories supporting the clinical studies in CLIN-Net
3. STAT-Net
   - The network of experts in methodological and statistical aspects of clinical studies in infectious diseases
4. EPI-Net
   - The network of experts in epidemiological studies in infectious diseases

CLIN-Net and LAB-Net achievements

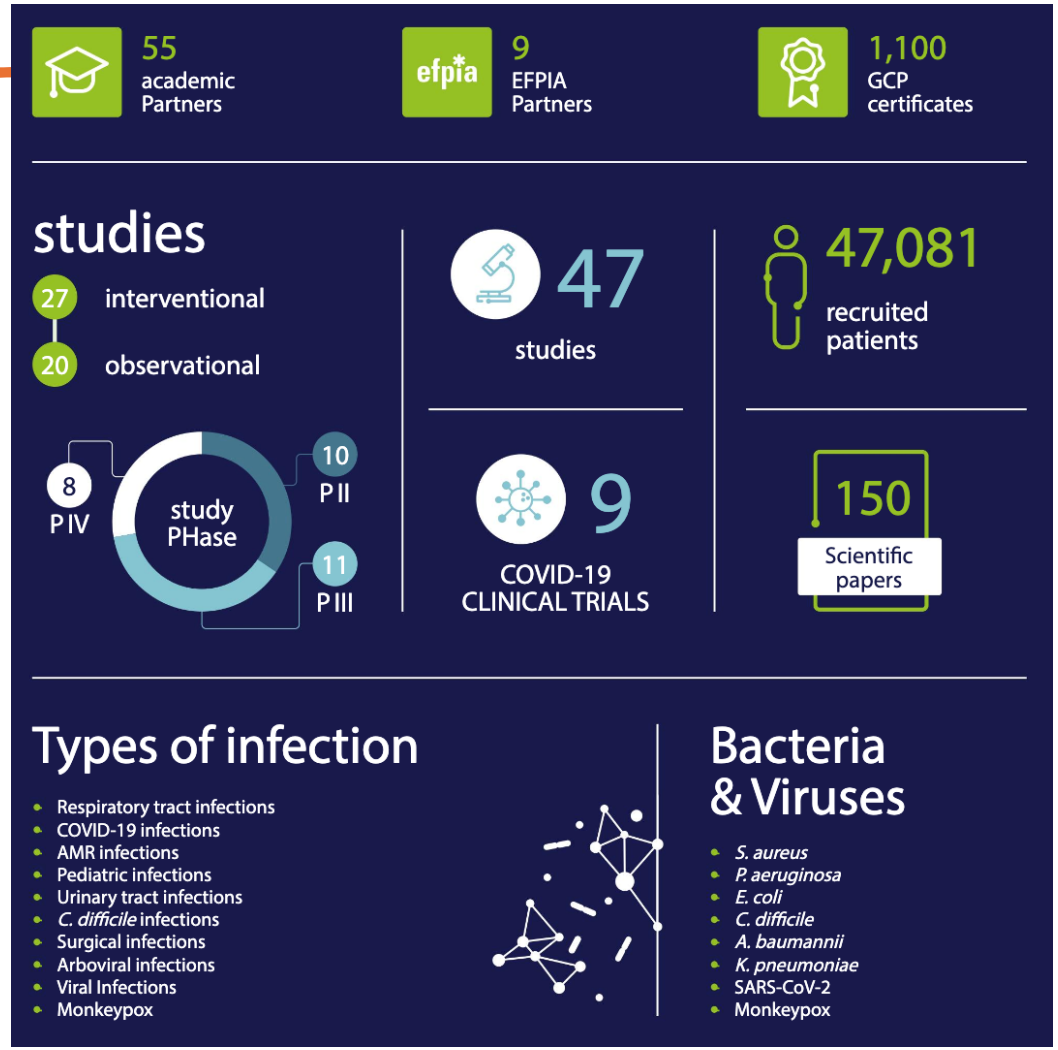
CLIN-Net	LAB-Net
GCP and GLP trainings (face-to-face & online) Protocolized site selection procedure Continuous growth of network	
Contracting of study sites Regulatory approvals of studies Site management during studies Building a portfolio of quality parameters of study sites	Quality control Sampling transports Sampling analysis Biobanking & Repository

ND BB COMBACTE NET

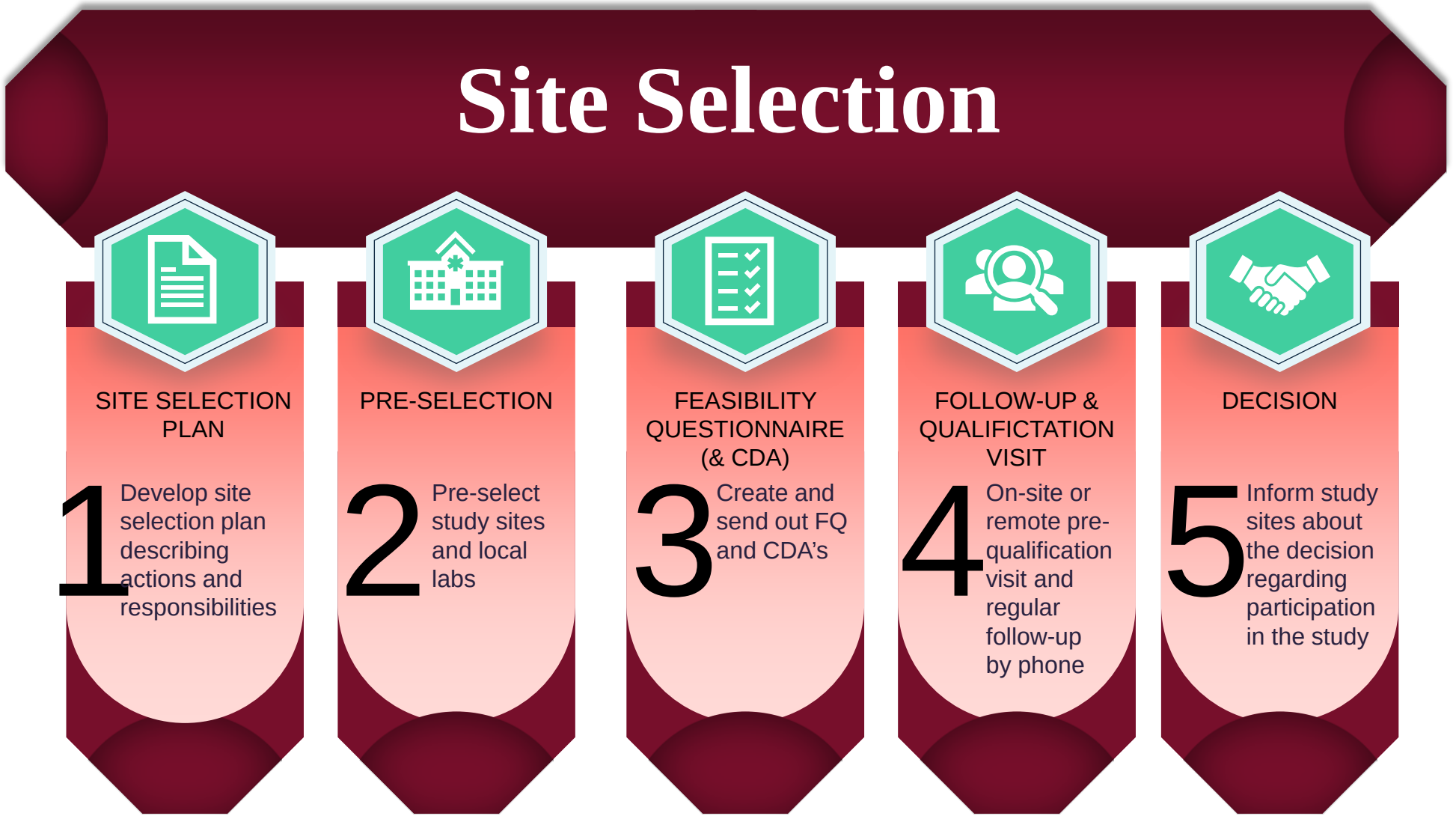
ND BB COMBACTE MAGNET

ND BB COMBACTE CARE

CLIN-Net and LAB-Net in figures



Site Selection



As of now, 614 sites selected by a Site Selection Board to participate in at least one study or selected for a site qualification visit.

EPI-Net achievements

1. Optimized surveillance for antibiotic resistance and infections in healthcare settings
2. Contributed to homogenization of current and future surveillance in Europe
3. Informing public health actions
4. Informing and guiding R&D for new antibiotics for multidrug-resistant pathogens

Consensus and recommendations to support homogenisation of surveillance strategies in EU countries

25 pubblications

Journal of Antimicrobial Chemotherapy

White Paper: Bridging the gap between human and animal surveillance data, antibiotic policy and stewardship in the hospital sector—practical guidance from the JPIAMR ARCH and COMBACTE-MAGNET EPI-Net networks

White Paper: Bridging the gap between surveillance data and antimicrobial stewardship in long-term care facilities—practical guidance from the JPIAMR ARCH and COMBACTE-MAGNET EPI-Net networks

White Paper: Bridging the gap between surveillance data and antimicrobial stewardship in the animal sector—practical guidance from the JPIAMR ARCH and COMBACTE-MAGNET EPI-Net networks

White Paper: Bridging the gap between surveillance data and antimicrobial stewardship in the outpatient sector—practical guidance from the JPIAMR ARCH and COMBACTE-MAGNET EPI-Net networks

Lancet Infectious Diseases 2018

Surveillance for control of antimicrobial resistance

Evelina Tacconelli, Frangiscos Sifakis, Stephan Harbarth, Remco Schrijver, Maaike van Mourik, Andreas Voss, Mike Sharland, Nithya Babu Rajendran, Jesús Rodríguez-Baño, on behalf of the EPI-Net COMBACTE-MAGNET Group*

Health Policy

Lancet Regional Health Europe 2023

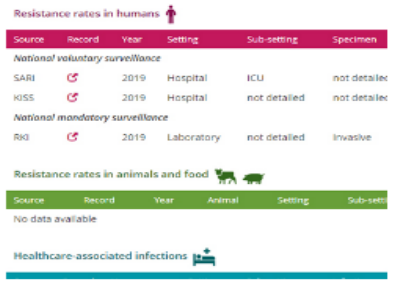
EPI-Net One Health reporting guideline for antimicrobial consumption and resistance surveillance data: a Delphi approach

Nithya Babu Rajendran,[a,ac] Fabiana Arieti,[b,ac] Carla Alejandra Mena-Benítez,[b,ac] Liliana Galia,[b,ad] Maela Tebon,[b,ad] Julio Alvarez,[c] Beryl Primrose Gladstone,[a,d] Lucie Collineau,[e] Giulia De Angelis,[f] Raquel Duro,[g] William Gaze,[h] Siri Göpel,[a,d] Souha S. Kanj,[i] Annemarie Käsbohrer,[j] Direk Limmathurotsakul,[k,l] Estibaliz Lopez de Abechuco,[j] Elena Mazzolini,[m] Nico T. Mutters,[n,o] Maria Diletta Pezzani,[b] Elisabeth Presterl,[o,p,q] Hanna Renk,[r] Jesús Rodríguez-Baño,[s,t] Oana Săndulescu,[u,v] Federico Scali,[w] Robert Skov,[x] Thirumalaisamy P. Velavan,[y,z] Cuong Vuong,[aa,ab] and Evelina Tacconelli,[b,o,*] on behalf of the EPI-Net One Health consensus working group

EPI-Net: a One-stop AMR/HAI epidemiology online platform yearly updated & public

epi-net.eu/overview

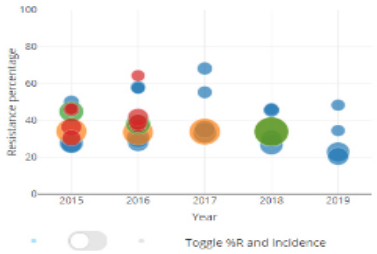
Prevalence/incidence of antibiotic resistance



Antibiotic resistance by country

All available data on a target pathogen fo a specific country

View data

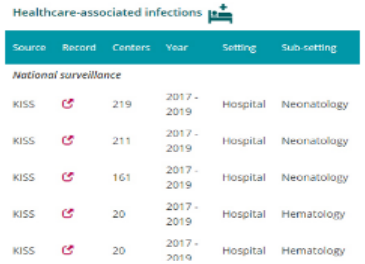


One Health resistance profile by country

Trends in resistance rates and outbreaks history

View data

Healthcare-associated infections



Healthcare-associated infections by country

Incidence data on target healthcare-associated infections for a specific country

View data

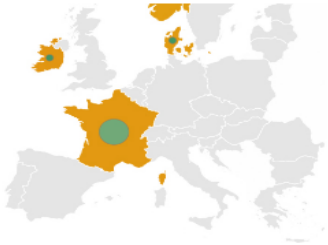
Emerging resistances to new antibiotics

Emerging resistances

View the most recently approved antibiotics for human medicine in EU and reports of resistances emerging for these antibiotics

View data

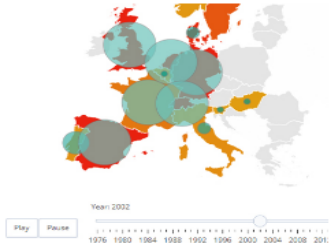
History of antibiotic resistance outbreaks



Outbreaks across Europe

Visualize where an outbreak was reported for a particular pathogen during a specific year

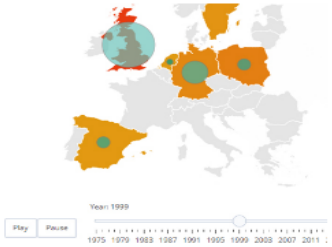
View data



Outbreaks across Europe (from the first outbreak)

Visualize outbreaks reported for a particular pathogen in chronological order through a time series heat map

View data



Outbreaks across Europe (from 1975)

Visualize outbreaks reported for a particular pathogen in chronological order through a time series heat map

View data

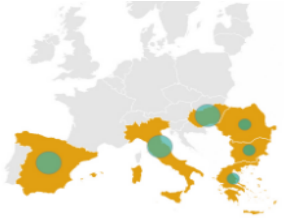
Antifungal resistance

Antifungal resistance across Europe

Antifungal resistance rates in Candida from multiple sources across Europe

View data

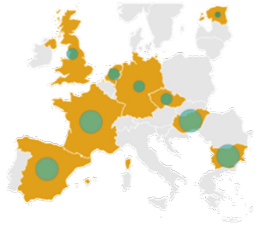
COMBACTE studies and trials



RESCUING

Study design: retrospective observational
Study period: 2013-2014
Geographical coverage: Europe
No. participating centers: 20

View data



ASPIRE-ICU

Study design: prospective observational
Study period: 2015-2018
Geographical coverage: Europe
No. participating centers: 29

View data

EPI-Net CDR

25 Target Pathogens

5 Target HAI

23.968.723 strains

932.140 strains

CDR: Surveillance systems

34 national human AMR (V); 14 national human AMR (M); 27 national human HAI; 19 national animal AMR, 1 international AMR human (3 countries); 1 international human HAI; 1 international animal AMR

Total Emerging resistance reports: 203

TOTAL Outbreaks (studies) : 619

TOTAL Outbreaks (mandatory notifications): 621

LAST DEVELOPMENTS

Candidemia Surveillance online (J fungi 2022)

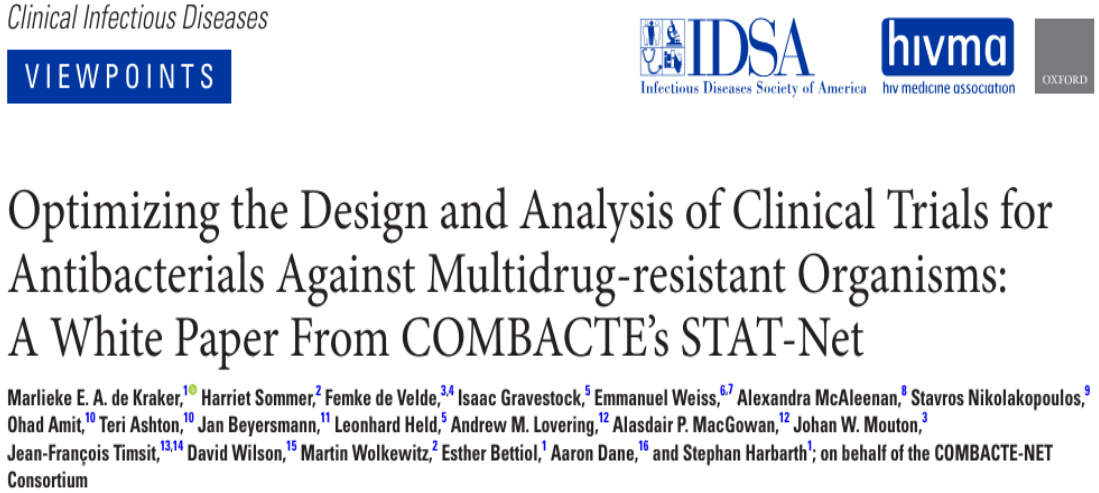
AMR Travel Tool online provides info on AMR for patients and medical doctors (see video at https://epi-net.eu/travel-tool/overview/)

Excellence Centers - network on centers specialised in surveillance (see video at https://epi-net.eu/excellence-centers/overview/)

ENSURE project implemented EPI-Net surveillance recommendations for surveillance in high endemic hospitals for AMR (J hosp infect 2024; one under review)

STAT-Net achievements

- Application of population PK models for PK variability and optimised dosing
- Rank-based composite end points to improve power and relevancy
- Multistate models to examine a range of time-dependent clinical outcomes
- Use of historical clinical trial data for design/ analysis
- Teach the next generation on platform trials



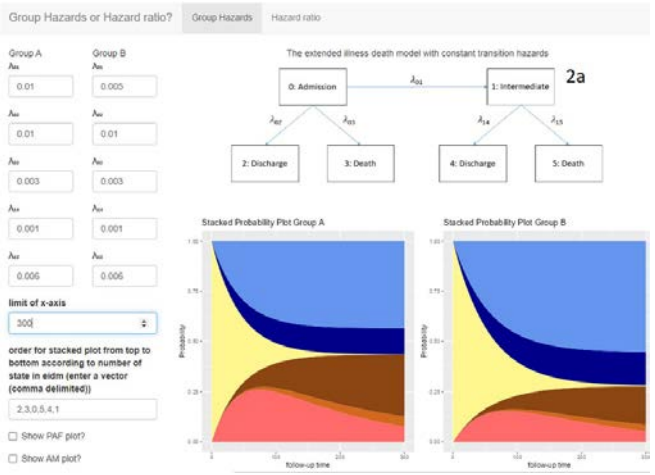
ND BB COMBACTE NET
ND BB COMBACTE MAGNET
ND BB COMBACTE CARE

Novel endpoints for ventilator-associated pneumonia RCTs

- **Evidence synthesis**: Critical Care 2017: 21;162. doi: 10.1186/s13054-017-1755-5
- **Expert consensus:** Clin Infect Dis 2019: 69; 1912-1918. doi: 10.1093/cid/ciz093
- **Implementation:** Crit Care. 2024; 28: 10. doi: 10.1186/s13054-023-04792-0

Shiny app improving insights in competing time-dependent outcomes in RCTs

- BMC Medical Research Methodology (2024) 24:116 https://doi.org/10.1186/s12874-024-02240-3



From COMBACTE to Ecraid

(European Clinical Research Alliance on Infectious Diseases)

- From public-private partnerschip consortium to a not-for-profit foundation led by academic investigators
- CLIN-Net, LAB-Net, STAT-Net and EPI-Net pillars of Ecraid
- International leadership
  - Based in Utrecht, currently 80 employees (research support)
  - Management board of 3 (2 EU countries)
  - Coordinating Committee of 17 (11 EU countries)
  - Ecraid Clinical Liaison Council of 24 (19 EU countries)
- Current activity: 11 international studies in 269 study sites in 24 EU countries
- Operational data collection tool according to FAIR data principles

Observational studies in COMBACTE

Jesús Rodríguez-Baño

Hospital Universitario Virgen Macarena and University of Sevilla

Epidemiological and observational studies

- **No intervention**
  - Burden of disease, risk factors for the infection
  - Management, predictors for outcomes
- Help to understand **priorities** in AMR research and **gaps** in knowledge
- Inform more **efficient design** of randomised trials
- Provide additional, generalizable information of "**real life**" data

- **Limitations** to assess casualty (treatments comparisons)

Observational studies within COMBACTE

- Projects:
  - COMBACTE-NET
    - ASPIRE-ICU, ASPIRE-SSI, ANTICIPATE, ARTHR-IS, EXPECT, HONEST-PREPS
  - COMBACTE-CARE
    - EURECA
  - COMBACTE-MAGNET
    - RESCUING

- Infections
  - Ventilator-associated pneumonia
  - Surgical site infections
  - Prosthetic joint infections
  - Urinary tract infections
- Microorganisms
  - *Staphylocccus aureus*
  - *Pseudomonas aeruginosa*
  - *Clostridioides difficile*
  - Carbapenem-resistant Enterobacterales
  - Carbapenem-resistant *Acinetobacter*

Scientific publications available at
https://www.combacte.com/publications/

Questions for carbapenem-resistant Enterobacterales

Risk factors? | Impact in mortality?

Usefulness for randomised trials

Efficient design | Sample size needed

Study design

Multinational matched case-control Study

EURECA: 50 hospitals, 10 European countries

Patients with CRE infections (N=235)	Patients with CSE infections (N=235)	Patients without infection (N=705)

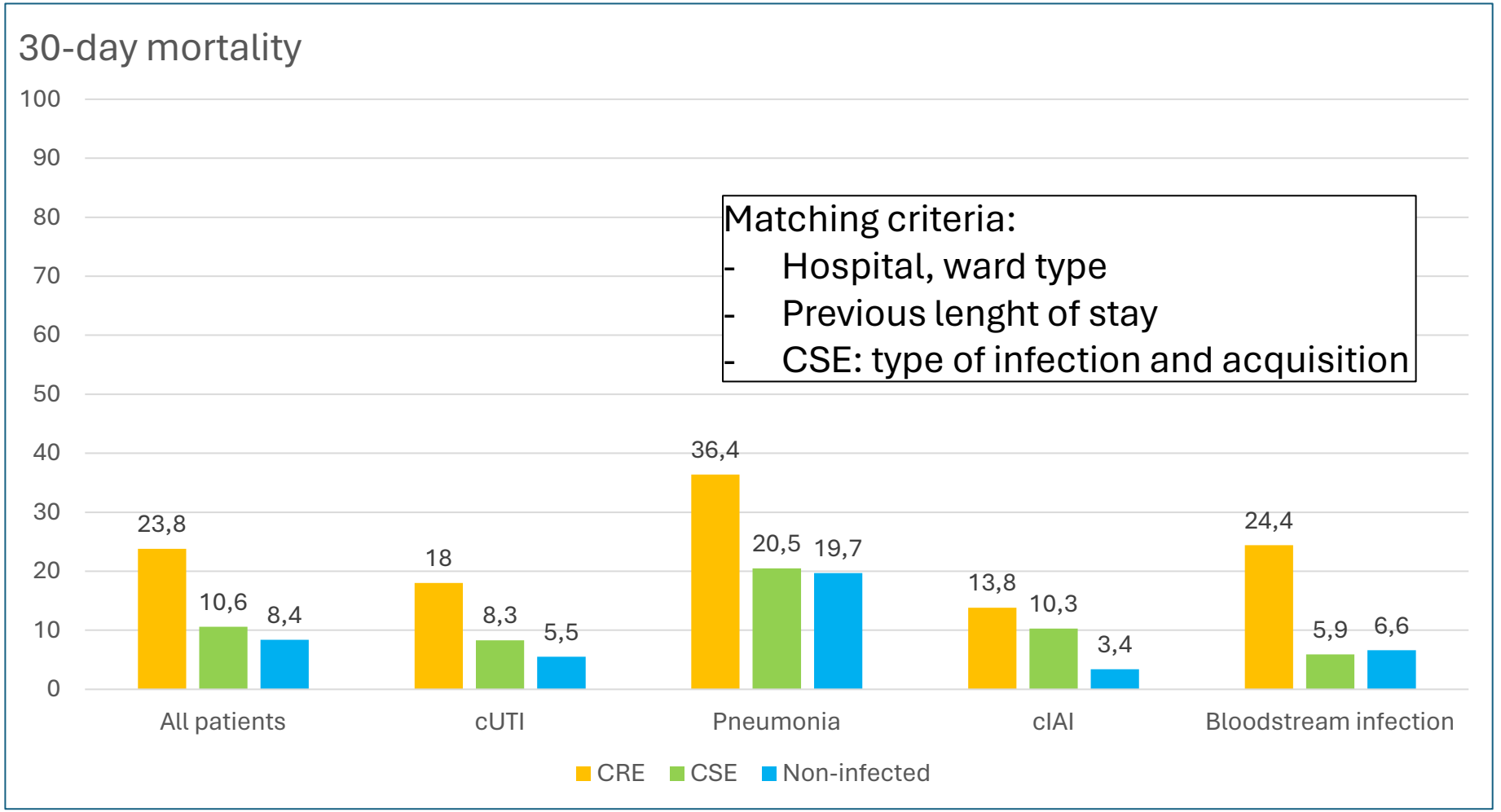
CRE: carbapenem-resistant Enterobacterales
CSE: carbapenem-susceptible Enterobacterales

Risk factors for carbapenem-resistant Enterobacterales (CRE) *vs* carbapenem-susceptible (CSE) or non-infected patients

	CRE vs CSE	CRE vs non-infected
Age		
Chronic renal failure		
Previous colonisation by CRE		
Previous hospital admission		
Urinary catheter		
Immunosupressive drugs		
Previous antibiotics		

Perez-Galera et al. eClinicalMedicine 2023
https://doi.org/10.1016/j.eclinm.2023.101871

Attributable mortality to carbapenem-resistance in Enterobacterales infection



CRE: carbapenem-resistant Enterobacterales CSE: carbapenem-resistant Enterobacterales
cUTI: complicated urinary tract infections. cIAI: complicated intraabdominal infections

Paniagua-García et al, Clin Microbiol Infect 2024

Beyond results - added value of multinational observational studies in COMBACTE

- Use of a clinical and laboratory network (CLIN-Net, LAB-Net)
  - Able to run complex, multinational studies in Europe
  - Sites trained for randomised trial participation
  - Able to perform complex data analysis (STAT-Net)
- Aggregated data incorporated to EPI-Net repository
  - Global epidemiology knowledge
  - Data sharing
- Preliminary data used for design of randomised trials
  - Target high risk population, sample size

IMI Impact on AMR

HALLEY ROGERS, PFIZER

31 MAY 2024

This research project receives support from the Innovative Medicines Initiative Joint Undertaking under grant agreement n° 115523 | 115620 | 115737 resources of which are composed of financial contribution from the European Union Seventh Framework Programme (FP7/2007-2013) and EFPIA companies in kind contribution.

UMC Utrecht

COMBACTE-CARE

COMBATTING BACTERIAL RESISTANCE IN EUROPE – CARBAPENEM-RESISTANCE

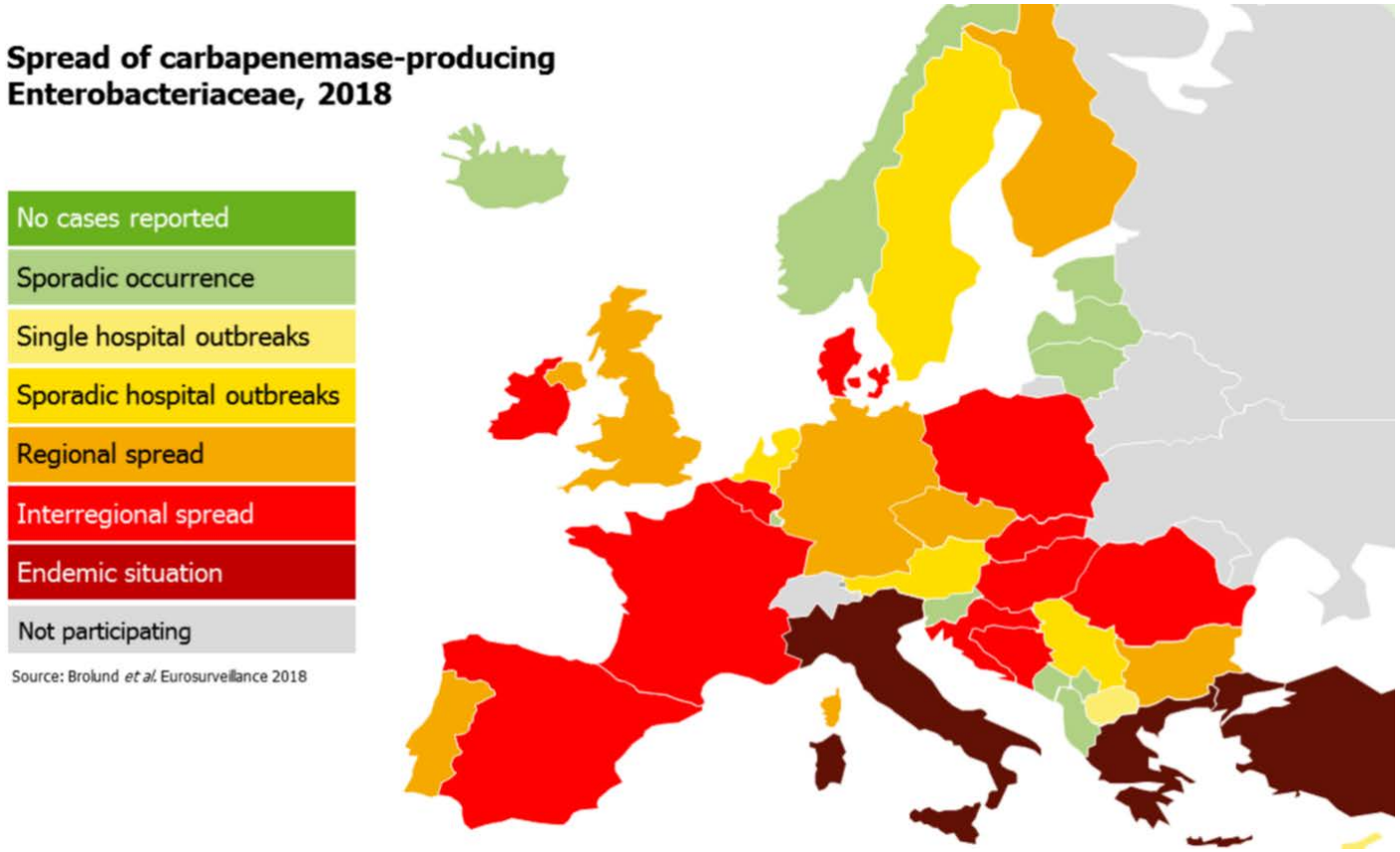
- **As stated on the COMBACTE-CARE site, the project aims to:**
  1. better understand multi-drug resistant bacterial infections such as carbapenem resistant Enterobacteriaceae (CRE) and to support the development of new treatment options;
  2. analyse observational clinical and epidemiological data sets to inform the design of randomised trials;
  3. **make significant contributions to the development of a novel treatment option, aztreonam-avibactam (ATM-AVI), for patients with serious Gram-negative bacterial infections, including those caused by a particular type of carbapenem-resistance (metallo-β-lactamase), for which there are limited or no treatment options**

This is where we will focus in this presentation

https://www.combacte.com/about/about-combacte-care-detail/

Introduction

- Antimicrobial resistance is a growing problem worldwide
- Infections caused by bacteria known as CREs are resistant to most available antibiotics and are so difficult to treat they are considered to be one of the most dangerous drug-resistant bacteria in the world.
- Cases of CRE infections are on the rise in Europe and globally.



European Centre for Disease Prevention and Control
CRE = carbapenem-resistant enterobacterales

Study C3601001 (REJUVENATE) was a Phase 2a, prospective, open-label, multicentre, non-comparative, dose-selection study

Objectives[1]

- To assess the PK (how the medicine interacts with the body), safety and tolerability and efficacy of a combination medicine called ATM-AVI for the treatment of complicated intra-abdominal infection (cIAI) in hospitalised adults

Patient eligibility and cohorts[1]

- Adult patients between the ages of 18 to 90 years with a diagnosis of cIAI
- Must have had/were planning to have a surgery within 24 hours administration of the first dose of ATM-AVI
- Patients who had failed prior antibacterial treatment for their current cIAI were eligible but must have had a known or suspected pathogen causing cIAI resistant to the prior therapy

*continuation with escalation of AVI dose**

Cohort 1
Patients with normal renal function or mild renal impairment

(CrCl >50 mL/min; **n=16**)

Cohorts 2+3
Patients with **normal renal function** or **mild or moderate renal impairment**

(**n=18** [n=17 with CrCl > 50 mL/min; **n=1** with CrCl >30–50 mL/min])

In WP2A REJUVENATE, COMBACTE CARE enrolled all 40 patients from 3 countries (Spain, France, Germany)

Abbreviations: ATM = aztreonam; AVI = avibactam; cIAI = complicated intra-abdominal infection; CrCl = creatinine clearance; mL/min = milliliter per minute; PK = pharmacokinetics

Lessons Learnt WP2A ➡ WP2B

- COMBACTE-CARE Spanish site (Virgen del Rocio in Seville) were particularly successful at recruiting patients for the **REJUVENATE** study

- Their learnings were key to support recruitment initiatives:
  - creation of a video highlighting the importance of a multidisciplinary study team
  - coordinating communications for successful recruitment and retention

- These lessons allowed the network to build upon the efficient and effective clinical recruitment within COMBACTE sites and translate them into the **WP2B REVISIT study**

Study C3601002 (REVISIT) was a Phase 3, prospective, open-label, multicentre, comparative study

Study treatments and endpoints

Adults ≥18 years with confirmed diagnosis of HAP/VAP or cIAI requiring IV antibiotic treatment

→ **Experimental arm: ATM–AVI ± MTZ (n=282)[a]**

→ **Active comparator: Meropenem (MER) ± Colistin (COL) (n=140)[b]**

- 422 subjects with complicated intra-abdominal infection (cIAI) or hospital-acquired pneumonia/ventilator-associated pneumonia (HAP/VAP) caused by Gram-negative bacteria in countries with emerging or high incidence of carbapenem resistance
- Approximately 165 sites in ~20 countries in the Americas, Europe, & Asia
- Minimum treatment duration: 5 days cIAI; 7 days for HAP/VAP
- Maximum treatment duration: 14 days

Primary endpoint: Clinical cure at Day 28/ Test of Cure (TOC) visit (ITT and CE populations)

Secondary endpoints:

- Clinical cure at TOC in a population of participants who meet specific microbiological and clinical criteria (mITT and ME populations)
- Microbiological response at End of Treatment and TOC (micro-ITT and ME populations)
- How ATM-AVI works in the body, and relationship between exposure and clinical and microbiological response
- Safety and tolerability profile
- 28-day mortality

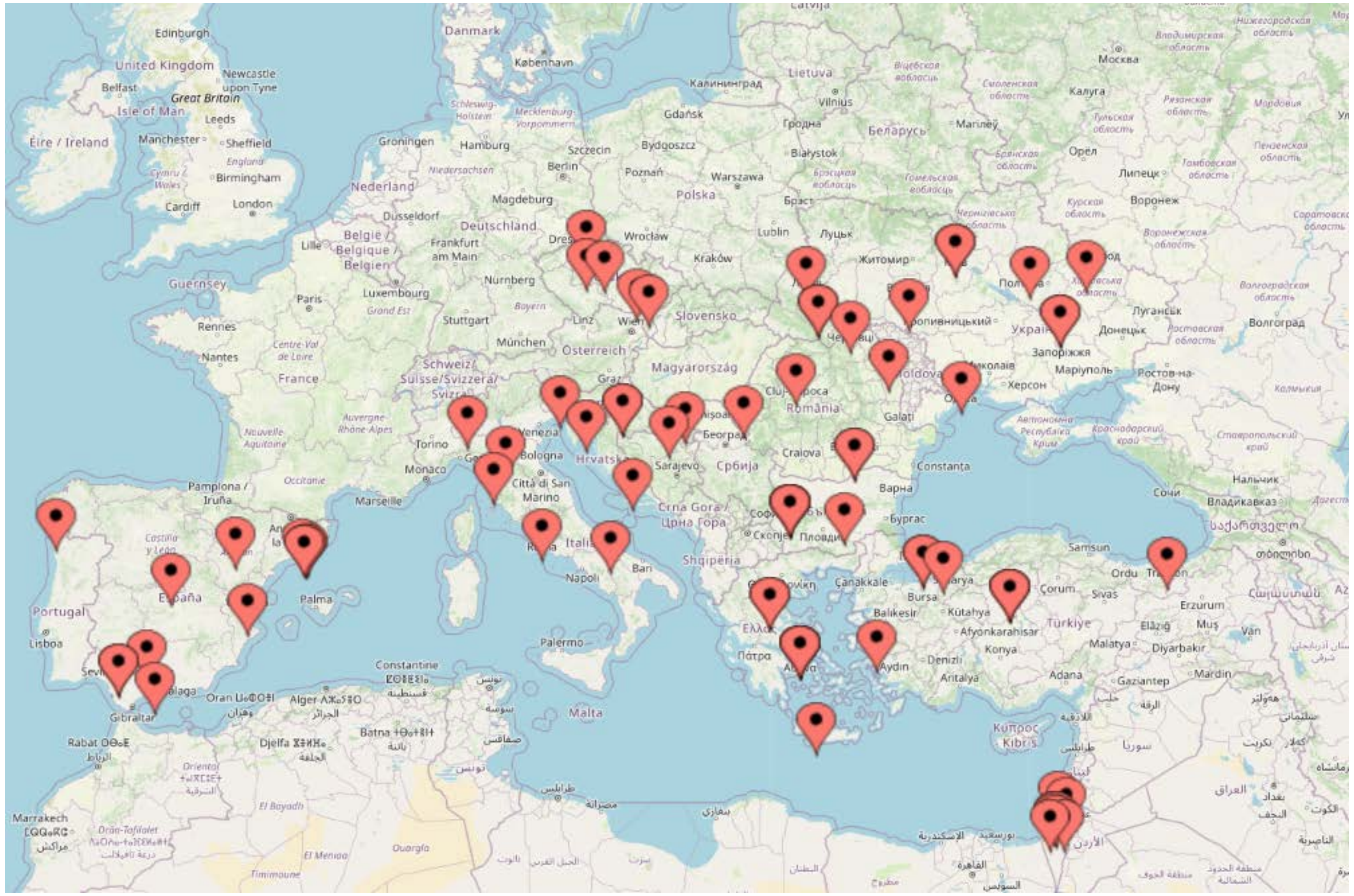
[a]All patients with cIAI will receive MTZ for anaerobic cover. [b]Addition of COL will be at investigator's discretion in line with the local practice regarding COL.

Abbreviations: ATM = aztreonam; AVI = avibactam; CE = clinically evaluable; cIAI = complicated intra-abdominal infection; COL = colistin; CrCl = creatinine clearance; EOT = end of treatment; HAP = hospital-acquired pneumonia; ITT = intent-to-treat; IV = intravenous; ME = microbiologically evaluable; MER = meropenem; mITT = modified intent-to-treat; MTZ = metronidazole; PK = pharmacokinetics; = TOC = test of cure; VAP = ventilator-associated pneumonia.

WP2B REVISIT Enrolment Summary

COMBACTE-CARE was a key contributor to the study

- 422 participants were enrolled around the world
- **Approximately 50% of all subjects randomized were at COMBACTE-CARE sites**
- 4 of the top 6 recruiting sites in the world were from the COMBACTE-CARE network



WP2B – REVISIT Challenges and Strategies

	Maximize site and country footprint	Patience and compassion for sites and their priorities	Collaborative, proactive and targeted site selection	Optimize manufacturers and suppliers	Just in Time training and training tools	Regional contacts and expertise
COVID-19	X	X		X	X	X
Geopolitical conflict		X				X
Site drop out/loss of motivation	X	X	X			X
Recruitment challenges	X	X	X		X	X
Clinical Drug Supply shortages				X		
Lab supply shortages and shutdowns	X			X		
Importation restrictions	X			X		X
Changes in Standard of Care since 2018			X			X

WP2B - REVISIT Specific Approaches

Collaborative, inter-departmental hospital study team

Enrollment video (produced by SAS)

Patient Pathway Identification Exercise

Virtual Investigator Meetings and remote monitoring, as permissible

Clinical Drug Supply flexibility

•Contracted with multiple drug supply manufacturers

Academic leads 24/7 telephone investigator support line

Study specific recruitment support tools (developed by Tel Aviv (TASMC)) and supporting training videos

Academic lead role in oversight of planning, study conduct, and medical support

Collaboration across COMBACTE-CARE partners was key

CONCLUSION and IMPACT

- COMBACTE CARE demonstrated that (and how) a public private partnership between industry and academia can work, reinforcing our common goal in finding novel solutions for patients with serious infections.

- These clinical studies have led to approval of a new antibiotic.
  - More information can be found at Emblaveo | European Medicines Agency (europa.eu)

- The close relationships grown from this consortium will:
  - Help the global fight against AMR
  - Provide evidence that Europe has the capacity/infrastructure to conduct clinical trials for novel antibacterial agents

Disclaimer: Pfizer makes no representation or warranty about the data and information contained herein, all of which is Confidential Information subject to the March 1, 2015 Project Agreement for COMBACTE-CARE. The Confidential Information presented is subject to change.

The contents of this presentation are not intended to be promotional, but rather to share information that is publicly available or content that is related to lessons learned through this dynamic partnership

COMBACTE Clinical Trials from investigator's perspective

IMI impact on AMR

Contribution of COMBACTE projects

BRUNO FRANÇOIS

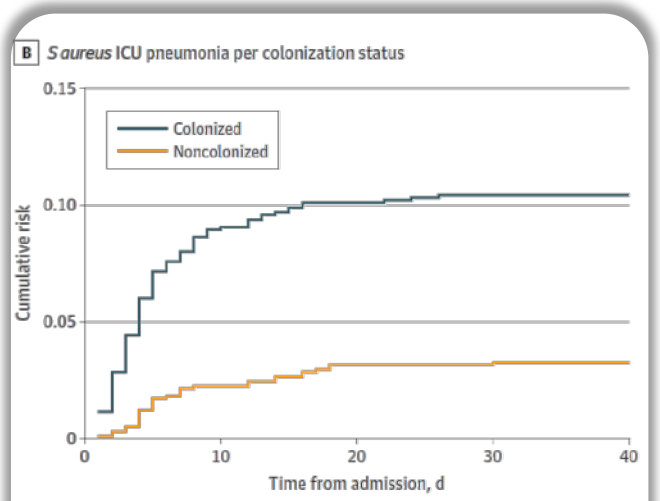
31ST MAY 2024

This research project receives support from the Innovative Medicines Initiative Joint Undertaking under grant agreement n° 115523 | 115620 | 115737 resources of which are composed of financial contribution from the European Union Seventh Framework Programme (FP7/2007-2013) and EFPIA companies in kind contribution.

Examples of studies run

ASPIRE-ICU **SAATELLITE** **SAATELLITE-2** **EVADE** **HONEST-PREPS**

Examples of studies run



ASPIRE-ICU

Observational
S aureus screening at admission
1933 inclusions

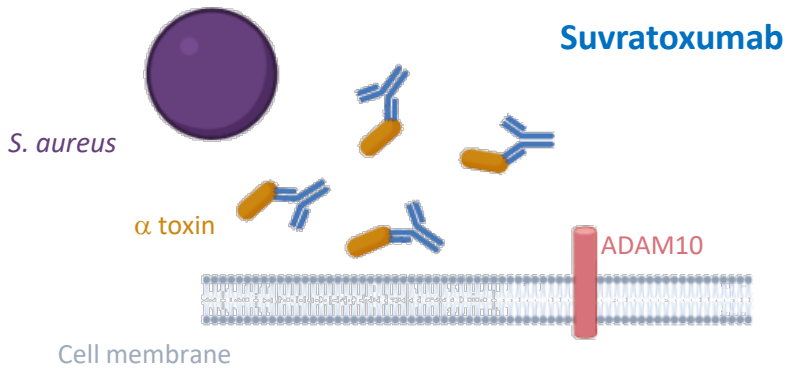
SAATELLITE

SAATELLITE-2

EVADE

HONEST-PREPS

Examples of studies run



ASPIRE-ICU

SAATELLITE

Phase II
767 screenings
213 randomizations
31 sites, 9 countries

SAATELLITE-2

Phase III
54 screenings
23 randomizations
33 sites

EVADE

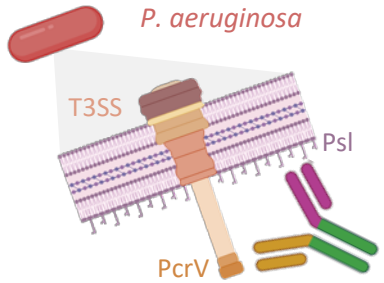
HONEST-PREPS

Examples of studies run

ASPIRE-ICU

SAATELLITE

SAATELLITE-2



Gremubamab

Cell membrane

EVADE

Phase II
1023 screenings
188 randomizations
31 sites, 9 countries

HONEST-PREPS

Examples of studies run

ASPIRE-ICU

SAATELLITE

SAATELLITE-2

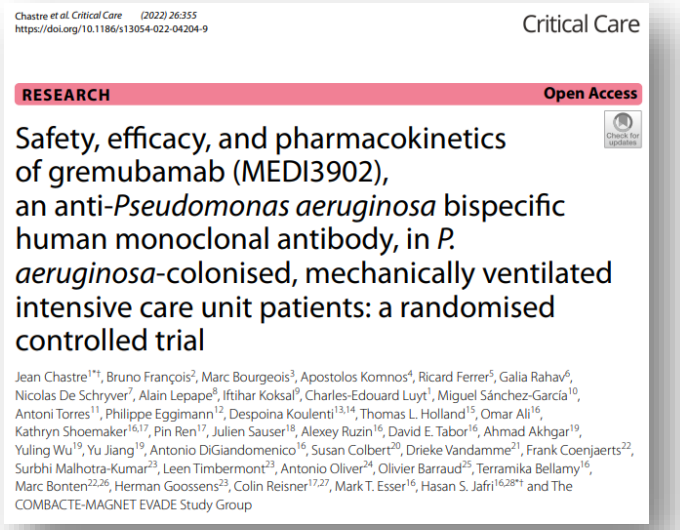
EVADE

HONEST-PREPS

Observational
Feasibility of VAP trials
2165 ICU patients
11 sites

Studies valorisation

EVADE Study



Chastre et al. Critical Care (2022) 26:355
https://doi.org/10.1186/s13054-022-04204-9

Critical Care

RESEARCH Open Access

Safety, efficacy, and pharmacokinetics of gremubamab (MEDI3902), an anti-*Pseudomonas aeruginosa* bispecific human monoclonal antibody, in *P. aeruginosa*-colonised, mechanically ventilated intensive care unit patients: a randomised controlled trial

Jean Chastre[1*†], Bruno François[2], Marc Bourgeois[3], Apostolos Komnos[4], Ricard Ferrer[5], Galia Rahav[6], Nicolas De Schryver[7], Alain Lepape[8], Iftihar Koksal[9], Charles-Edouard Luyt[1], Miguel Sánchez-García[10], Antoni Torres[11], Philippe Eggimann[12], Despoina Koulenti[13,14], Thomas L. Holland[15], Omar Ali[16], Kathryn Shoemaker[16,17], Pin Ren[17], Julien Sauser[18], Alexey Ruzin[16], David E. Tabor[16], Ahmad Akhgar[19], Yuling Wu[19], Yu Jiang[19], Antonio DiGiandomenico[16], Susan Colbert[20], Drieke Vandamme[21], Frank Coenjaerts[22], Surbhi Malhotra-Kumar[23], Leen Timbermont[23], Antonio Oliver[24], Olivier Barraud[25], Terramika Bellamy[16], Marc Bonten[22,26], Herman Goossens[23], Colin Reisner[17,27], Mark T. Esser[16], Hasan S. Jafri[16,28*†] and The COMBACTE-MAGNET EVADE Study Group

SAATELLITE Study

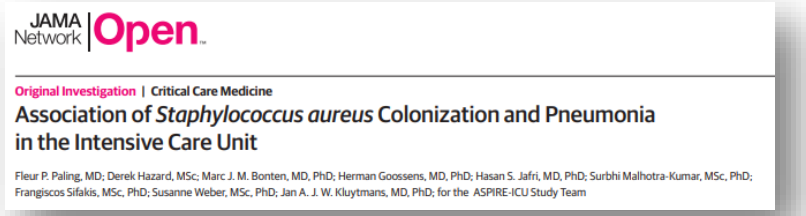
Antimicrobial Chemotherapy | Research Article | 27 June 2022

Journal of Clinical Microbiology

Performance of the Cepheid Methicillin-Resistant *Staphylococcus aureus*/*S. aureus* Skin and Soft Tissue Infection PCR Assay on Respiratory Samples from Mechanically Ventilated Patients for *S. aureus* Screening during the Phase 2 Double-Blind SAATELLITE Study

Authors: Alexey Ruzin, Olivier Barraud, Li Yu, Bruno François, Miguel Sánchez-Garcia, Philippe Eggimann, Pierre-François Dequin , SHOW ALL (29 AUTHORS) on behalf of the SAATELLITE Study Group | AUTHORS INFO & AFFILIATIONS

ASPIRE ICU Study



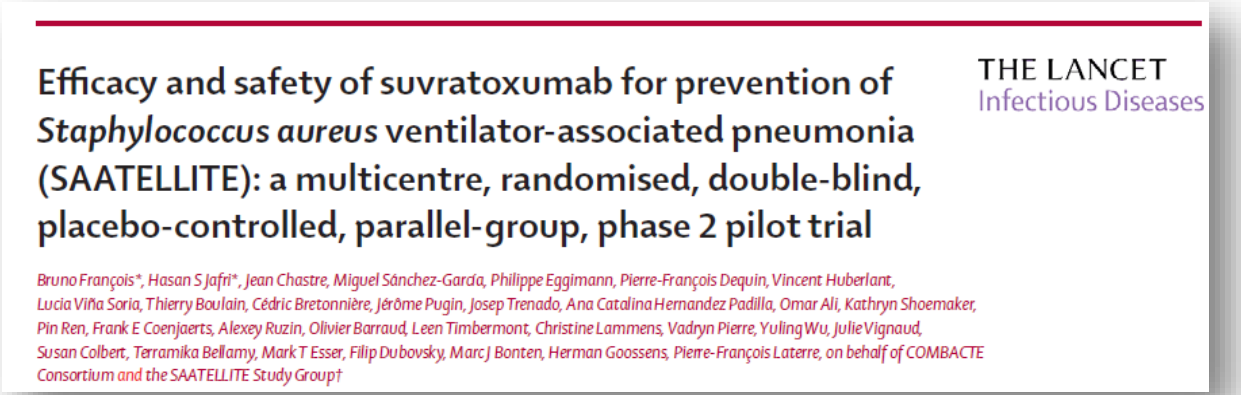
JAMA Network Open

Original Investigation | Critical Care Medicine

Association of *Staphylococcus aureus* Colonization and Pneumonia in the Intensive Care Unit

Fleur P. Paling, MD; Derek Hazard, MSc; Marc J. M. Bonten, MD, PhD; Herman Goossens, MD, PhD; Hasan S. Jafri, MD, PhD; Surbhi Malhotra-Kumar, MSc, PhD; Frangiscos Sifakis, MSc, PhD; Susanne Weber, MSc, PhD; Jan A. J. W. Kluytmans, MD, PhD; for the ASPIRE-ICU Study Team

SAATELLITE Study



THE LANCET Infectious Diseases

Efficacy and safety of suvratoxumab for prevention of *Staphylococcus aureus* ventilator-associated pneumonia (SAATELLITE): a multicentre, randomised, double-blind, placebo-controlled, parallel-group, phase 2 pilot trial

Bruno François, Hasan S Jafri*, Jean Chastre, Miguel Sánchez-García, Philippe Eggimann, Pierre-François Dequin, Vincent Huberlant, Lucia Viña Soria, Thierry Boulain, Cédric Bretonnière, Jérôme Pugin, Josep Trenado, Ana Catalina Hernandez Padilla, Omar Ali, Kathryn Shoemaker, Pin Ren, Frank E Coenjaerts, Alexey Ruzin, Olivier Barraud, Leen Timbermont, Christine Lammens, Vadryn Pierre, Yuling Wu, Julie Vignaud, Susan Colbert, Terramika Bellamy, Mark T Esser, Filip Dubovsky, Marc J Bonten, Herman Goossens, Pierre-François Laterre, on behalf of COMBACTE Consortium and the SAATELLITE Study Group†*

Synergies in the partnerships

- **Strong collaboration with EFPIA partners**
  - Designing clinical trials to assess the safety and efficacy of anti-virulence agents is challenging and cannot be done efficiently without combining the forces and expertise of academia and pharma companies
  - Strategic discussions, transparency in the process used, joint decision-making (balanced governance structures)
- **Open and direct communication between academics and medical leaders, industrials and sites**
- **Interdisciplinary collaboration**
- **Greater involvement of the academic partners in every steps of the trial**
  - Participation in the study boards: scientific (protocol design), site selection (equal voting members)
  - Involvement in the discussions with regulatory bodies (EMA, FDA)
  - Data analysis and redaction of the clinical study report / study publication
- **As partner: access to all studies data and biological samples (creation of biocollections)**

Networking opportunities

- **Collaboration with multidisciplinary teams**
- **Establishment of new contacts in Europe and creation of national networks**
  - CLIN-Net: Europe-wide network of hospitals prepared for performing high-quality clinical studies with new antimicrobials
- **Creation of a collective dynamism in clinical research**
- **Acquisition of new skills**
- **Site capacity building through investigator and laboratory trainings, site visits, site calls, providing sites with state-of-the-art molecular diagnostic tools**
- **Opportunities for less experienced site personnel to visit top performing sites for on-site training**

And for the patients?

- **Possibility to participate in innovative clinical trials in terms of therapeutics and methodology**
  - Monoclonal antibodies represent a potential alternative to systemic antibiotics for the prevention of infections because they do not influence antibiotic sensitivity

- **The design of clinical trials protocols are more realistic and feasible in real life**
  - Patients inclusion and follow-up is optimized

What remains beyond COMBACTE?

- **Creation of investigational networks and identification of National Clinical Liaison Teams**
  - > 40 countries, > 1000 hospitals, > 3400 contacts
  - Facilitates the initiation of new studies based on sites capabilities and performances

- **All know-how built during COMBACTE is now integrated into ECRAID**
  - Which opens up to general practice: more patients can be involved and more pathologies can be considered

Q&A time

Use the **chat** below to ask questions to the speakers

innovative health initiative

innovative health initiative

Thank you for your attention

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efpia

EuropaBio The European Association for Bioindustries

MedTech Europe from diagnosis to cure

Vaccines Europe

Co-funded by the European Union