DIPLOME UNIVERSITAIRE
ANTIBIOTIQUES ET ANTIBIOTHERAPIE
2023/2024

Phagothérapie et thérapies dérivées des phages dans les infections bactériennes sévères

Tristan Ferry, MD, PhD

tristan.ferry@univ-lyon1.fr

@FerryLyon

Infectious and Tropical Diseases Unit, Croix-Rousse Hospital , Hospices Civils de Lyon, Claude Bernard Lyon1 University, Lyon
Centre International de Recherche en Infectiologie, CIRI, Inserm U1111, CNRS UMR5308, ENS de Lyon, UCBL1, Lyon, France
Clinical officer ESCMID Study group for Non-Traditional Antibacterial therapy (ESGNTA)
Centre de Référence des IOA complexes de Lyon (CRIOAc Lyon)
Président du Comité Scientifique des CRIOAc 2017-2022

Lyon 1 · CRIOAc LYON · PHAGE*in*LYON · ESGNTA ESCMID STUDY GROUP FOR NON-TRADITIONAL ANTIBACTERIAL THERAPY · European Society of Clinical Microbiology and Infectious Diseases · CIRI Centre International de Recherche en Infectiologie · HCL Hospices Civils de Lyon

Two major issues, sometimes combined

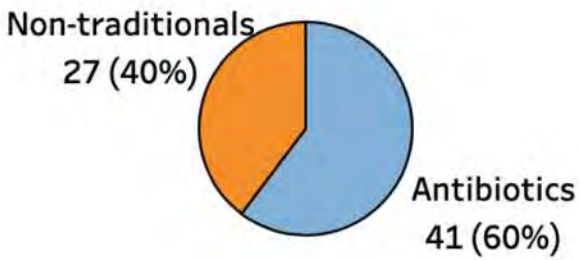
AMR: Antimicrobial resistance

2020 ANTIBACTERIAL AGENTS IN CLINICAL AND PRECLINICAL DEVELOPMENT

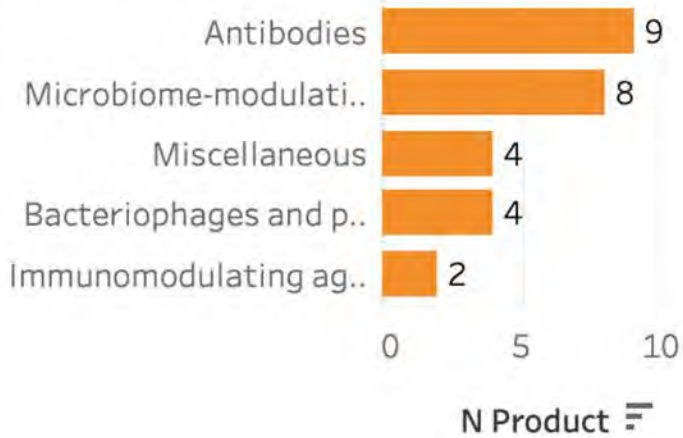
an overview and analysis

World Health Organization

A.1. Products by type



A.2. No. of non traditional products by category



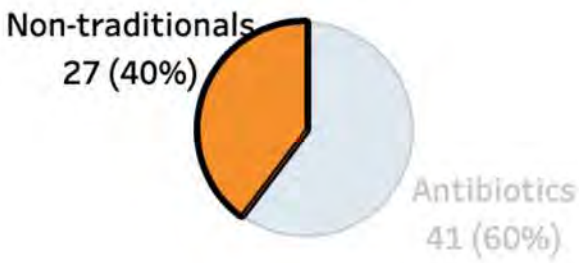
A.3. Products by pathogen category and phase

Pathogen category	Phase I	Phase II	Phase	Unkno..	Total
Priority pathogens	18	15	9	1	43
Mycobacterium tuberculosis	3	9			12
Clostridium difficile	3	8	2		13
Total	24	32	11	1	68

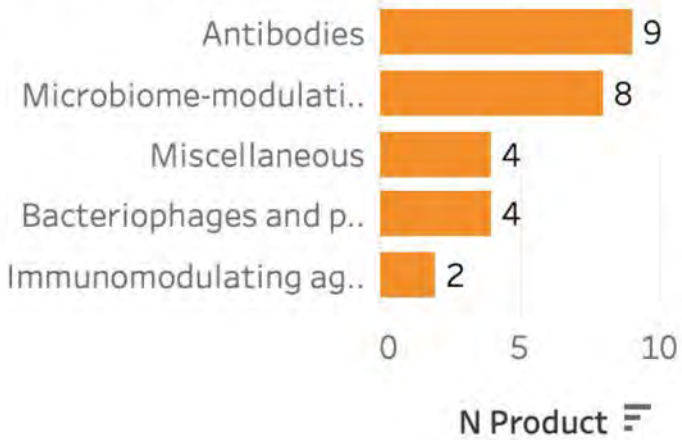
B. Expected activity against priority pathogens

	Critical priority pathogens					Other priority pathogens								
Active?	Acinetobac baumannii	Pseudomor aeruginosa	Enteroba..	All critical priority pathogens	Subtotal	Gram-positive priority p..	Neisseria gonnorhoea	Helicobact pylori	Staphyloco aureus	Enterococc faecium	Streptococ pneumonia	Campyloba spp.	Subtotal	Total
Yes	7	7	14	3	**21**	17	3	2	17	3	2	2	**21**	**38**
Possibly	3	3	3	2	**6**	1	1	1	1	1			**2**	**8**
No	12	17	10	17	**18**	3	7	8	3	7	7	8	**10**	**20**

A.1. Products by type



A.2. No. of non traditional products by category



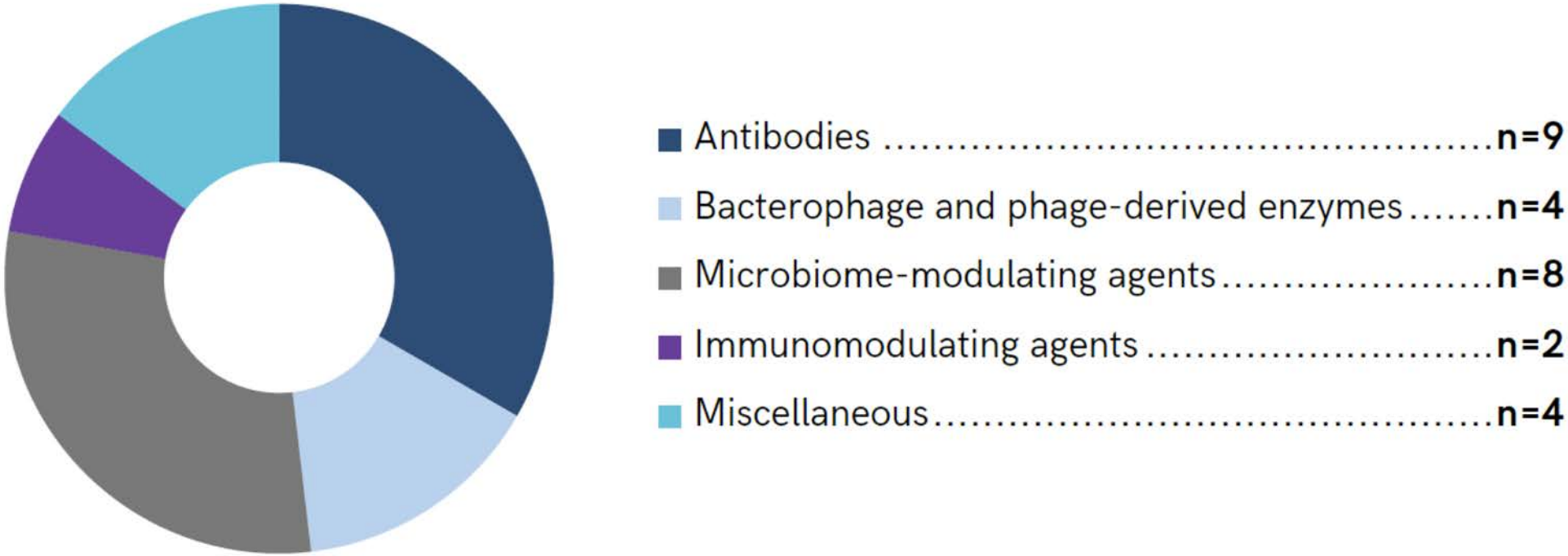
A.3. Products by pathogen category and phase

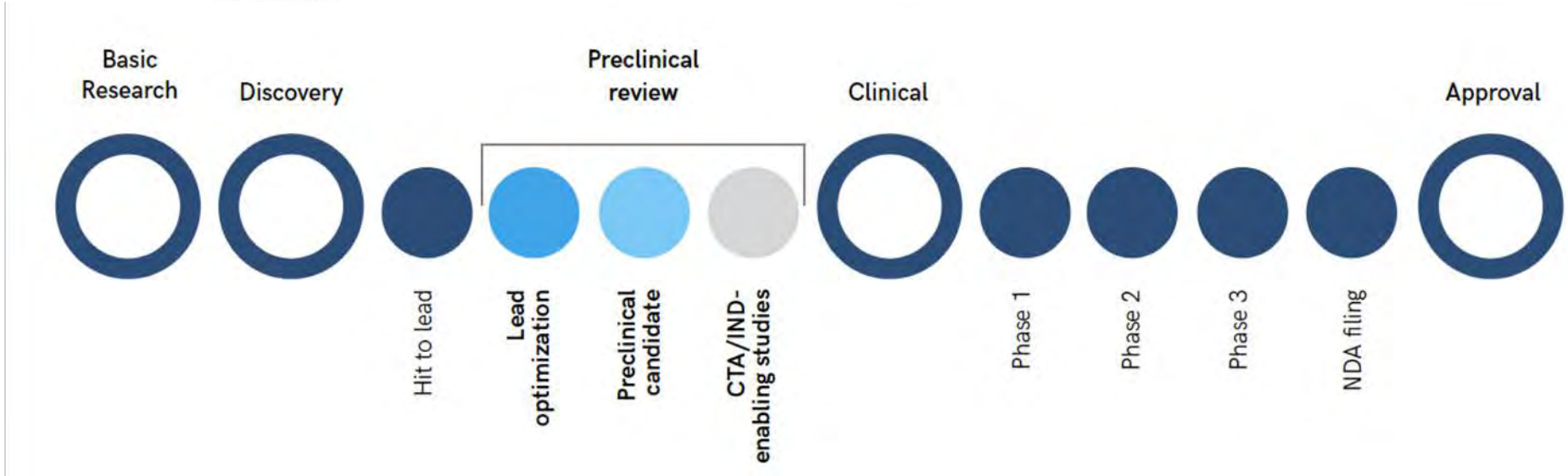
Pathogen category	Phase I	Phase II	Phase	Unkno..	Total
Priority pathogens	4	11	3	1	19
Clostridium difficile	2	5	1		8
Total	6	16	4	1	27

B. Expected activity against priority pathogens

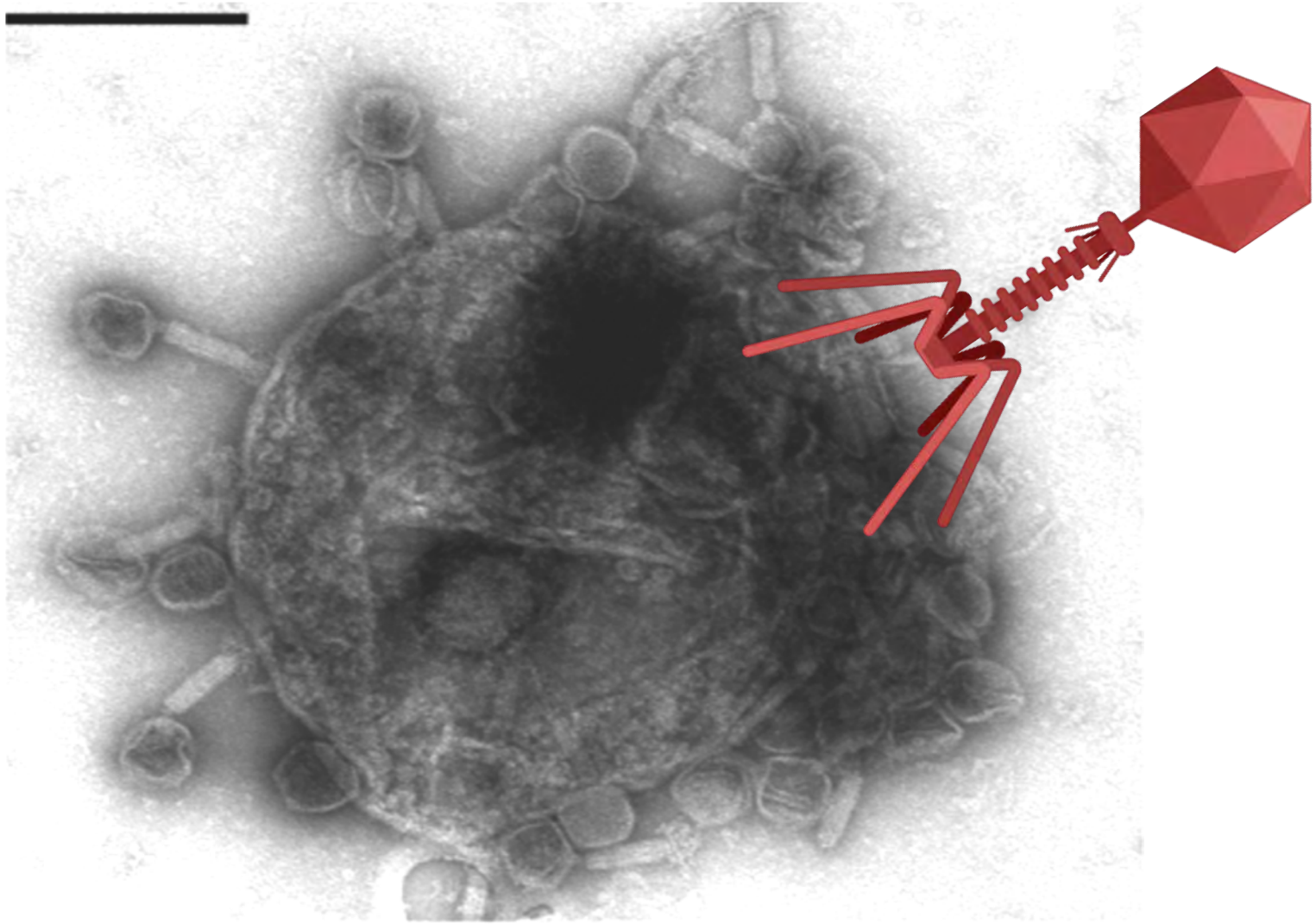
Active?	Critical priority pathogens					Other priority pathogens								Total
	Acinetobac baumannii	Pseudomor aeruginosa	Enteroba..	All critical priority pathogens	Subtotal	Gram-positive priority p..	Neisseria gonnorhoe	Helicobact pylori	Staphyloco aureus	Enterococc faecium	Streptococ pneumonia	Campyloba spp.	Subtotal	
Yes	1	5	6	1	**10**	10	1	1	10	2	1	2	**12**	**19**

Fig. 7. Number of non-traditional antibacterials in the clinical pipeline.





Bacteria have also their pandemia!



Merabishvili et al. *PloS ONE* 2009

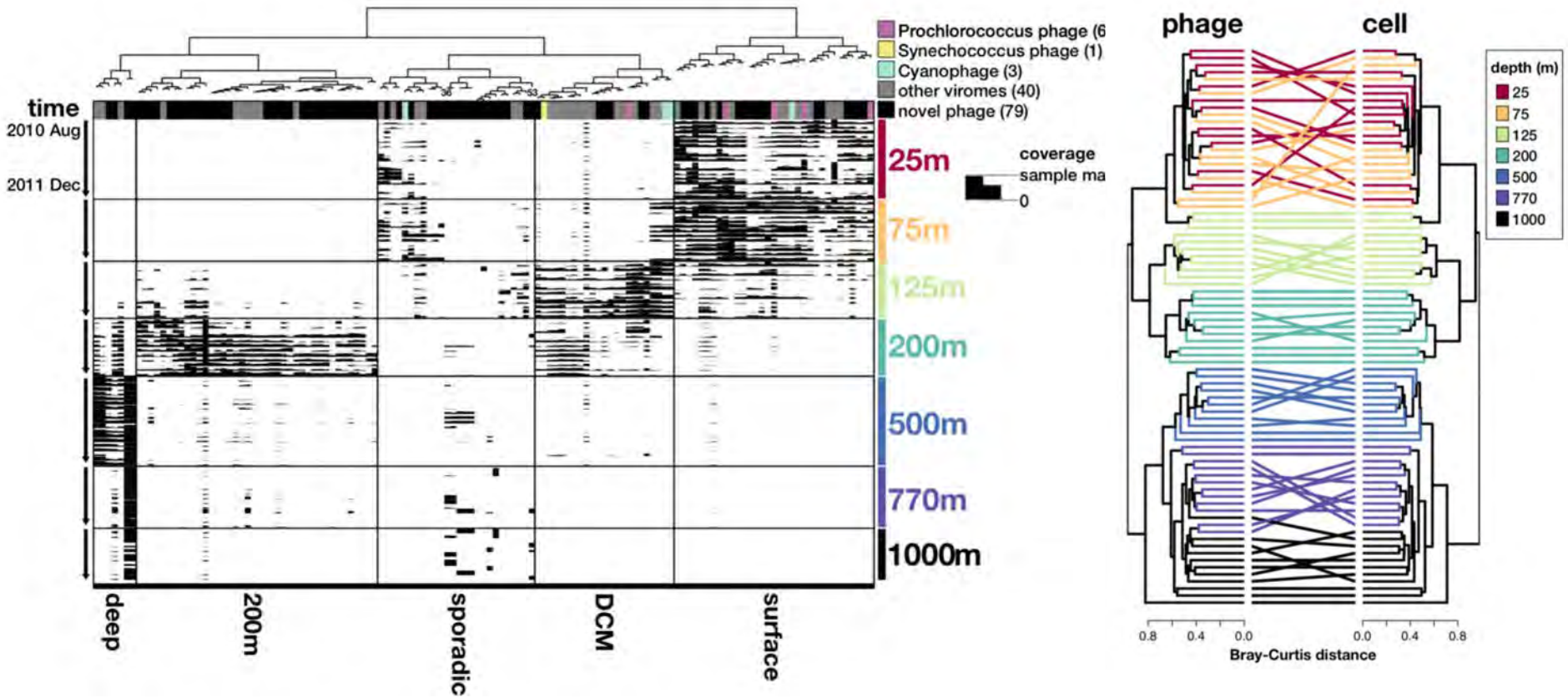
Bacteriophage Distributions and Temporal Variability in the Ocean's Interior

AMERICAN SOCIETY FOR MICROBIOLOGY | mBio®

2017

Elaine Luo, Frank O. Aylward,* Daniel R. Mende, Edward F. DeLong

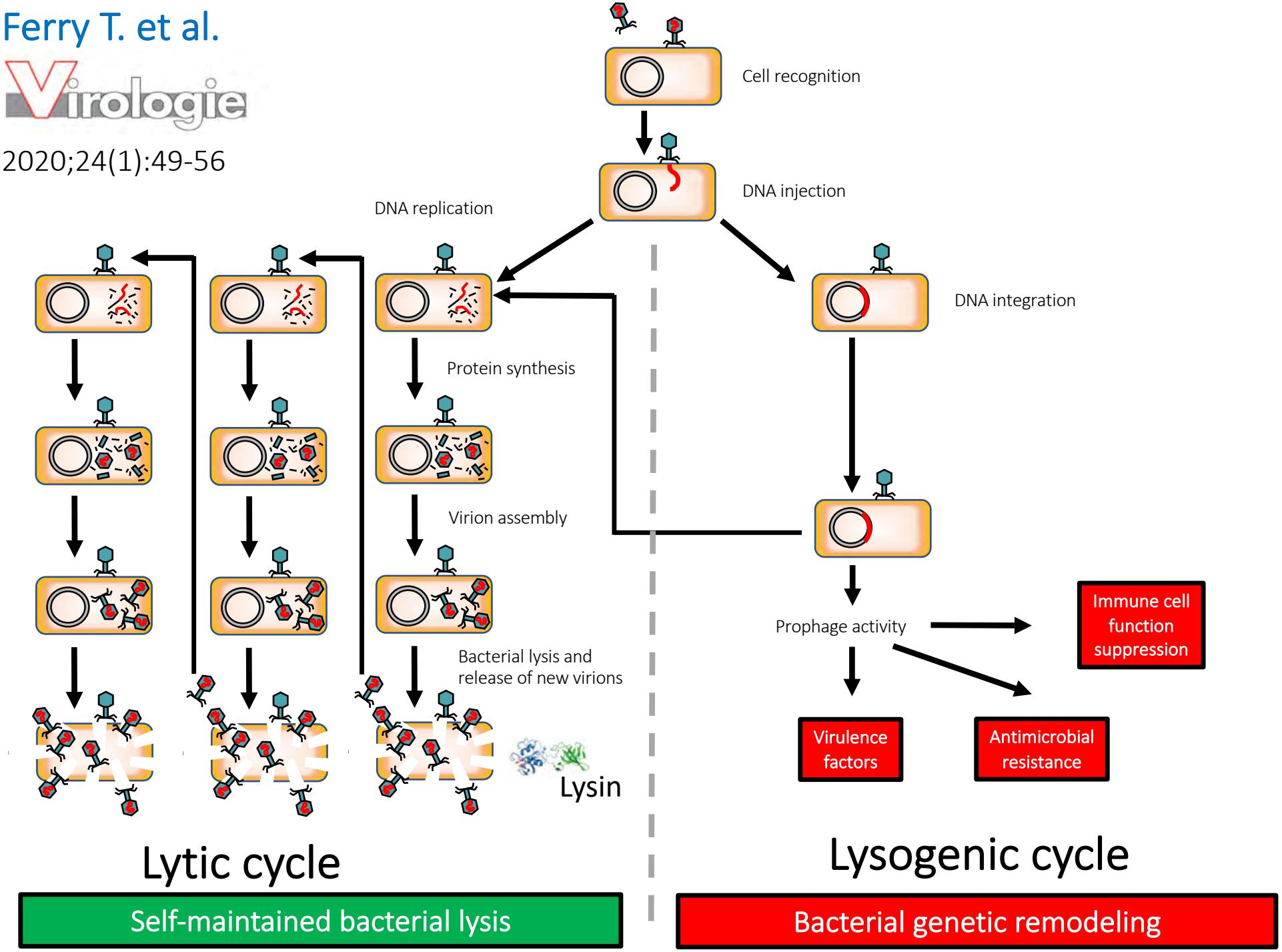
Daniel K. Inouye Center for Microbial Oceanography: Research and Education, University of Hawaii, Honolulu, Hawaii, USA



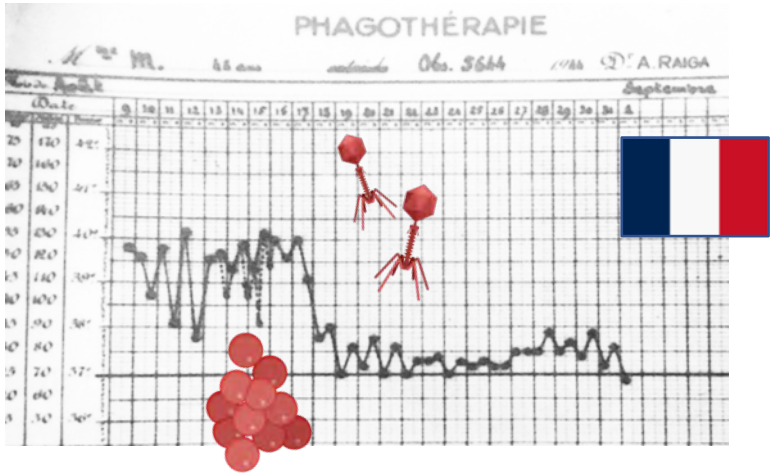
Ferry T. et al.

Virologie

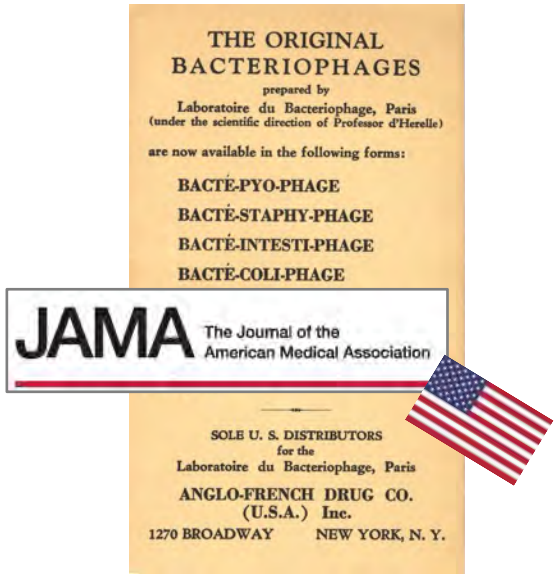
2020;24(1):49-56

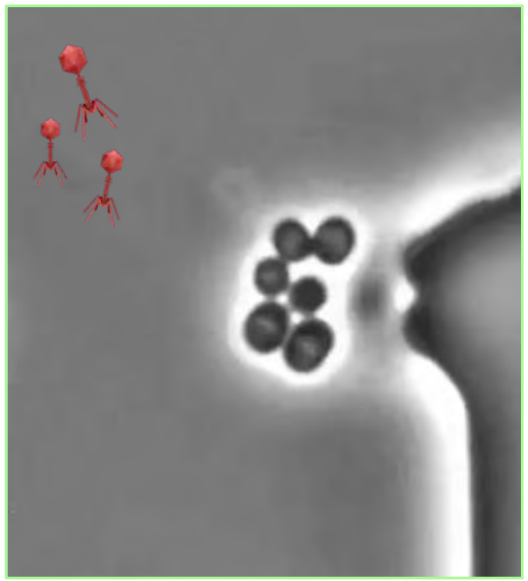


Phage therapy is fascinating



- **Viral therapy** for bacterial infections
- Story of phage therapy is connected to **worldwide geopolicital events**
- Potential **incredible** preclinical **efficacy**
- Failure to implement phage therapy in the west





S. aureus being lysed by the Sa2 phage

Bacterial DNA appeared in green

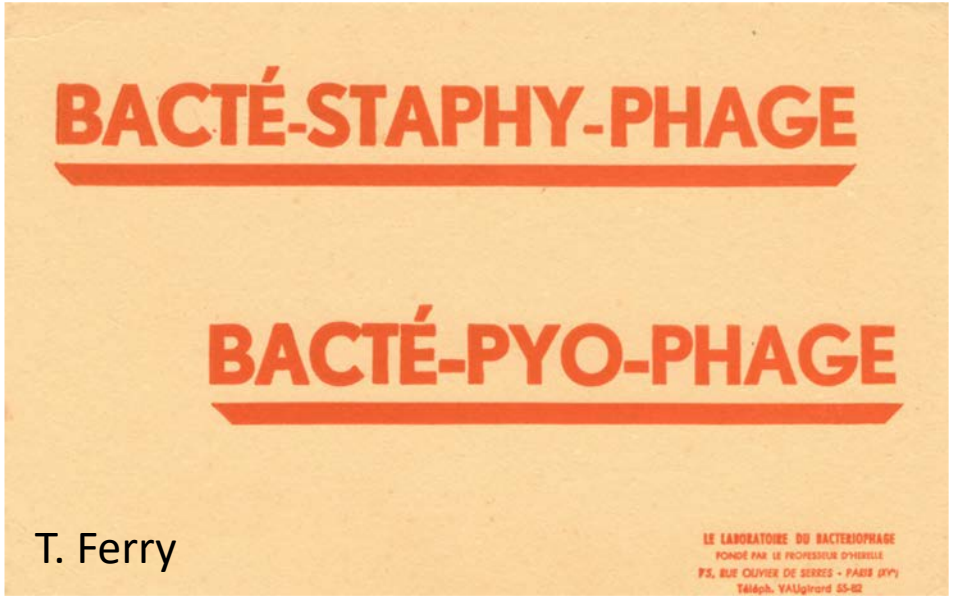
Courtesy Pascal Maguin
Luciano Marraffini Lab
THE ROCKEFELLER UNIVERSITY

Story of phage Therapy

Creation from F. d'Herelle (dismissed from Pasteur Institute):

- Laboratoire du bactériophage (Paris)
- Eliava Center (Georgia)
  - Fixed cocktails to treat **digestive-tract infections**
  - Fixed cocktails to treat **skin and soft tissue infections**

T. Ferry



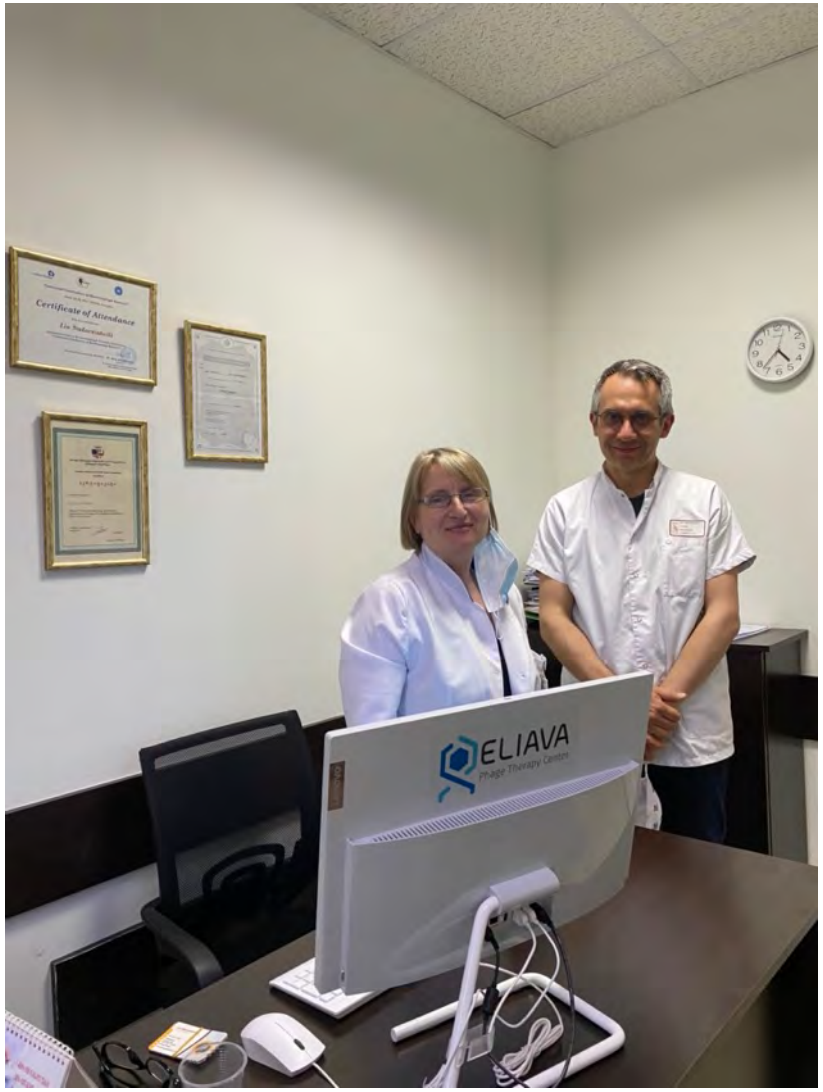
T. Ferry

Ferry T. et al. Virologie 2020;24(1):49-56

Eliava Institute (Georgia)

100th anniversary

Eliava Institute (Georgia)



Story of phage Therapy in Lyon

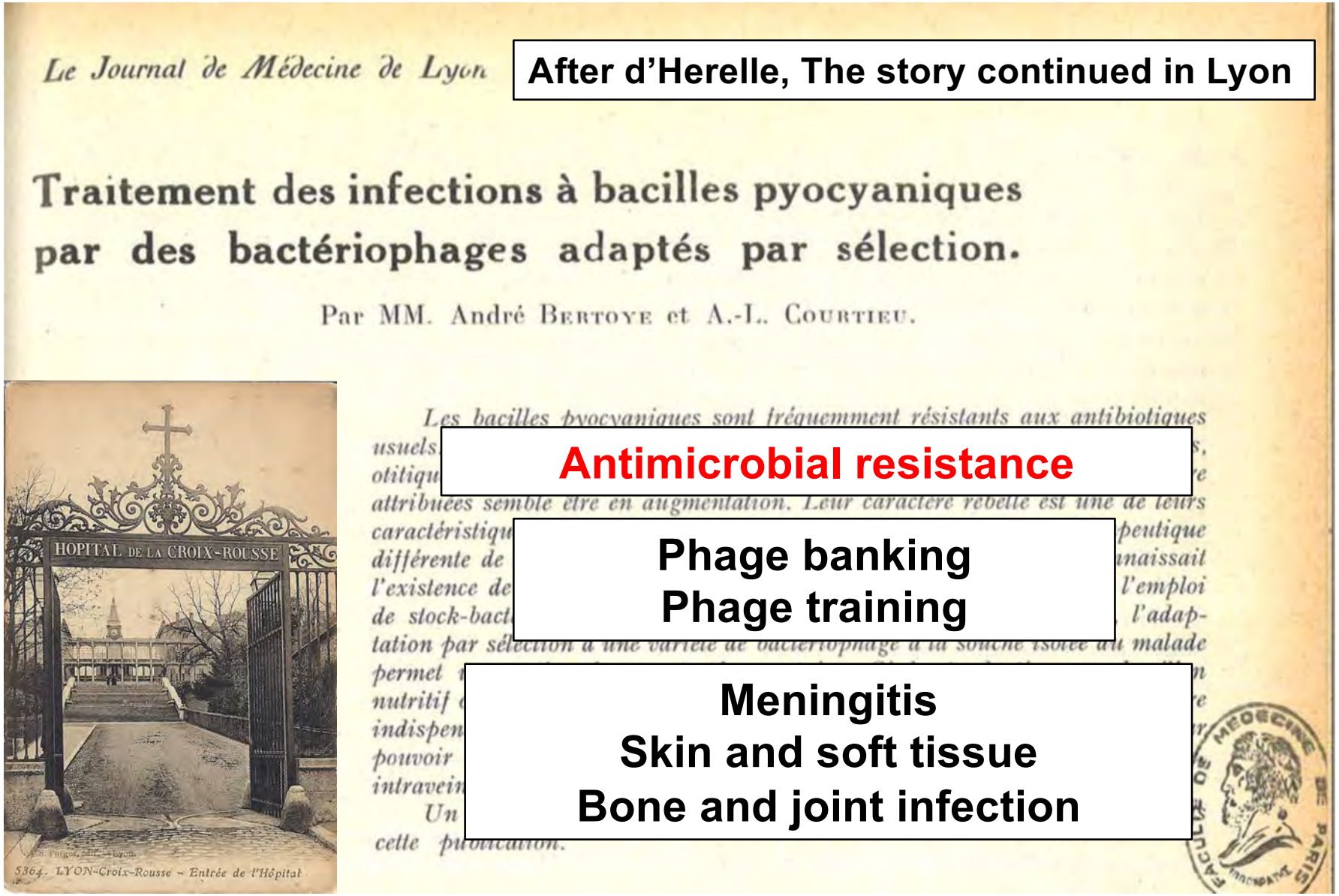
Dr. Emile PESCE

- Medical thesis "Contribution to the study of the treatment of furuncles and anthrax by bacteriophage", 1931

"Need for a microbiological analysis to select the phage, based on its activity on the patient's strain"

"If microbiological analysis could not be done, use fixed cocktail"

Archives from Ferry T.



After d'Herelle, The story continued in Lyon

Antimicrobial resistance

Phage banking
Phage training

Meningitis
Skin and soft tissue
Bone and joint infection

Clinique des Maladies Infectieuses, Hôpital de la Croix-Rousse
Hospices Civils de Lyon

1958-1960

Méningite purulente à colibacilles traitée par un bactériophage adapté intrarachidien

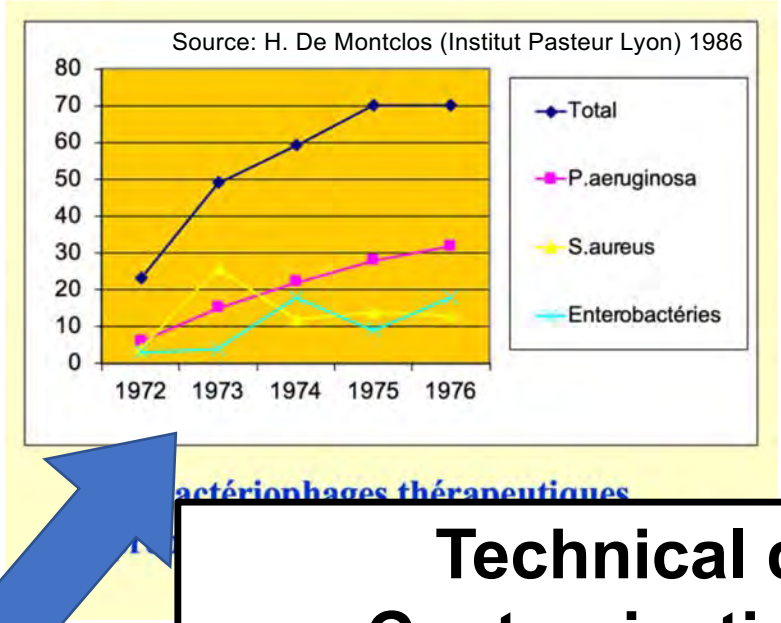
Par MM. P. SEDALLIAN, A. BERTOYE, J. GAUTHIER. J.-M. MULLER et A.-L. COURTIEU.

Clinique des Maladies Infectieuses et Institut Pasteur de Lyon

Une injection intrarachidienne d'1/10 de centimètre cube n'ayant été suivie d'aucun accident, on commence, dès le lendemain 30 septembre, le traitement aux doses thérapeutiques : 1 centimètre cube de bactériophage intraventriculaire et 1 centimètre cube intrarachidien par vingt-quatre heures. Rapidement, le nombre des éléments du liquide céphalo-rachidien s'effondre à 356 contre 1.800 deux jours auparavant. Dès lors, la situation va s'améliorer très vite et on peut espérer la partie gagnée, malgré la persistance dans le liquide céphalo-rachidien d'un taux d'albumine aux alentours d'un gramme et de 50 à 200 éléments.

A une demande de **M. Roche, M. Bertoye** précise que nombre de germes peuvent être dotés d'un bactériophage. Il faut quatre à cinq jours pour l'adaptation du bactériophage : ce ne peut donc pas être une médication d'urgence.

Lyon Med. 1958 Mar 30;90(13):509-12



L'INSTITUT BACTÉRIOLOGIQUE DE LYON

Lyon Pasteur Institute

Active and trained bacteriophages

Technical development
Customisation of treatment
Academic multidisciplinary approach
70 patients/year!

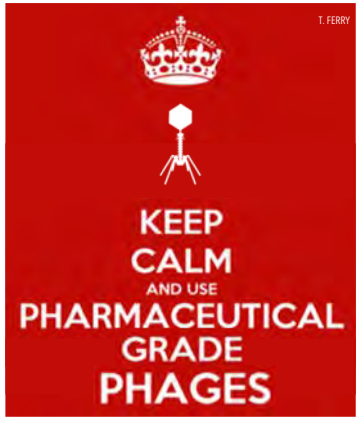
Isolation of the isolates responsible for the infection

Infectious diseases clinic

HCL
HOSPICES CIVILS DE LYON

Contemporary

Previous clinical trials have not « failed »



- Most of them were phase I/IIa/IIb and **not phase III**
- Phages are **particular anti-infective agents** (≠ antibiotics)
- Need a **specific** purification process
- Purified phages or phage cocktails are potentially **not stable during time**
- **High specificity** of phages
- Potential need for a **phagogram** (like antibiogram) before treatment

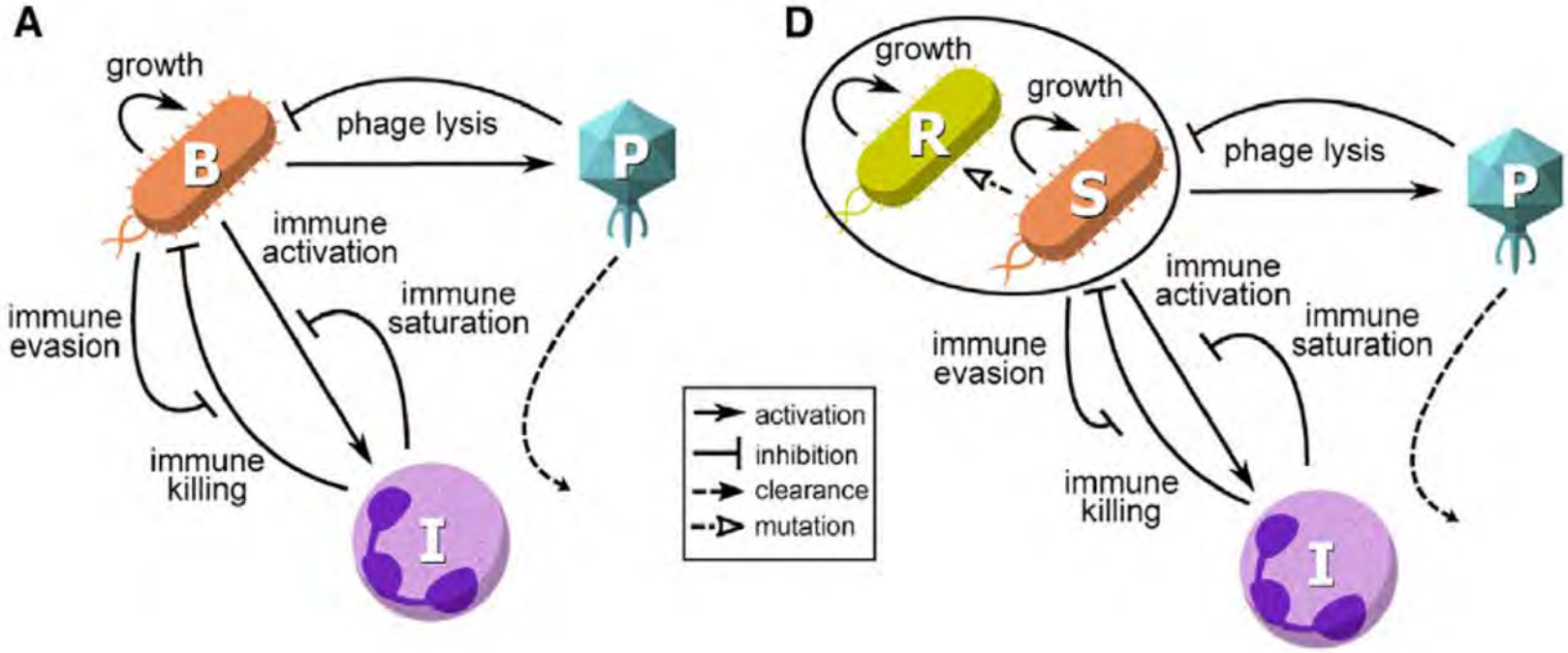
Don’t forget the lessons of the past

Respect the experience of the East

Cell Host & Microbe

Synergy between the Host Immune System and Bacteriophage Is Essential for Successful Phage Therapy against an Acute Respiratory Pathogen

Roach et al., 2017, Cell Host & Microbe 22, 38–47



The role of the animal host in the management of bacteriophage resistance during phage therapy

Baptiste Gaborieau[1,2,3] and Laurent Debarbieux[1]

Current Opinion in Virology 2023, **58**:101290

T. FERRY

KEEP CALM AND USE PHARMACEUTICAL GRADE PHAGES

PHAGE 2.0 THERAPY

ESCMID MANAGING INFECTIONS PROMOTING SCIENCE

ESGNTA ESCMID STUDY GROUP FOR NON-TRADITIONAL ANTIBACTERIAL THERAPY

European Society of Clinical Microbiology and Infectious Diseases

Elected Executive Committee:

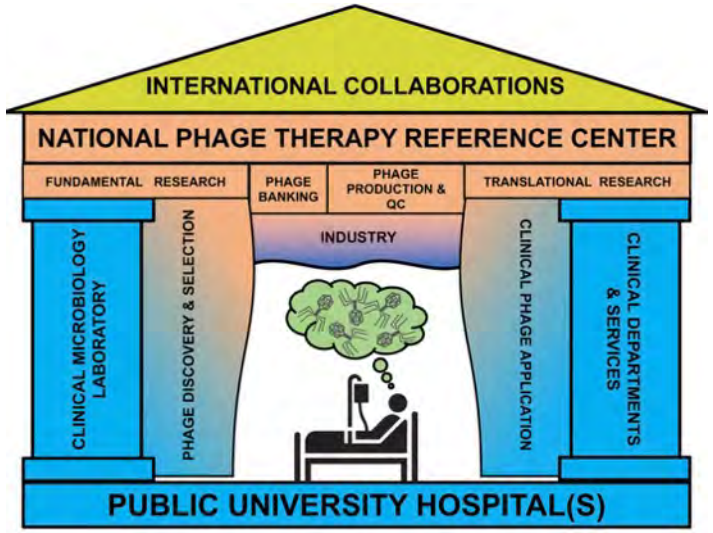
Ran Nir-Paz, **Israël**

Jean-Paul Pirnay, **Belgium**

Clinical officer: Tristan Ferry, France

Shawna Mc Callin, **Switzerland**

Zuzanna Drulis-kawa, **Poland**

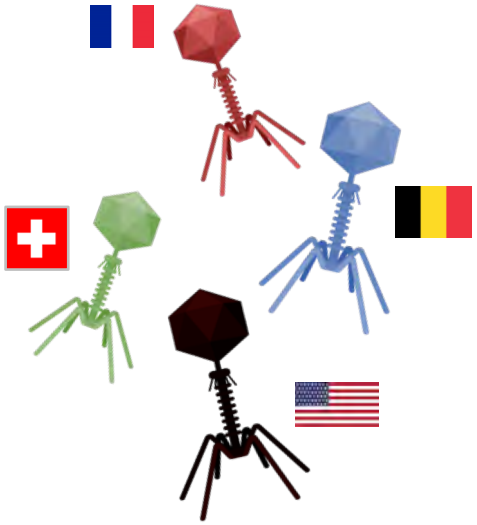


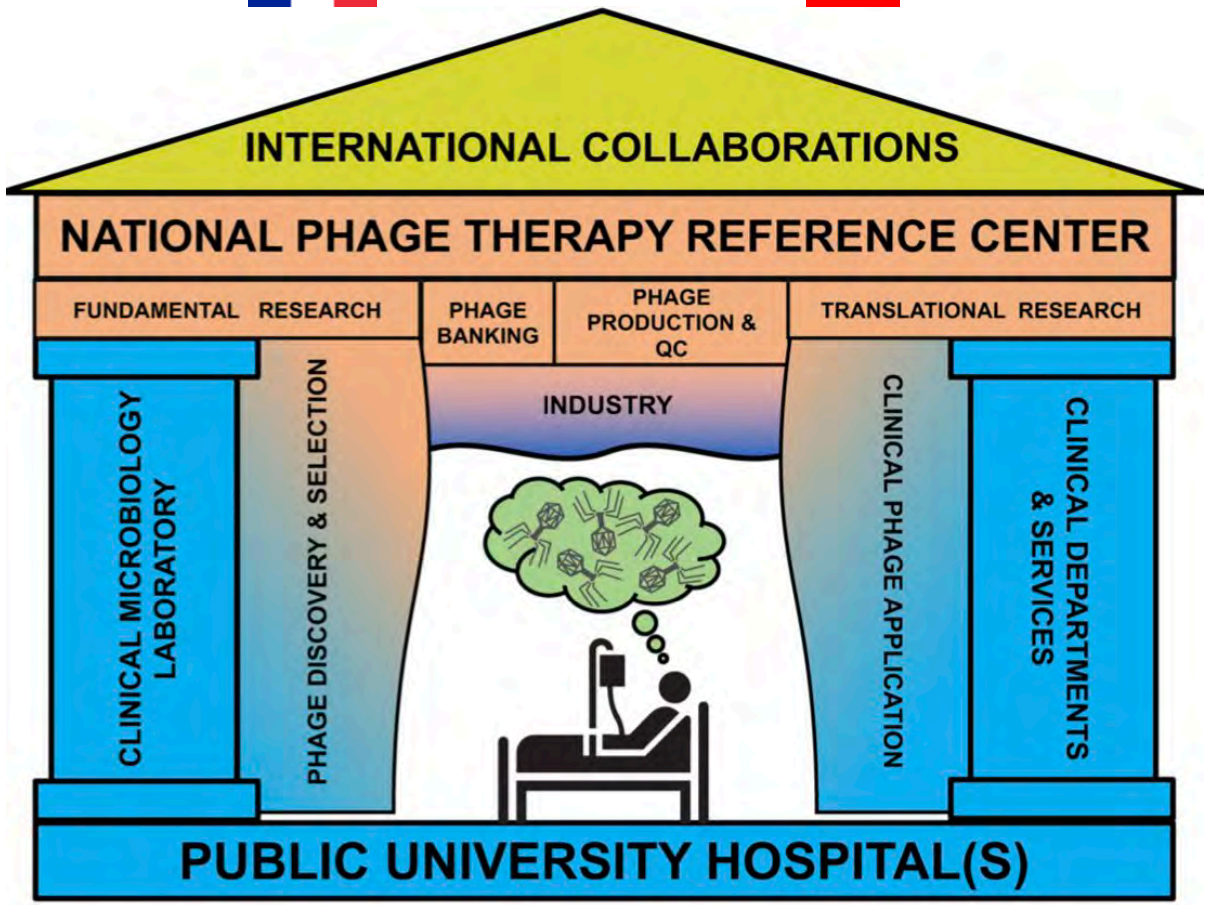
REVIEW ARTICLE

Recent progress toward the implementation of phage therapy in Western medicine

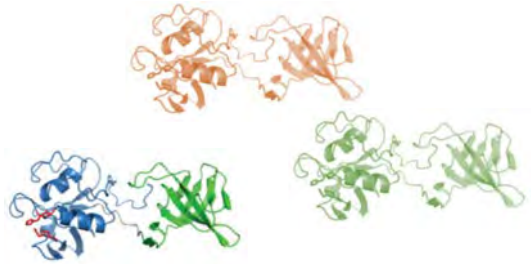
Jean-Paul Pirnay[1,†], Tristan Ferry[2,3,†] and Grégory Resch[4,*,†]

Phages





Lysins



FEMS *Microbiology Reviews*
2021

THE MYTHOLOGY
OF PHAGE THERAPY

T. FERRY

VS.

T. FERRY

PHAGE*in*LYON
Clinic

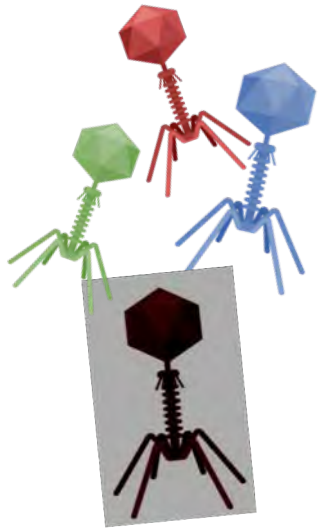


Photo: Tristan Ferry

Infectious diseases department

Clinical developement

Multidisciplinar meetings

Identifying relevant indications

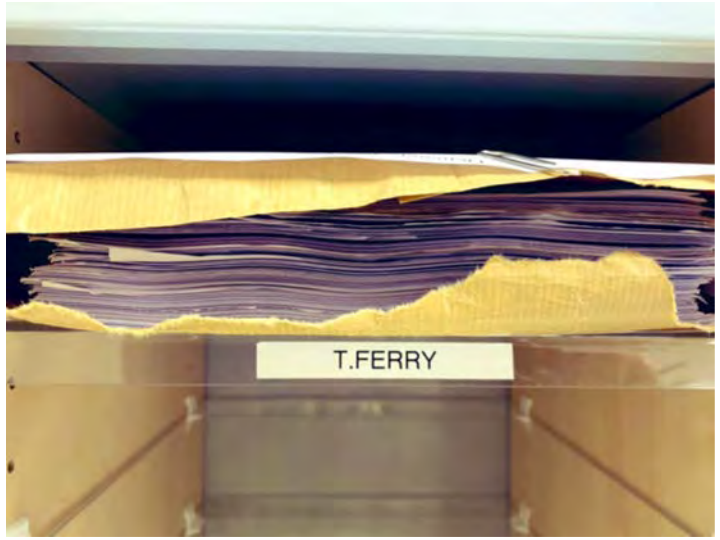
Managing the patient

Compassionate use

Cohort studies

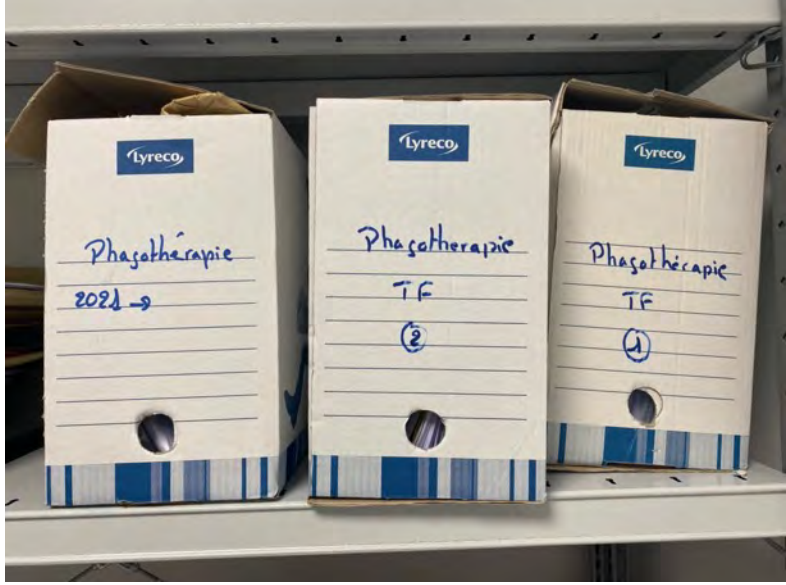
Pharmacokinetic in humans

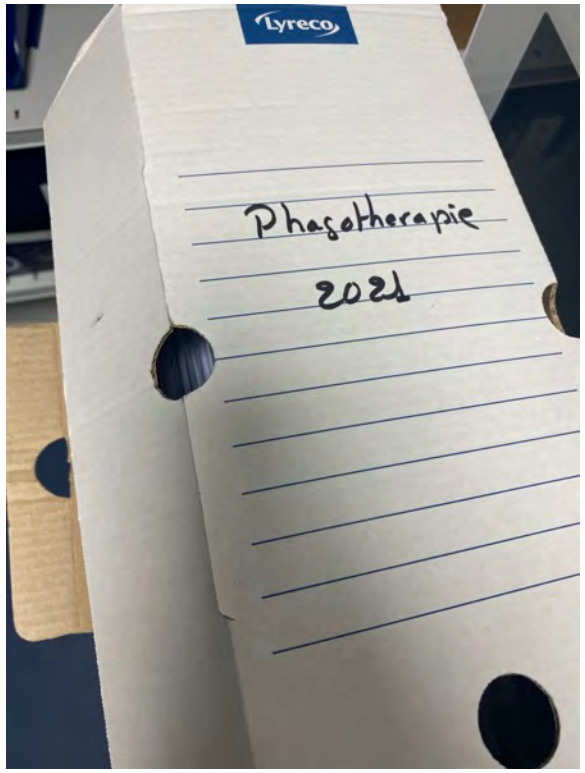
Clinical trials



PHAGE*in*LYON
Clinic

HCL
HOSPICES CIVILS DE LYON



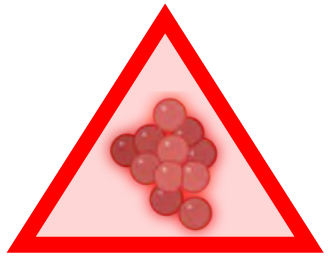


Infections ostéoarticulaires ?
Autres indications ?
Infections en réanimation ?
Infections pulmonaires ?
Infections cardiovasculaires ?
Infections en réanimation ?
Pédiatrie ?

Indications pertinentes vs. non pertinentes

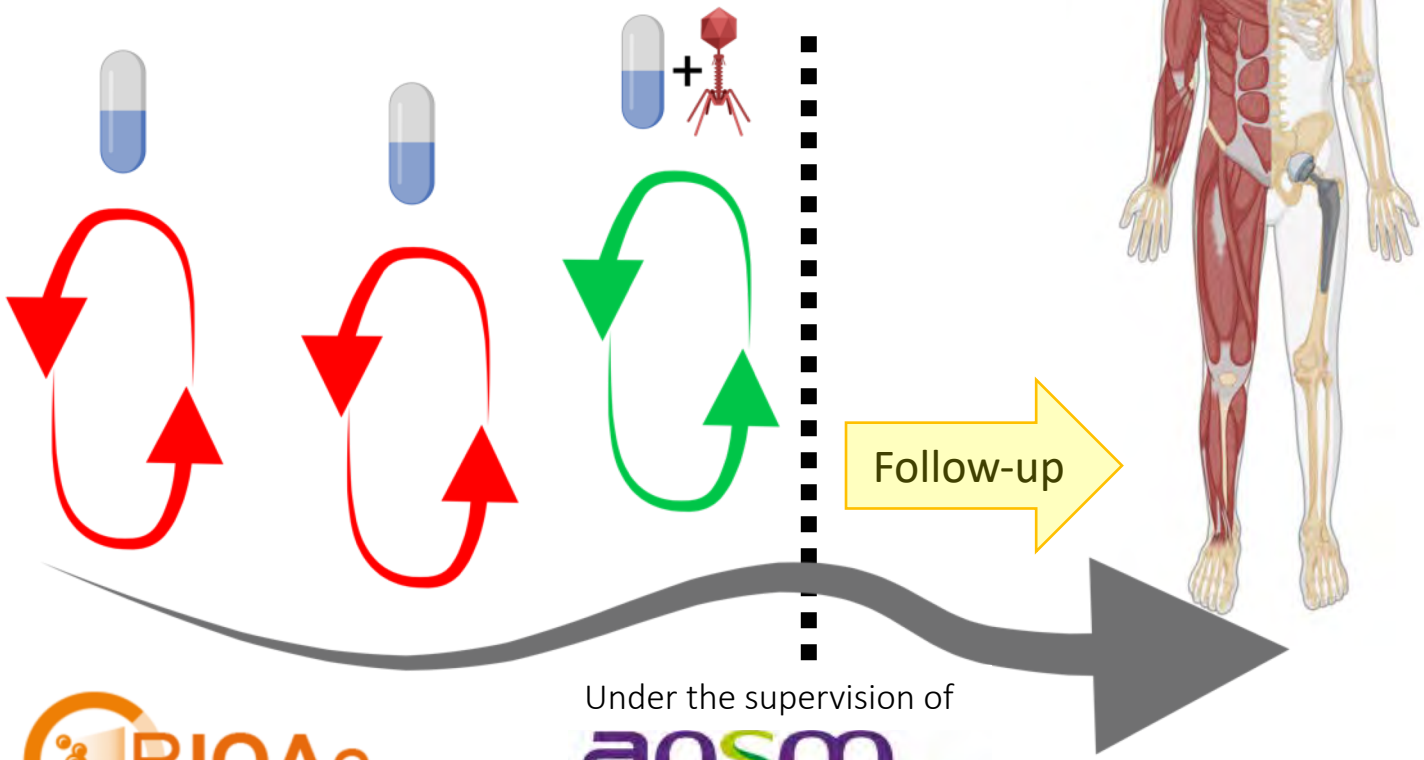
Se limiter aux infections à BMR ?

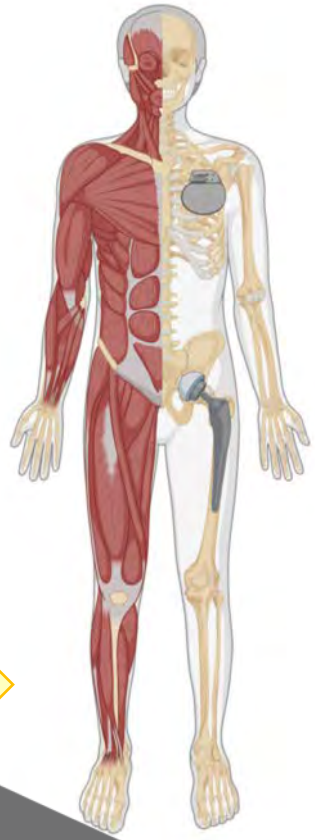
A large panel of **severe** bacterial infections



Some **positive signals**
in these infections

The patient is his “own control”





FONDATION HCL HOSPICES CIVILS DE LYON

PHAGE*in*LYON Clinic

HCL HOSPICES CIVILS DE LYON

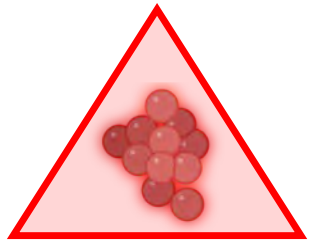
CRIOAc LYON

Under the supervision of

ansm Agence nationale de sécurité du médicament et des produits de santé

French Health Authority

A large panel of **severe** bacterial infections



Central nervous system infections

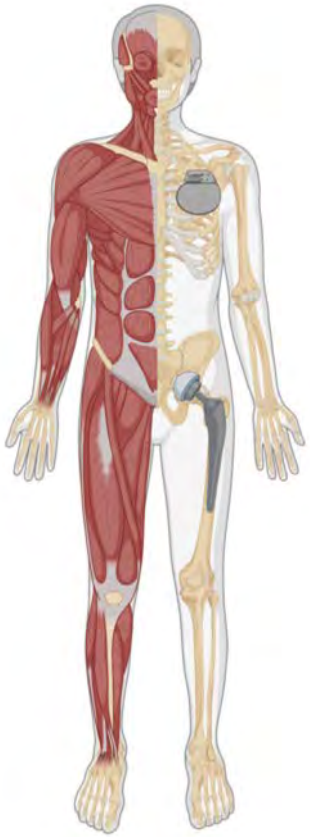
Implant-associated meningitis

Lung infections

Ventilator-associated pneumonia
Exacerbation in cystic fibrosis
Exacerbations in bronchiectasis

Urinary tract infections

Pyelonephritis
Ureteral stent-associated infection



Cardiovascular infections

Endocarditis
Cardiac electronic device infection
Prosthetic-valve endocarditis
Vascular graft infection

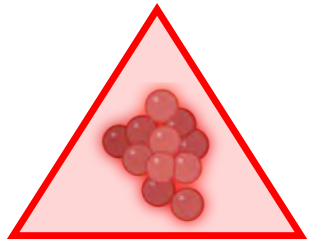
Muskuloskeletal infections

Wound infection
Osteomyelitis, fracture-related infection
Implant-associated bone and joint infection
Prosthetic joint infection

Digestive-tract infections

Typhoid fever, shigellosis
Cholera

A large panel of **severe** bacterial infections



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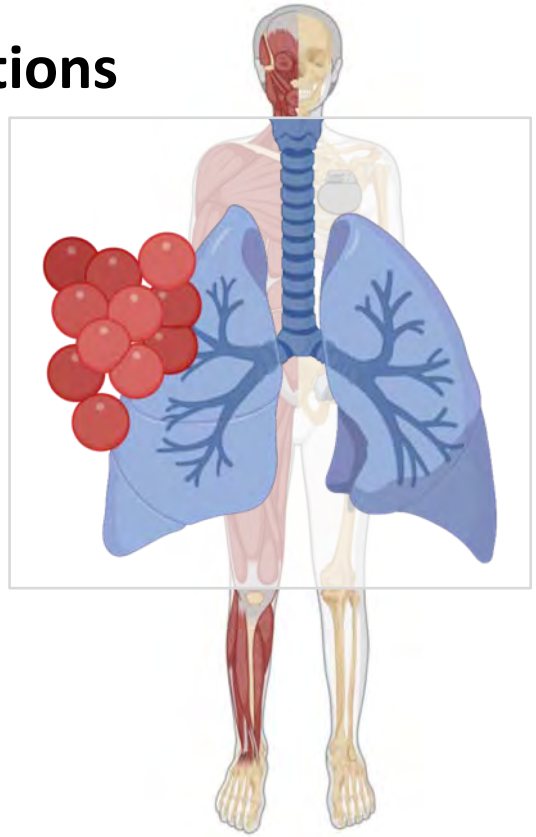

Cardiovascular infections

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Digestive-tract infections

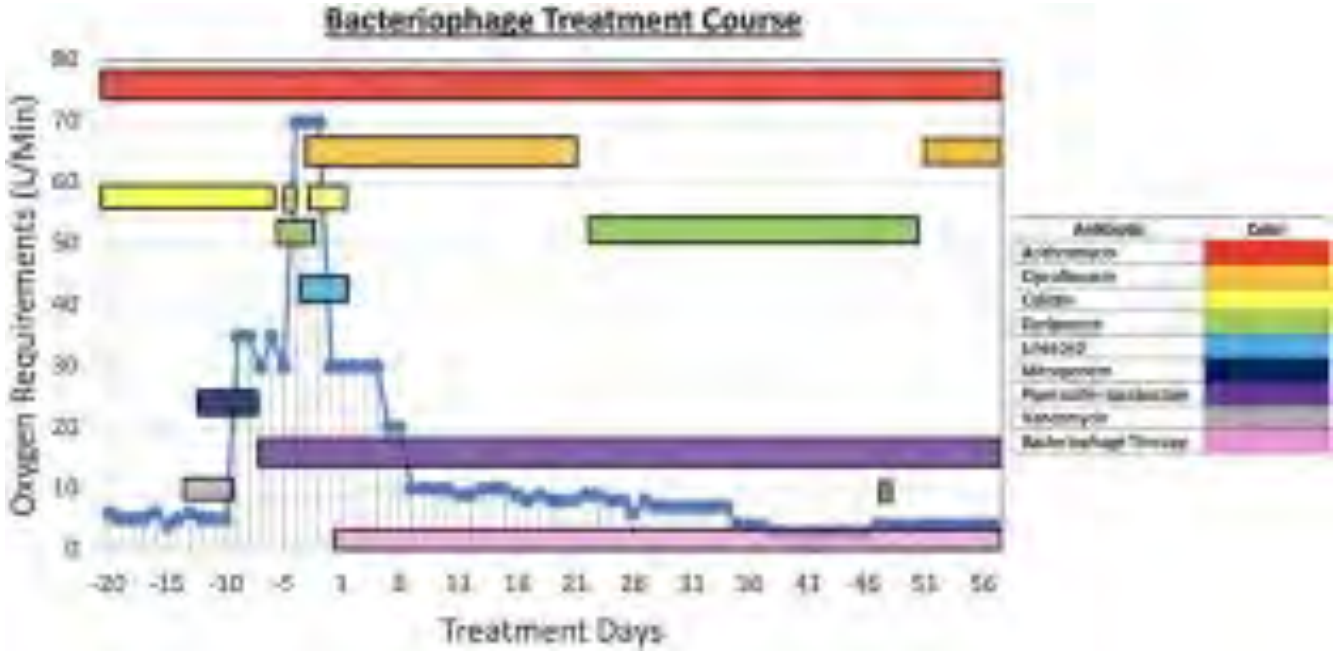
Typhoid fever, shigellosis
Cholera

Case Report | Published: 17 May 2019

Successful adjunctive use of bacteriophage therapy for treatment of multidrug-resistant *Pseudomonas aeruginosa* infection in a cystic fibrosis patient

Nancy Law ✉, Cathy Logan, Gordon Yung, Carrie-Lynn Langlais Furr, Susan M. Lehman, Sandra Morales, Francisco Rosas, Alexander Gaidamaka, Igor Bilinsky, Paul Grint, Robert T. Schooley & Saima Aslam

Infection **47**, 665–668 (2019) | Cite this article

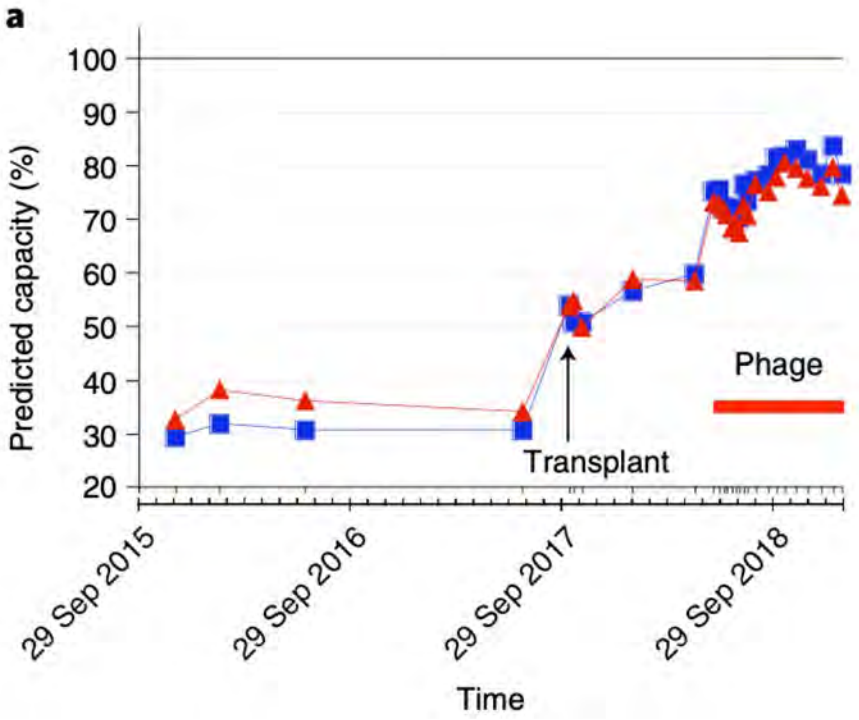


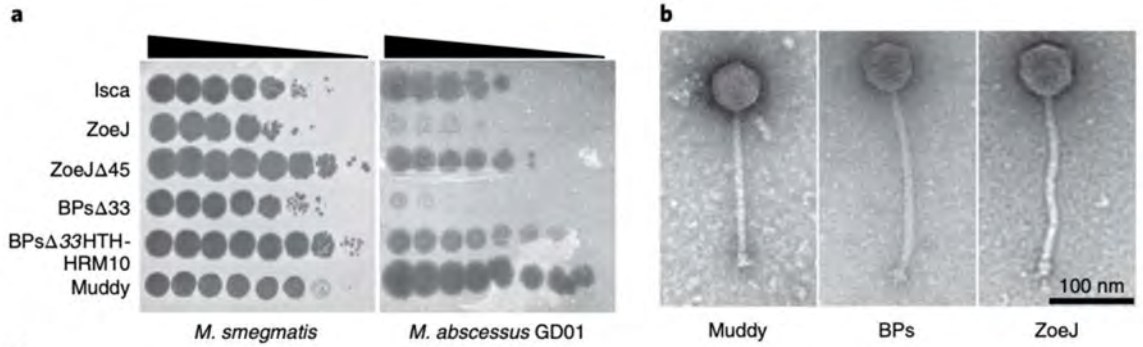
Eight weeks of INTRAVENOUS phages (1 injection each 6 hours)

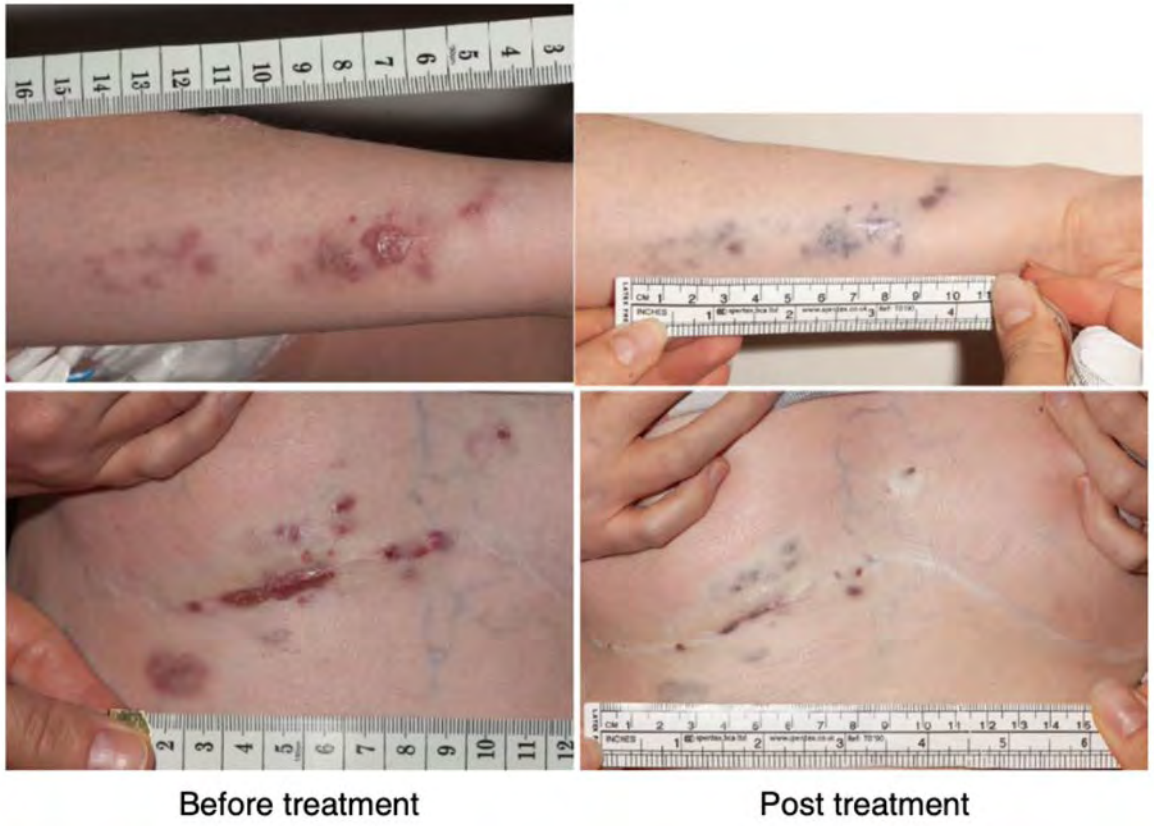
BRIEF COMMUNICATION
https://doi.org/10.1038/s41591-019-0437-z
nature medicine

Engineered bacteriophages for treatment of a patient with a disseminated drug-resistant *Mycobacterium abscessus*

Rebekah M. Dedrick[1,4], Carlos A. Guerrero-Bustamante[1,4], Rebecca A. Garlena[1], Daniel A. Russell[1], Katrina Ford[2], Kathryn Harris[2], Kimberly C. Gilmour[2], James Soothill[2], Deborah Jacobs-Sera[1], Robert T. Schooley[3], Graham F. Hatfull[1*] and Helen Spencer[2*]







Eight weeks of <u>INTRAVENOUS</u> phages (1 injection each 12 hours)

NIH U.S. National Library of Medicine

ClinicalTrials.gov

CYstic Fibrosis bacterioPHage Study at Yale (CYPHY)

Yale

Ph 1/2 Study Evaluating Safety and Tolerability of Inhaled AP-PA02 in Subjects With Chronic Pseudomonas Aeruginosa Lung Infections and Cystic Fibrosis (SWARM-Pa)

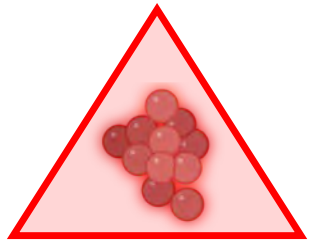
ARMATA PHARMACEUTICALS
PURPOSEFUL • PRECISE • POWERFUL

Personalized Phage Treatment in Covid-19 Patients With Bacterial Co-Infections Microbials for Pneumonia or Bacteremia/Septicemia

adaptive phage THERAPEUTICS

Etc.

A large panel of **severe** bacterial infections



Central nervous system infections

Implant-associated meningitis

Lung infections

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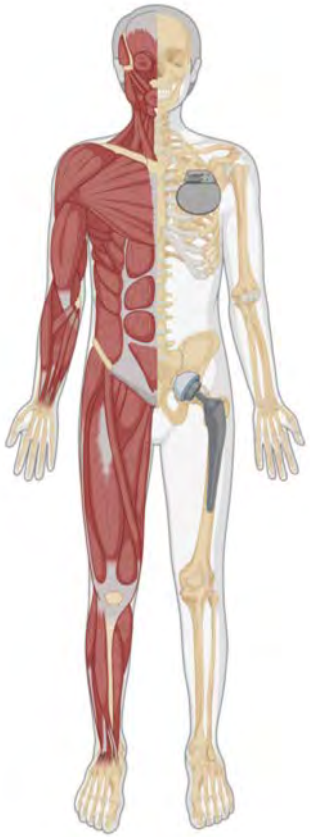
Urinary tract infections

Pyelonephritis
Ureteral stent-associated infection



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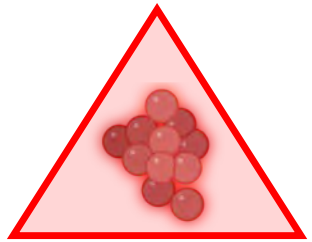

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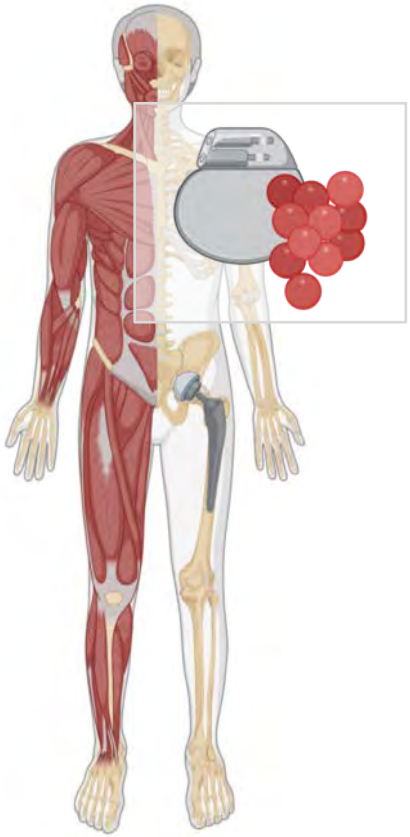

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Typhoid fever, shigellosis
Cholera

Novel bacteriophage therapy for treatment of left ventricular assist device infection

Saima Aslam, MD,[a] Victor Pretorius, MD,[b] Susan M. Lehman, PhD,[c] Sandra Morales, PhD,[c] and Robert T. Schooley, MD[a]

The Journal of Heart and Lung Transplantation
The Official Publication of the International Society for Heart and Lung Transplantation

UC San Diego School of Medicine

Center for Innovative Phage Applications and Therapeutics
In the Division of Infectious Diseases & Global Public Health

igure 1 Sternal wound at baseline (A) and at end of bacteriophage therapy (B) with visible ventricular assist device. (A) Wound with urulence and poorly granulating tissue. (B) Healthy red granulation tissue and reduced purulence.

Open Forum Infectious Diseases

MAJOR ARTICLE

IDSA Infectious Diseases Society of America
hivma hiv medicine association
OXFORD

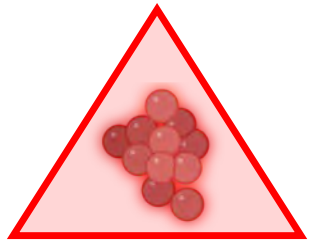
Lessons Learned From the First 10 Consecutive Cases of Intravenous Bacteriophage Therapy to Treat Multidrug-Resistant Bacterial Infections at a Single Center in the United States

Saima Aslam,[1,2] Elizabeth Lampley,[2] Darcy Wooten,[1] Maile Karris,[1] Constance Benson,[1,2] Steffanie Strathdee,[1,2] and Robert T. Schooley[1,2]

[1]Division of Infectious Diseases and Global Public Health, University of California, San Diego, La Jolla, California, USA, and [2]Center for Innovative Phage Applications and Therapeutics, University of California, San Diego, La Jolla, California, USA

AMPLIPHI BIOSCIENCES CORPORATION

A large panel of **severe** bacterial infections



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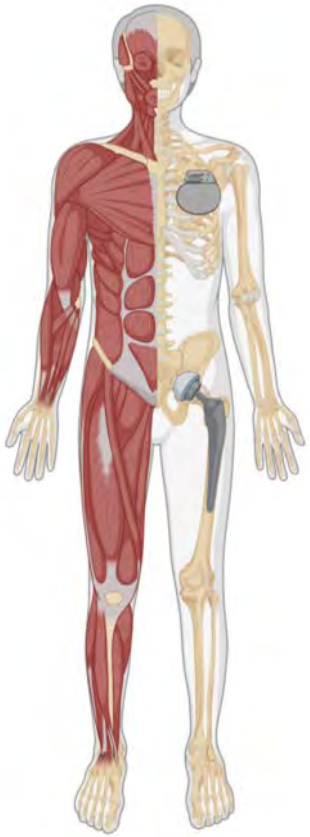

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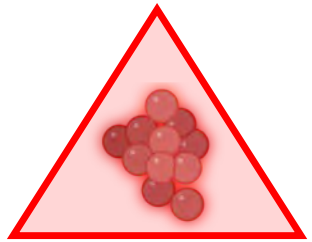

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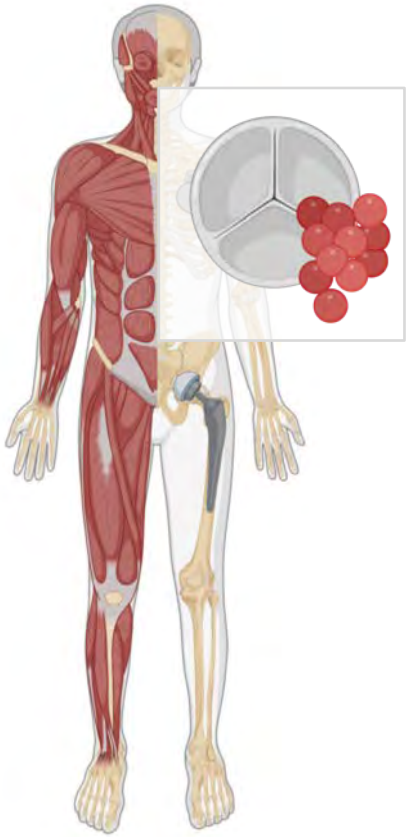

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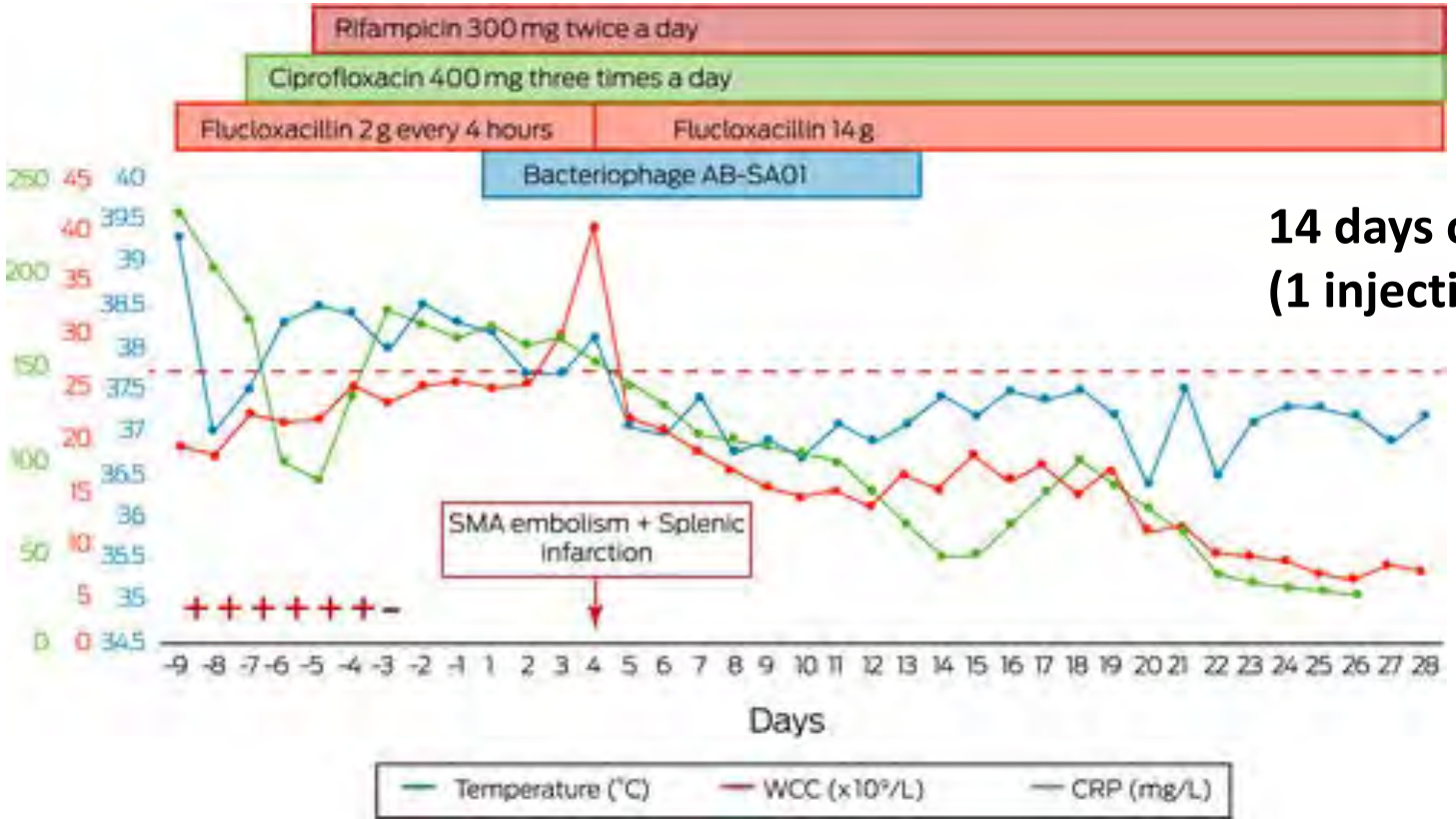
MJA The Medical Journal of Australia
Australia's most trusted source of medical information

Adjunctive bacteriophage therapy for prosthetic valve endocarditis due to *Staphylococcus aureus*

Timothy Gilbey, Josephine Ho, Louise A Cooley, Aleksandra Petrovic Fabijan, Jonathan R Iredell



14 days of <u>INTRAVENOUS</u> phages (1 injection each 12 hours)

AMPLIPHI BIOSCIENCES CORPORATION

NIH U.S. National Library of Medicine

ClinicalTrials.gov

No Studies found for: **phage | Endocarditis, Bacterial**

nature microbiology

ARTICLES

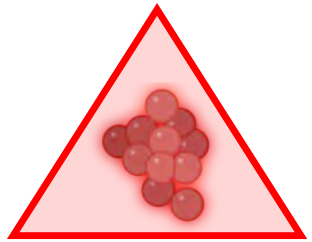
https://doi.org/10.1038/s41564-019-0634-z

Safety of bacteriophage therapy in severe *Staphylococcus aureus* infection

Aleksandra Petrovic Fabijan[1,2,6], Ruby C. Y. Lin[1,2,3,4,6], Josephine Ho[1,2], Susan Maddocks[1,2,3], Nouri L. Ben Zakour[1,3], Jonathan R. Iredell[1,2,3]* and Westmead Bacteriophage Therapy Team[5]

A lot of things are learned from compassionate cases

A large panel of **severe** bacterial infections



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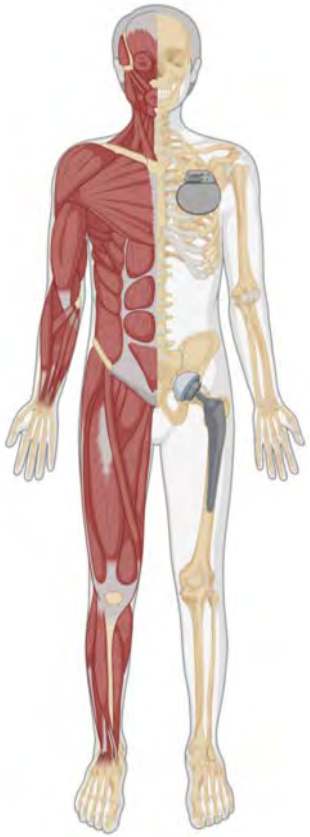

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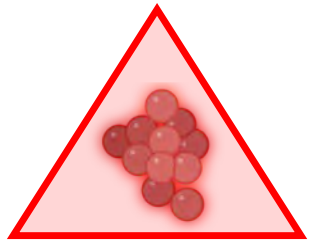

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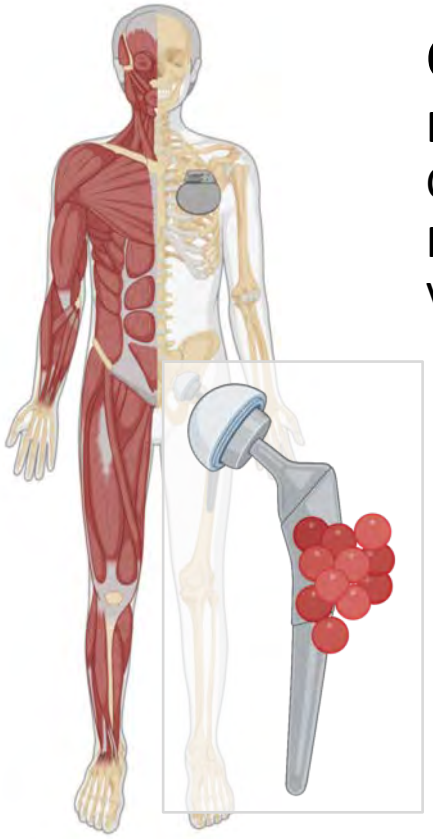

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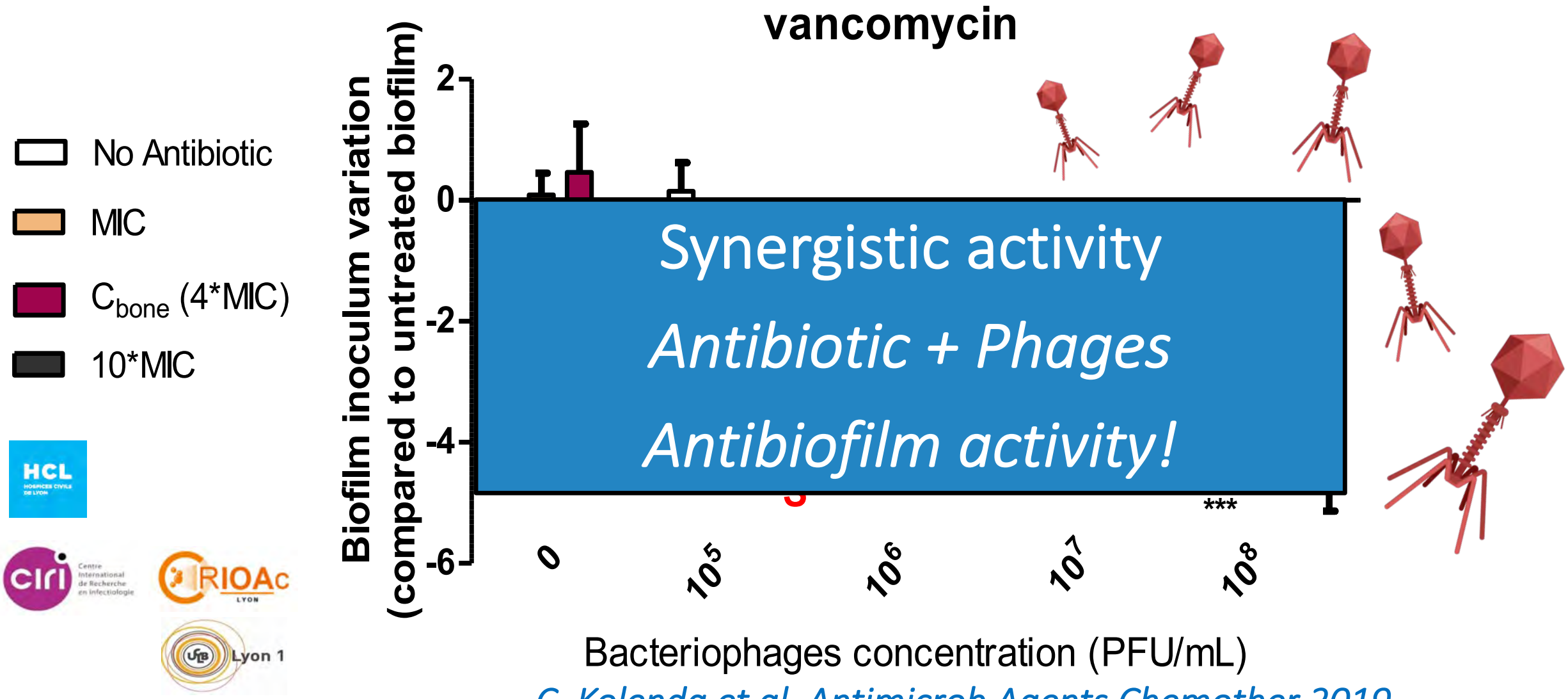
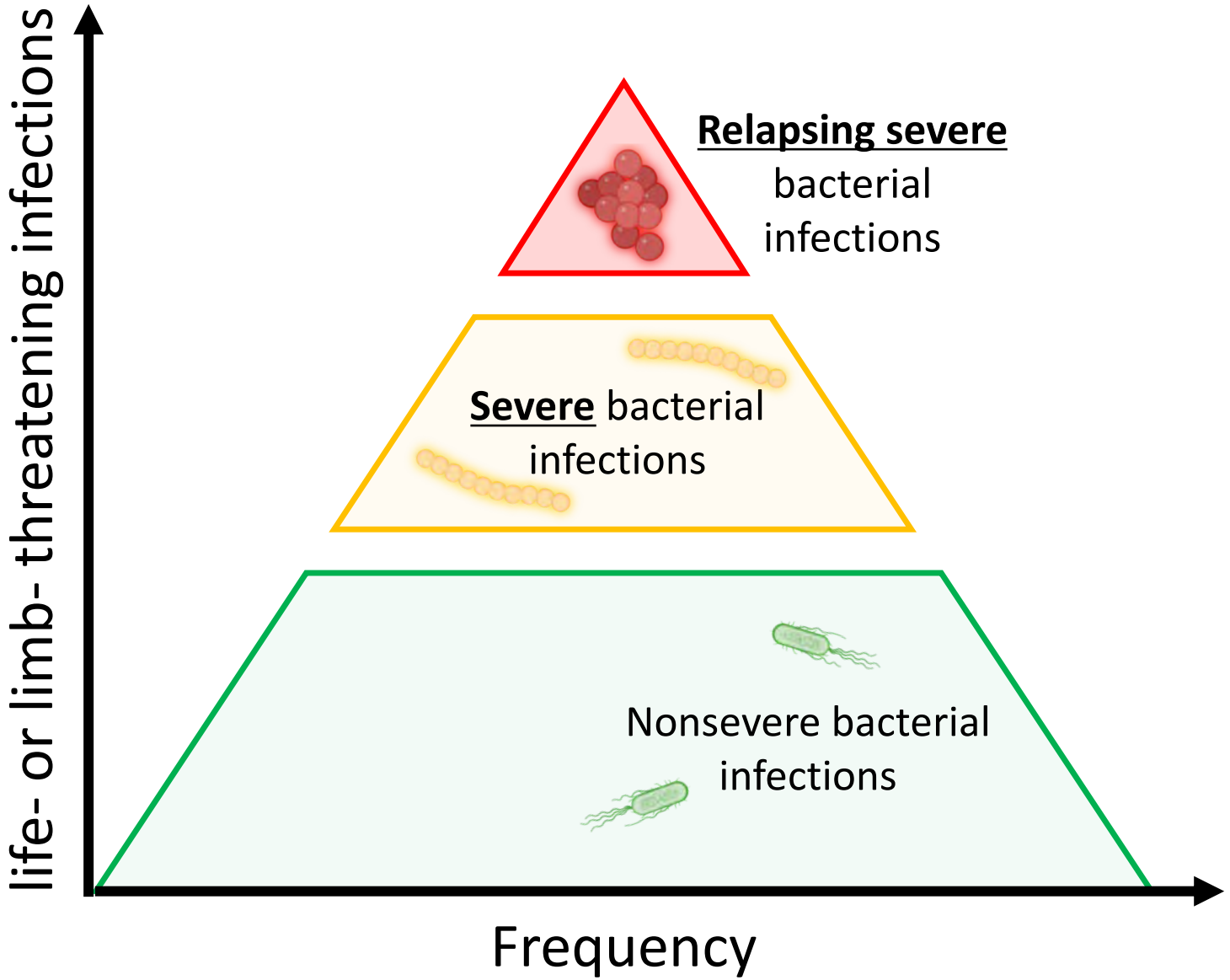
Phages have antibiofilm activity



C. Kolenda et al. Antimicrob Agents Chemother 2019

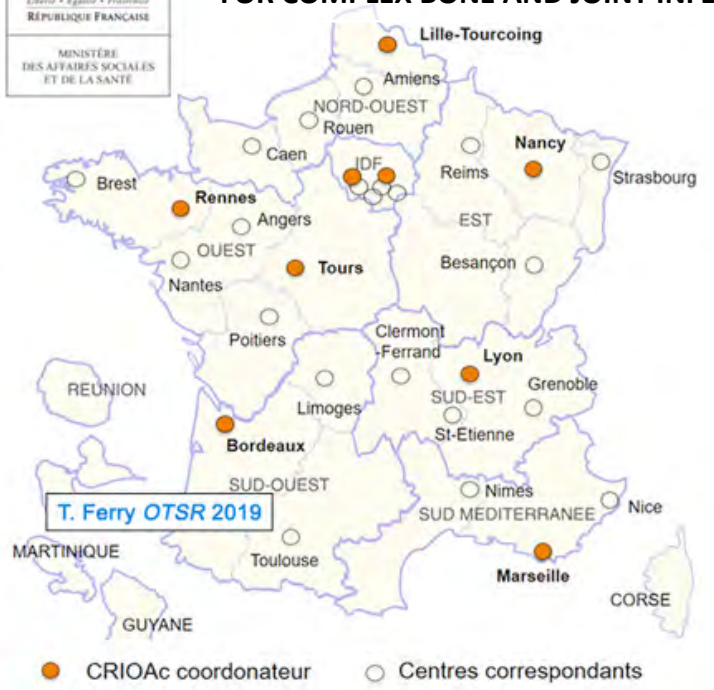
The pyramid of bacterial infectious diseases



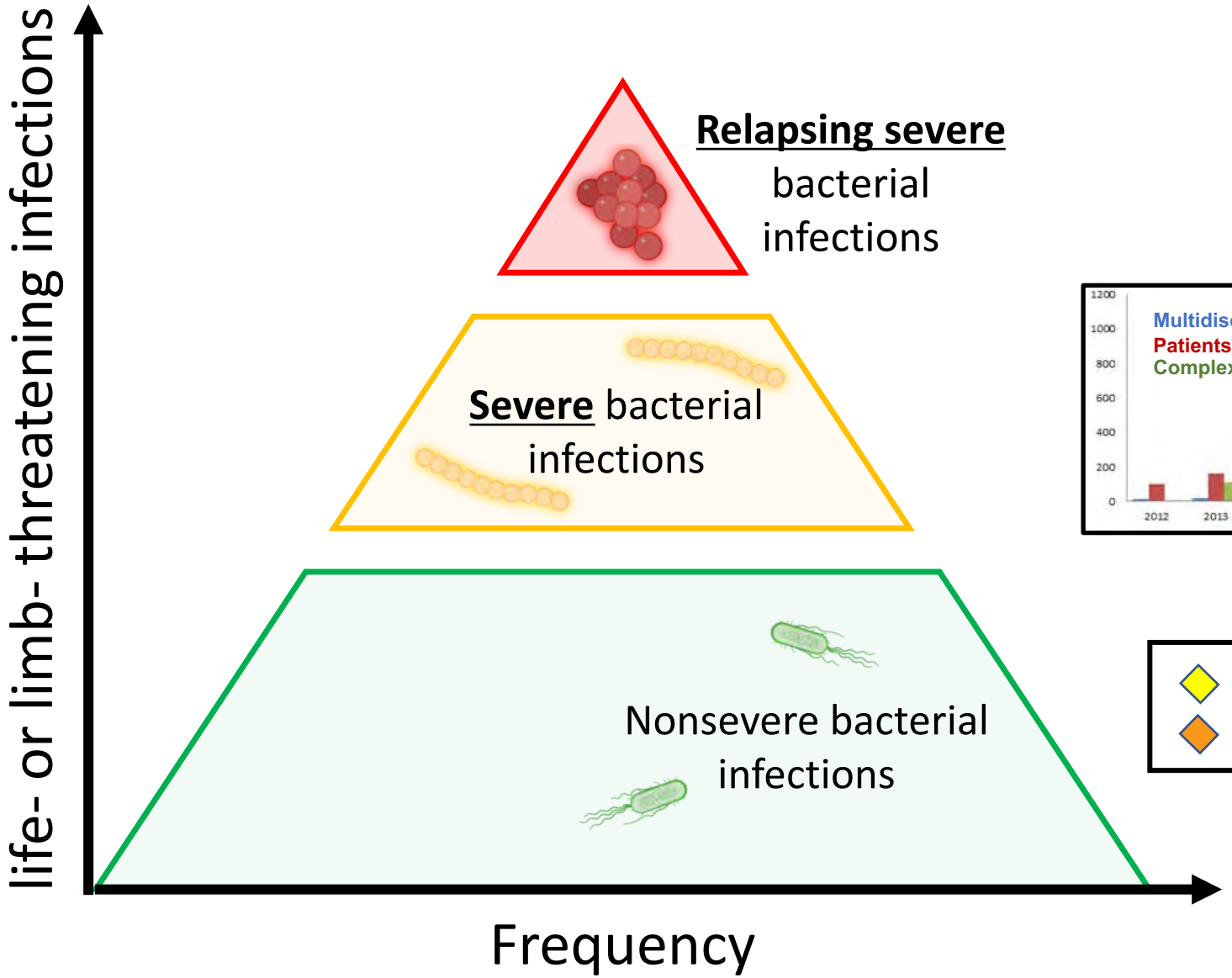
CRIOAc LYON

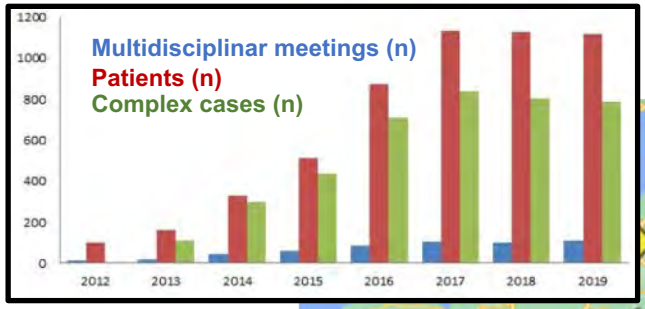
HCL HOSPICES CIVILS DE LYON

DEDICATED NETWORK
FOR COMPLEX BONE AND JOINT INFECTIONS

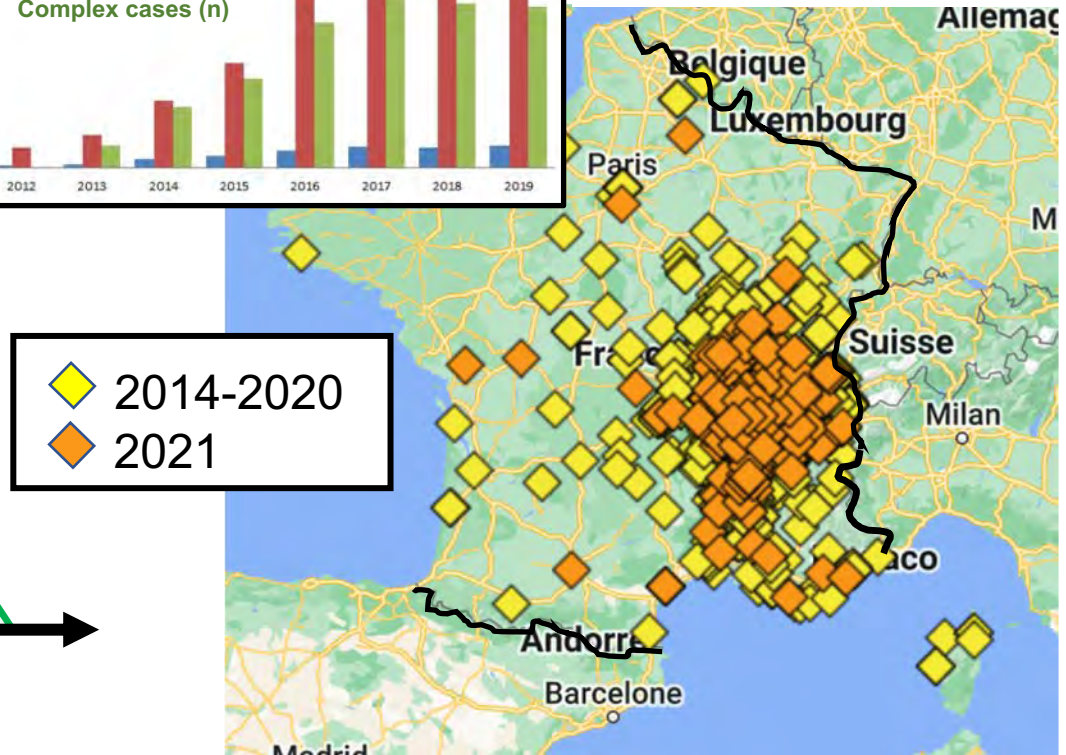


The pyramid of bacterial infectious diseases

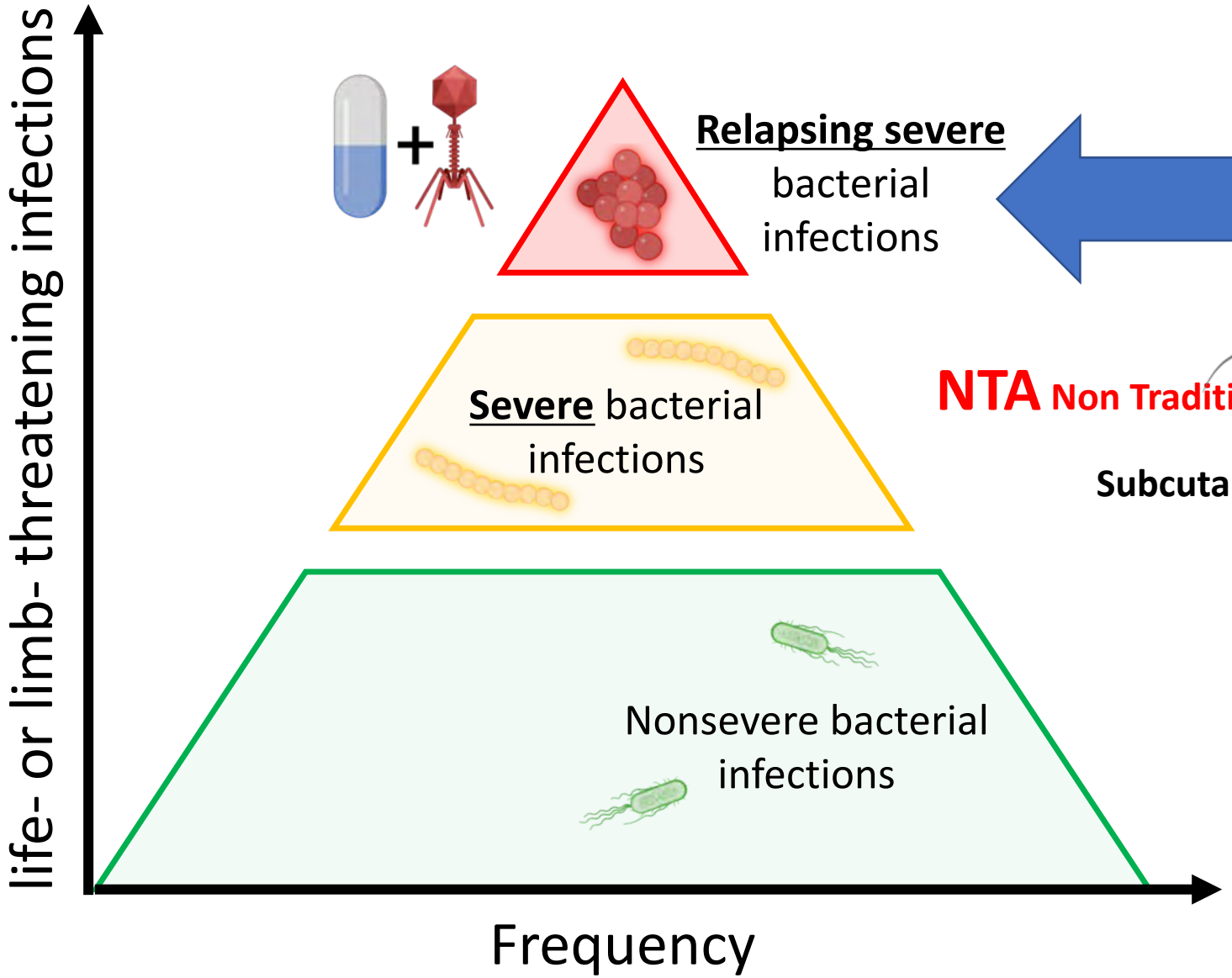




PATIENT'S RESIDENCE



The pyramid of bacterial infectious diseases



PHAGE*in*LYON

CRIOAc LYON

HCL HOSPICES CIVILS DE LYON

NTA Non Traditionnal Anti-bacterial therapies (phages and lysins)

Subcutaneous suppressive therapies

Antibiotics-loaded bone substitutes

Antibiotics-loaded cements

New antibiofilm drugs

PHAGE *in* LYON *Clinic*

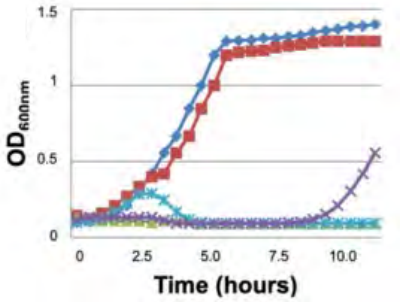
- Dedicated program to **phage therapy** development (**N**on-**T**raditional **A**ntibacterials WHO)
- Close relationship with the **French health authority**
- Integrated in our **referral center** for complex BJI
- For patients in **dead-end** clinical situations or at high risk of significant loss of function
- **Pharmaceutical grade** phages only
- Fulfilling list of **quality controls**
- **Phagogram** demonstrating the phage susceptibility
- Use in **cocktail** (≥ two active phages), with antibiotics
- Prepared by the **hospital pharmacist** under sterile conditions at the time of injection

World Health Organization

ansm
Agence nationale de sécurité du médicament et des produits de santé

CRIOAc LYON

HCL HOSPICES CIVILS DE LYON



PHAGE *in* LYON Clinic

- **Type of BJI in our scope**
  - Prosthetic joint infections
  - BJI with puncturable abscesses

- **Type of BJI not in our scope***
  - Septic nonunion
  - Osteomyelitis
  - Decubitus ulcer with osteomyelitis
  - Diabetic foot osteomyelitis

Reasons*

- Microbiological diagnosis unknown before surgery
- Infected bone difficult to access
- No closed anatomic space for phage local injection
- Co-infection with other bacteria not targeted by phages
- Exposed bone
- Absorbable $CaSO_4$ bone substitutes are more appropriate

viruses

Lyon BJI study group

PHAGE*in*LYON

MDPI

Review

Past and Future of Phage Therapy and Phage-Derived Proteins in Pat

Tristan Fe
Jérôme Jos
Frédéric L
on behalf

REVIEW ARTICLE OPEN ACCESS

Medical innovations to maintain the function in patients with chronic PJI for whom explantation is not desirable: a pathophysiology-, multidisciplinary-, and experience-based approach

Tristan Ferry[1,2,3,4,*], Cécile Batailler[2,3,5], Sophie Brosset[2,3,6], Camille Kolenda[2,3,4,7], Sylvain Goutelle[2,3,8,9], Elliot Sappey-Marinier[2,3,5], Jérôme Josse[2,3,4,7], Frédéric Laurent[2,3,4,7], Sébastien Lustig[2,3,5], On Behalf of the Lyon BJI Study Group,[a]

Virologie

t une infection ostéoarticulaire : historique, fondements, faisabilité et perspectives en France

Phage therapy in bone and joint infection: history, rationale, feasibility and perspectives in France

Case Report: Arthroscopic "Debridement Antibiotics and Implant Retention" With Local Injection of Personalized Phage Therapy to Salvage a Relapsing *Pseudomonas Aeruginosa* Prosthetic Knee Infection

Tristan Ferry[1,2,3,4], Camille Kolenda[2,3,4,5], Cécile Batailler[2,3,6], Romain Gaillard[3,6], Claude-Alexandre Gustave[2,3,4,5], Sébastien Lustig[2,3,6], Cindy Fevre[7], Charlotte Petitjean[7], Gilles Leboucher[8], Frédéric Laurent[2,3,4,5] and the Lyon BJI Study group*

Open Forum Infectious Diseases
BRIEF REPORT

Salvage Debridement, Antibiotics and Implant Retention ("DAIR") With Local Injection of a Selected Cocktail of Bacteriophages: Is It an Option for an Elderly Patient With Relapsing Staphylococcus *aureus* Prosthetic-Joint Infection?

Tristan Ferry,[1,2,3,4] Gilles Leboucher,[5] Cindy Fevre,[6] Yannick Herry,[2,4,7] Anne Conrad,[1,2,3,4] Jérôme Josse,[2,3,4,8] Cécile Batailler,[2,4,7] Christian Chidiac,[1,2,3,4] Mathieu Medina,[6] S. Lustig,[7] and Frédéric Laurent[2,3,4,8]; on behalf of the Lyon BJI Study Group

Phage Therapy as Adjuvant to Conservative Surgery and Antibiotics to Salvage Patients With Relapsing *S. aureus* Prosthetic Knee Infection

Tristan Ferry[1,2,3,4], Camille Kolenda[2,3,4,5], Cécile Batailler[2,3,6], Claude-Alexandre Gustave[2,3,4,5], Sébastien Lustig[2,3,6], Matthieu Malatray[3,6], Cindy Fevre[7], Jérôme Josse[2,3,4,5], Charlotte Petitjean[7], Christian Chidiac[1,2,3,4], Gilles Leboucher[8] and Frédéric Laurent[2,3,4,5] on behalf of the Lyon BJI Study group*

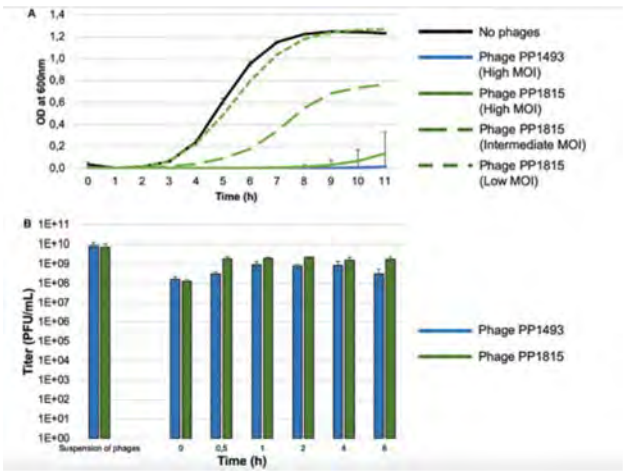
The Potential Innovative Use of Bacteriophages Within the DAC® Hydrogel to Treat Patients With Knee Megaprosthesis Infection Requiring "Debridement Antibiotics and Implant Retention" and Soft Tissue Coverage as Salvage Therapy

Tristan Ferry[1,2,3,4], Cécile Batailler[2,3,5], Charlotte Petitjean[6], Joseph Chateau[7], Cindy Fevre[6], Emmanuel Forestier[8], Sophie Brosset[7], Gilles Leboucher[9], Camille Kolenda[2,3,4,10], Frédéric Laurent[2,3,4,10] and Sébastien Lustig[2,3,5] on behalf of the Lyon BJI Study Group*

4,970

TOTAL VIEWS

Am score 10



J Antimicrob Chemother 2018; **73**: 2901–2903
doi:10.1093/jac/dky263
Advance Access publication 27 July 2018

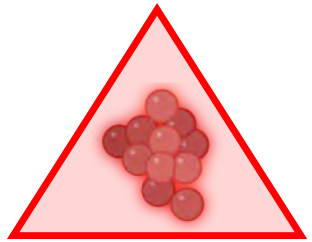
Innovations for the treatment of a complex bone and joint infection due to XDR *Pseudomonas aeruginosa* including local application of a selected cocktail of bacteriophages

Tristan Ferry[1–4]*, Fabien Boucher[1,4,5], Cindy Fevre[6], Thomas Perpoint[1,4], Joseph Chateau[1,2,4,5], Charlotte Petitjean[6], Jérôme Josse[2–4,7], Christian Chidiac[1,2–4], Guillaume L'hostis[6], Gilles Leboucher[8] and Frédéric Laurent[2–4,7] on behalf of the Lyon Bone and Joint Infection Study Group[†]

CITATIONS 49 | VIEWS 2,316 | ALTMETRIC 16

More metrics information

A large panel of **severe** bacterial infections



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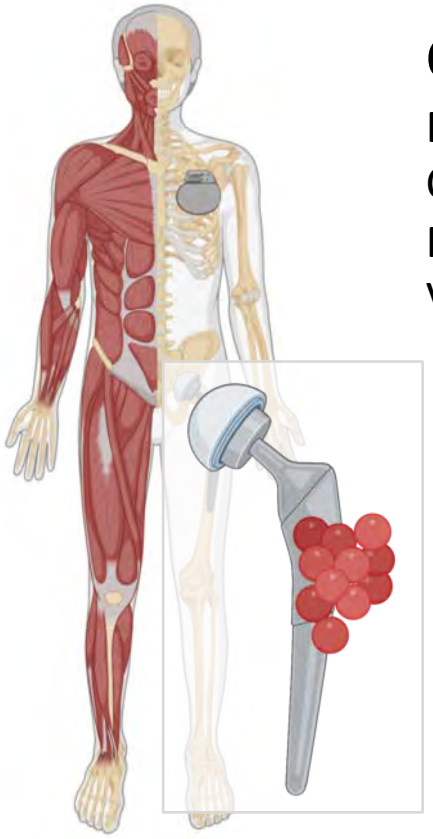

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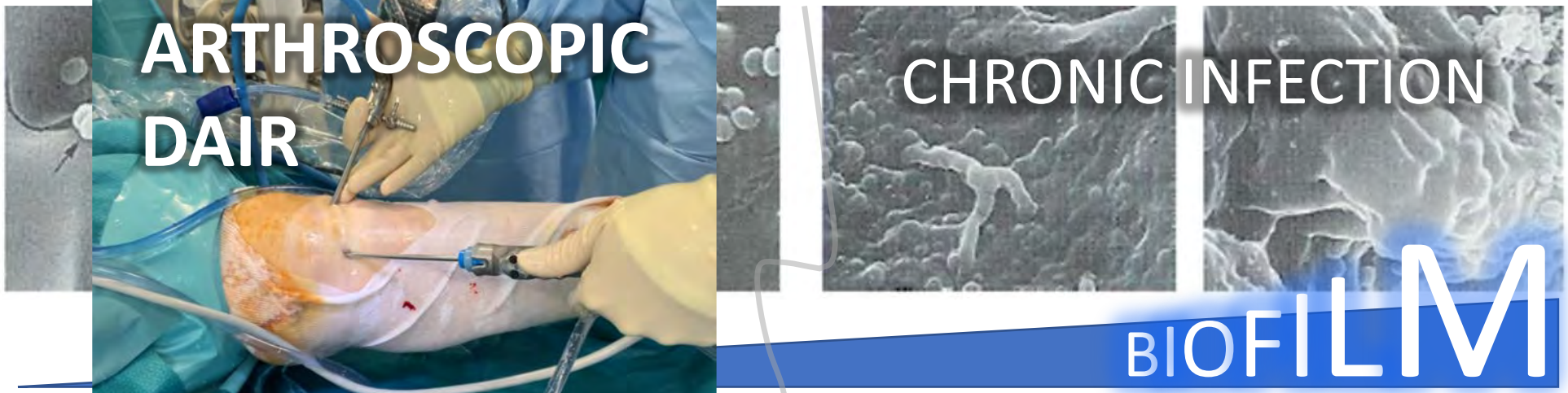


RIOAc LYON

HCL HOSPICES CIVILS DE LYON

Conservative approach: DAIR

'Debridement, Antibiotics and Implant Retention'

Probability to **control** the disease

~60%

Guidelines

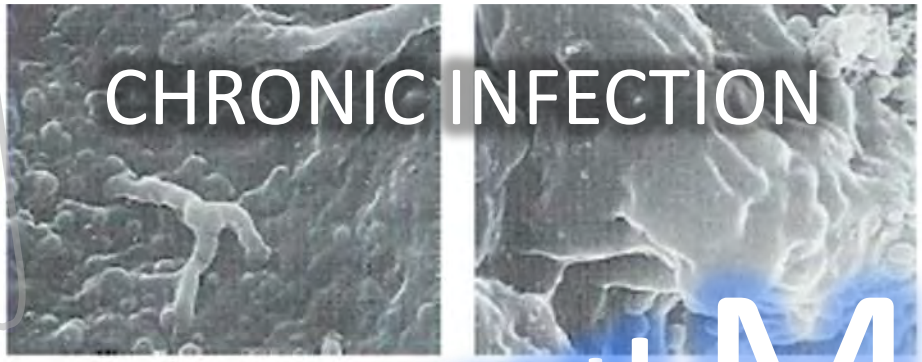
2013

DAIR

+ Suppressive antimicrobial therapy

2017

SAT



CRIOAc LYON

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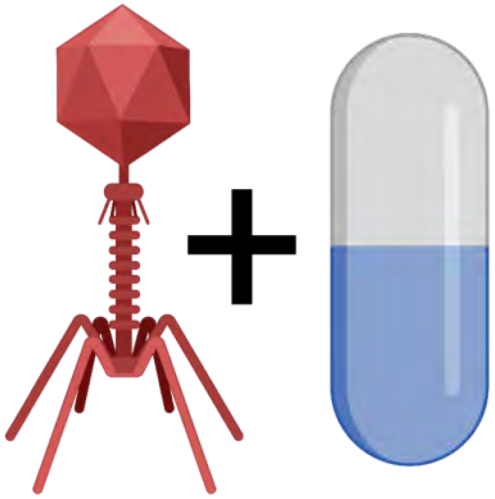


Guidelines

2013

DAIR

+ Suppressive antimicrobial therapy

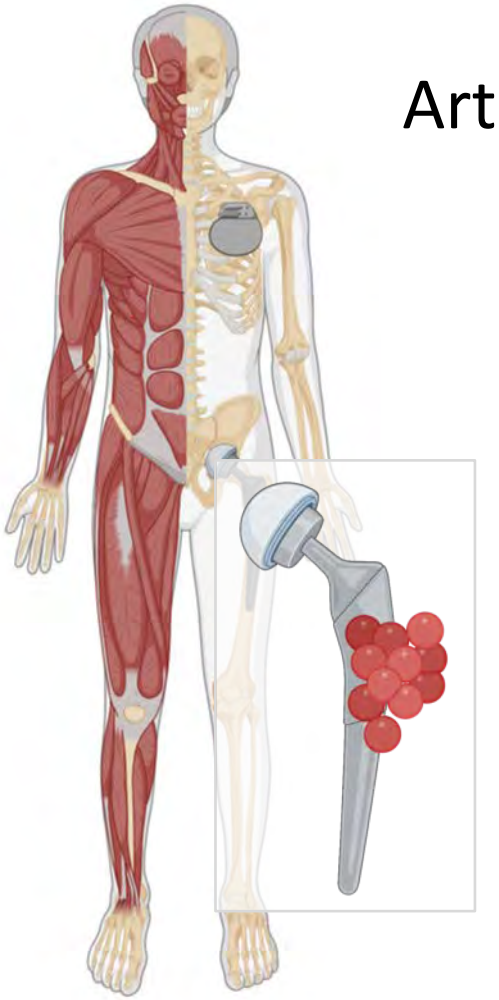
SAT 2017

Conservative approach: DAIR

'Debridement, Antibiotics and Implant Retention'

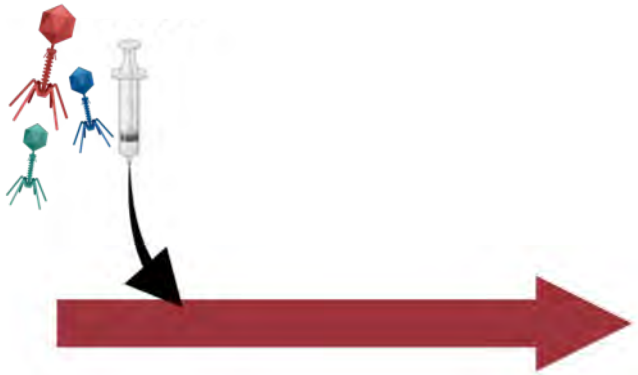
PHAGE*in*LYON

Clinic



Arthroscopic or open

DAIR



Case series RIOAc procedure called « PhagoDAIR »

Phage Therapy as Adjuvant to Conservative Surgery and Antibiotics to Salvage Patients With Relapsing *S. aureus* Prosthetic Knee Infection

5,711
TOTAL VIEWS
Am score 78

Tristan Ferry[1,2,3,4], Camille Kolenda[2,3,4,5], Cécile Batailler[2,3,6], Claude-Alexandre Gustave[2,3,4,5], Sébastien Lustig[2,3,6], Matthieu Malatray[3,6], Cindy Fevre[7], Jérôme Josse[2,3,4,5], Charlotte Petitjean[7], Christian Chidiac[1,2,3,4], Gilles Leboucher[8] and Frédéric Laurent[2,3,4,5] on behalf of the Lyon BJI Study group*

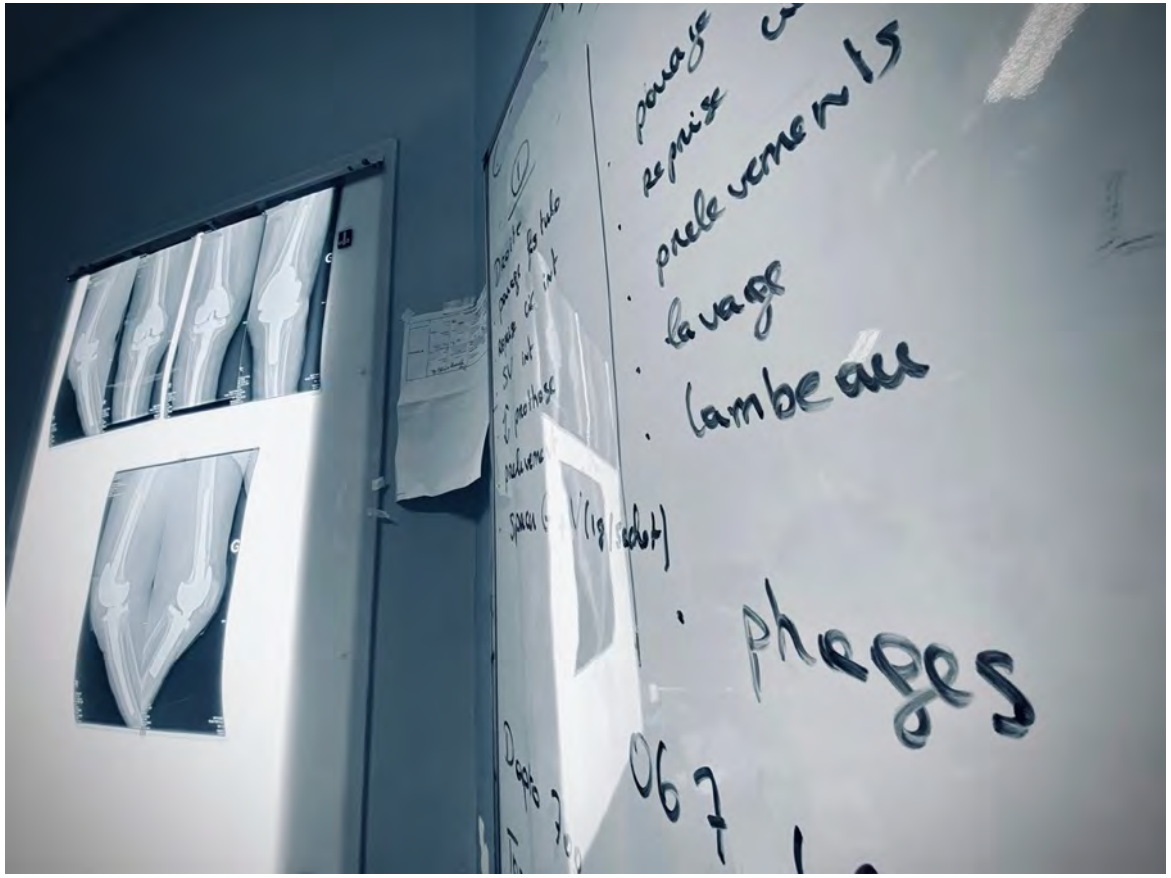
frontiers in Medicine

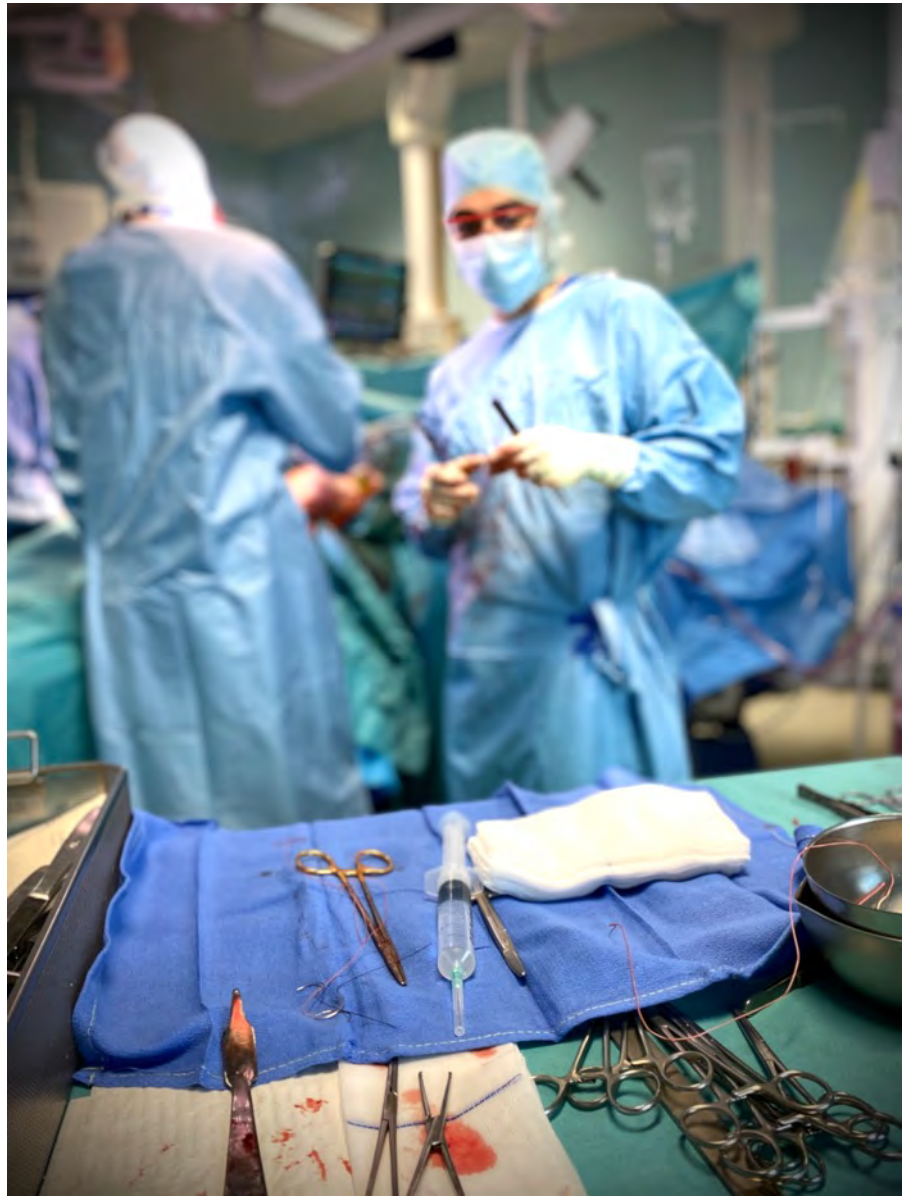
CASE REPORT
published: 16 November 2020
doi: 10.3389/fmed.2020.570572

#PhagoDAIR

Debridement Antibiotics and Implant Retention

#PhagoDAIR procedure





HCL HOSPICES CIVILS DE LYON

Lyon 1

PHAGE*in*LYON Clinic

ciri Centre International de Recherche en Infectiologie

FONDATION HCL HOSPICES CIVILS DE LYON

#PhagoDAIR procedure

>1 billion of **active viruses infecting *S. aureus*** in a syringe

HCL HOSPICES CIVILS DE LYON

Lyon 1

PHAGE*in*LYON *Clinic*

ciri Centre International de Recherche en Infectiologie

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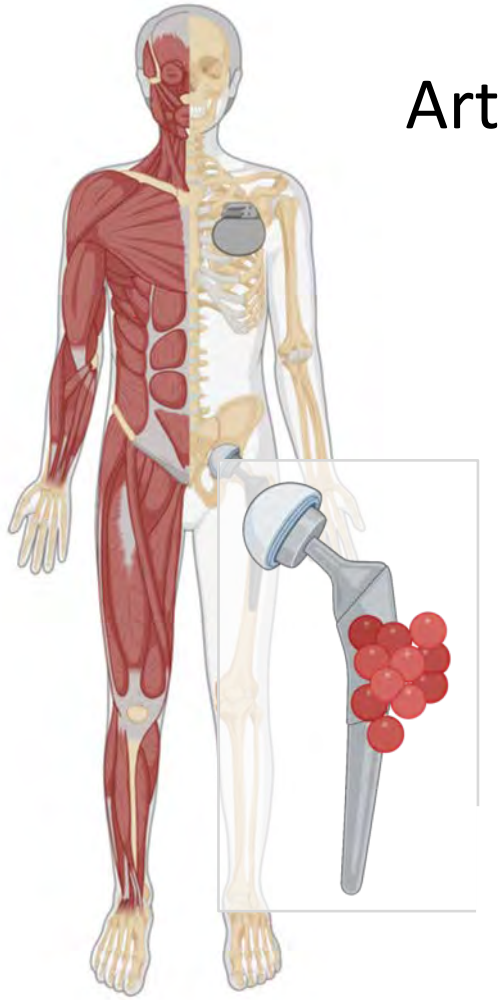
PHAGE*in*LYON

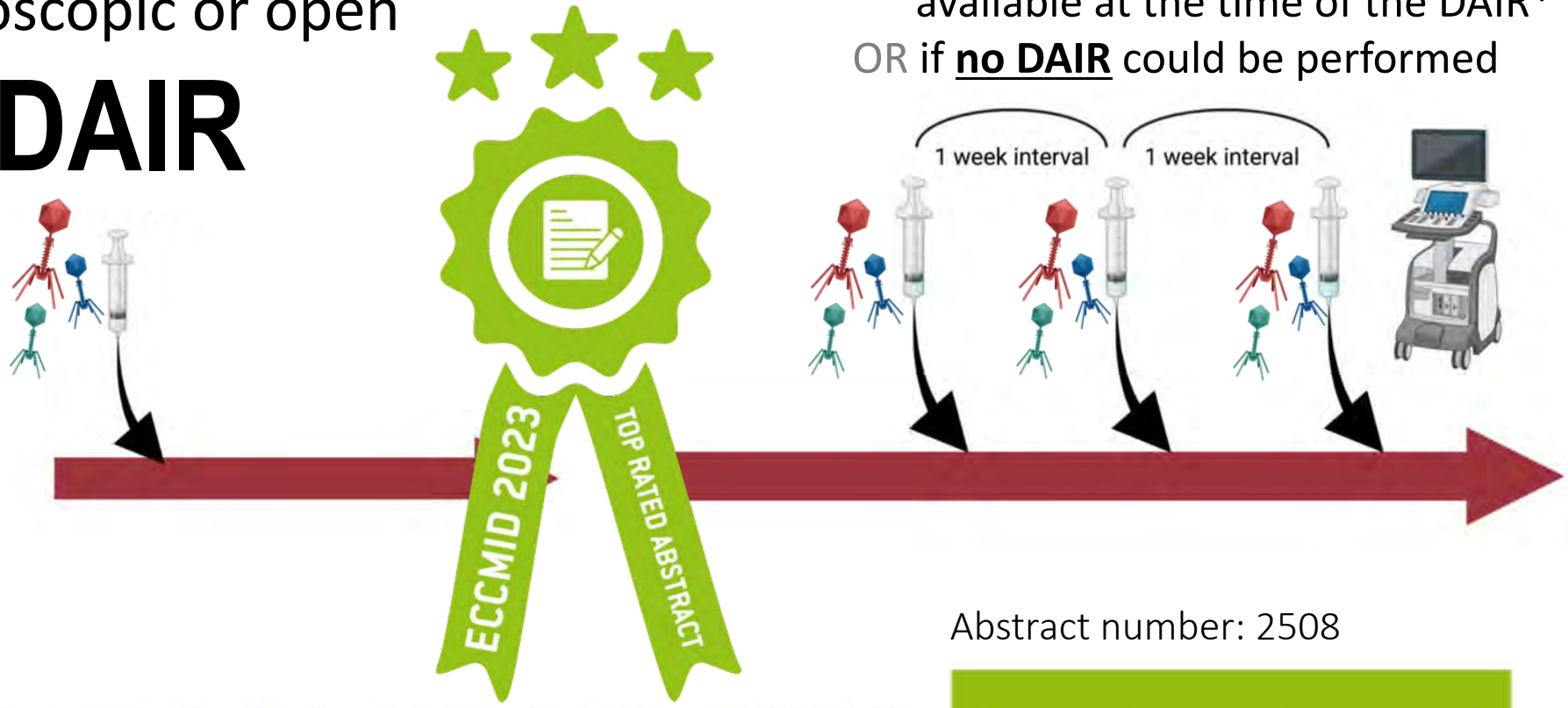
Clinic



Arthroscopic or open

DAIR

in case of **relapse**
OR **after DAIR** if no phages were available at the time of the DAIR*
OR if **no DAIR** could be performed



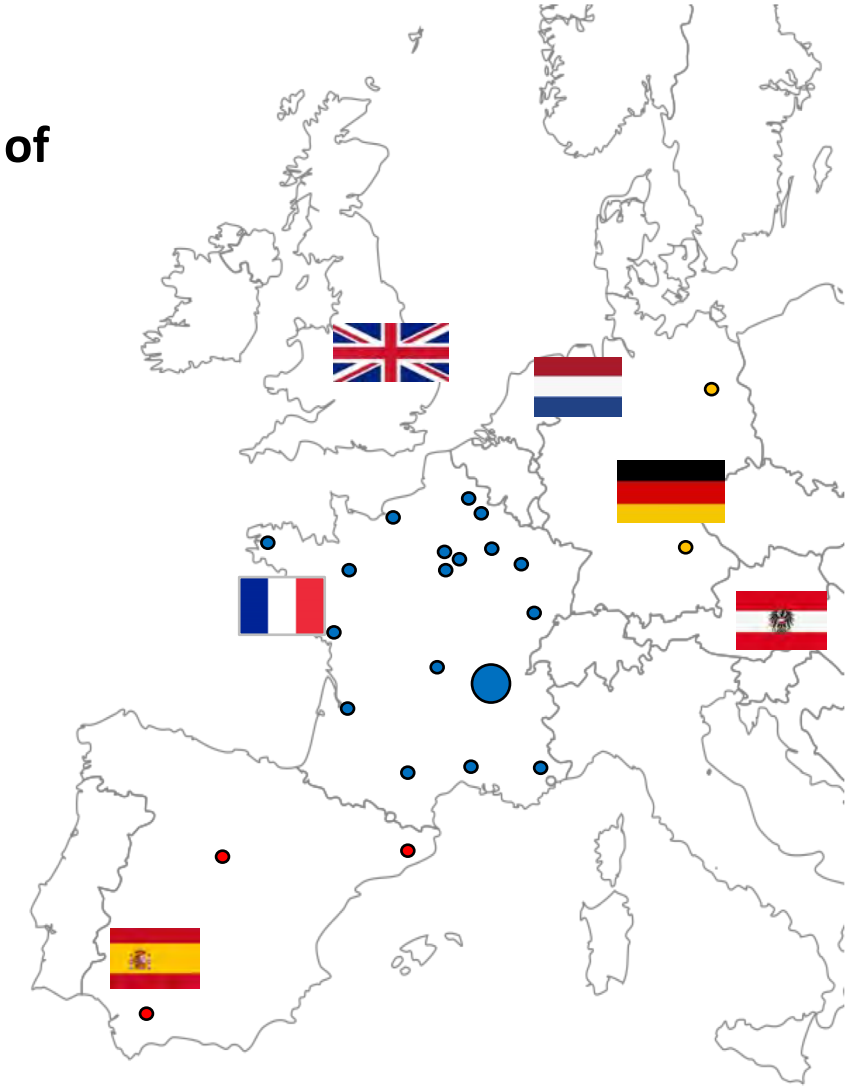
Abstract number: 2508

33rd ECCMID EUROPEAN CONGRESS OF CLINICAL MICROBIOLOGY AND INFECTIOUS DISEASES

Copenhagen, Denmark
15–18 April 2023

PhagoDAIR I

A Pilot, Multicenter, Randomized, Non-Comparative, Double-Blind Study of Phage Therapy in Patients with Hip or Knee PJI due to *S. aureus* Treated with DAIR and Antibiotic Therapy



Inclusion Criteria

1. ***S. aureus* monomicrobial** knee or hip **PJI** with clinical signs of infection with indication of **DAIR** and **Suppressive Antibiotics Therapy (SAT).**
2. Phagogram displaying the susceptibility of the strain to at least one of the anti-*Staphylococcus aureus* bacteriophages

Primary Objective

To estimate the **rate of clinical control of infection at Week 12±2** which will allow to calculate the sample size for future comparative studies.

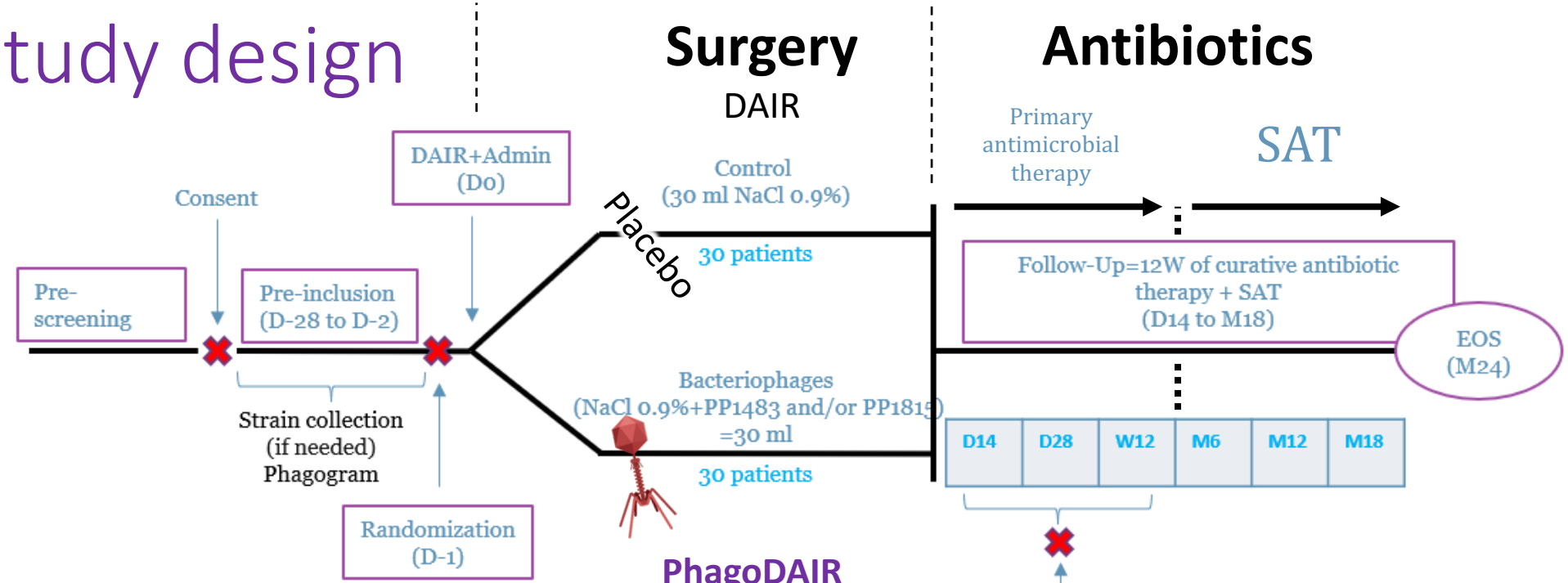
PHAXIAM

Ex- PHERECYDES PHARMA

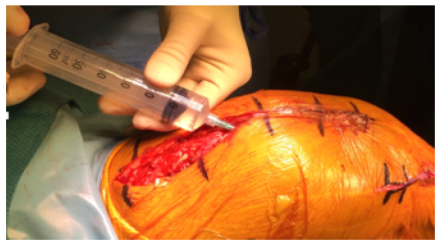
PhagoDAIR I

A Pilot, Multicenter, Randomized, Non-Comparative, Double-Blind Study of Phage Therapy in Patients with Hip or Knee PJI due to *S. aureus* Treated with DAIR and Antibiotic Therapy

Study design



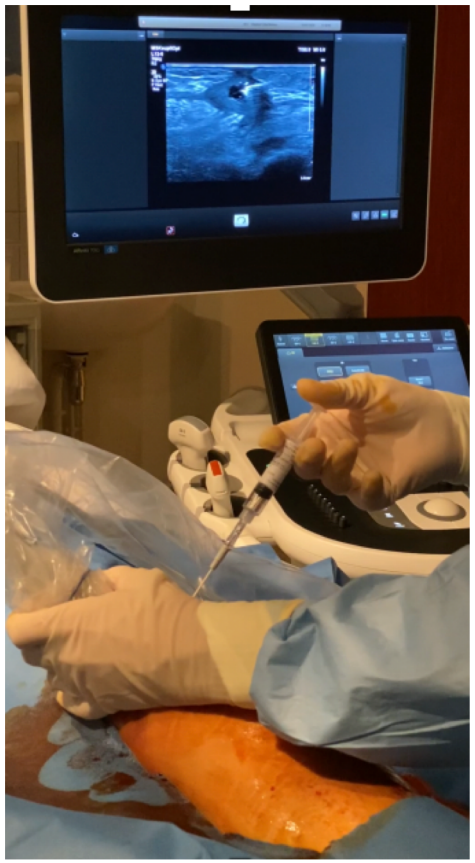
PhagoDAIR



Salvage procedure

- Pre-treatment (D-15 to D-1)
- Active phages admin at D0-RT, D7-RT, and D14-RT
- Follow-Up (D28-RT to M18)
- EOS at M24

Salvage procedure



Clinical Infectious Diseases
MAJOR ARTICLE
2020
IDSA Infectious Diseases Society of America
hivma hiv medicine association

Phage Therapy for Limb-threatening Prosthetic Knee *Klebsiella pneumoniae* Infection: Case Report and In Vitro Characterization of Anti-biofilm Activity

Edison J. Cano,[1,2] Katherine M. Caflisch,[2,3] Paul L. Bollyky,[4] Jonas D. Van Belleghem,[4] Robin Patel,[1,2,5] Joseph Fackler,[6] Michael J. Brownstein,[6] Bri'Anna Horne,[6] Biswajit Biswas,[7] Matthew Henry,[7,8] Francisco Malagon,[7] David G. Lewallen,[9] and Gina A. Suh[1]

[1]Division of Infectious Diseases, Mayo Clinic, Rochester, Minnesota, USA, [2]Infectious Diseases Research Laboratory, Mayo Clinic, Rochester, Minnesota, USA, [3]Department of Molecular Pharmacology and Experimental Therapeutics, Mayo Clinic, Rochester, Minnesota, USA, [4]Division of Infectious Diseases and Geographic Medicine, Department of Medicine, Stanford University School of Medicine, Stanford, California, USA, [5]Division of Clinical Microbiology, Mayo Clinic, Rochester, Minnesota, USA, [6]Adaptive Phage Therapeutics, Gaithersburg, Maryland, USA, [7]Genomics and Bioinformatics Department, Biological Defense Research Directorate, Naval Medical Research Center-Frederick, Fort Detrick, Maryland, USA, [8]Geneva Foundation, Tacoma, Washington, USA, and [9]Department of Orthopedic Surgery, Mayo Clinic, Rochester, Minnesota, USA

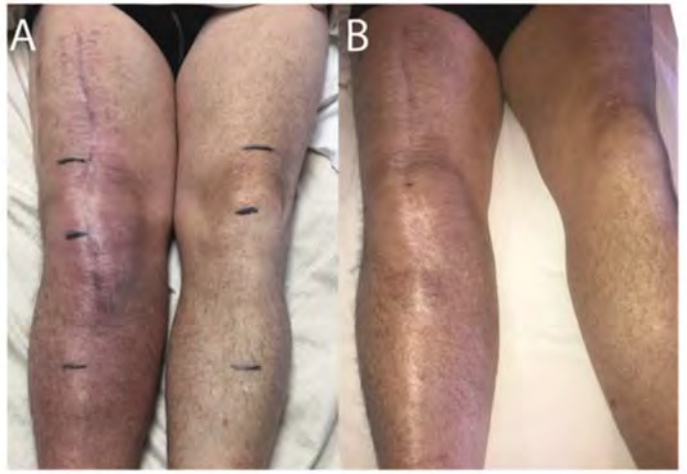


Figure 3. Phage therapy resulted in reduced erythema and swelling. Images are shown of the patient's lower extremities (*A*) before and (*B*) after completion of phage therapy.

NO SURGERY! 40 doses of exclusive <u>INTRAVENOUS</u> phages (1 injection each weekday)

adaptive phage THERAPEUTICS

pharmaceuticals
2021
MDPI

Case Report

Successful Treatment of a Recalcitrant *Staphylococcus epidermidis* Prosthetic Knee Infection with Intraoperative Bacteriophage Therapy

James B. Doub [1,*], Vincent Y. Ng [2], Eleanor Wilson [1], Lorenzo Corsini [3] and Benjamin K. Chan [4]

Single <u>LOCAL</u> injection during DAIR

PHAGOMED
PHAGE-BASED THERAPIES

NIH U.S. National Library of Medicine

ClinicalTrials.gov

A Randomized, Double-Blind, Placebo-Controlled, Multicenter Study to Evaluate the Safety and Efficacy of Phage Therapy Versus Placebo in Conjunction With DAIR in Patients With Chronic Prosthetic Joint Infection Who Previously Failed Surgery for PJI

adaptive phage THERAPEUTICS

An Open-Label Multicenter Study to Evaluate the Safety and Efficacy of PhageBank™ Phage Therapy in Conjunction With Debridement, Antibiotics, and Implant Retention (DAIR) for Patients With First Time Culture Proven Chronic Prosthetic Joint Infection

adaptive phage THERAPEUTICS

A Pilot, Multicenter, Randomized, Non-Comparative, Double-Blind Study of Phage Therapy in Patients with Hip or Knee PJI due to *S. aureus* Treated with DAIR and Antibiotic Therapy

PHERECYDES PHARMA

Etc.

Clinical case (3rd treated patient)

Arthroscopic DAIR with phages to salvage *P. aeruginosa* prosthetic knee infection

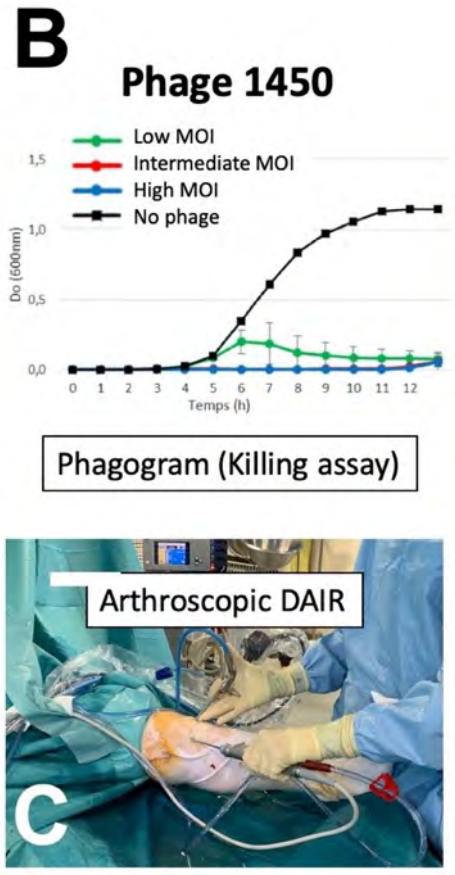
frontiers in Medicine 2021

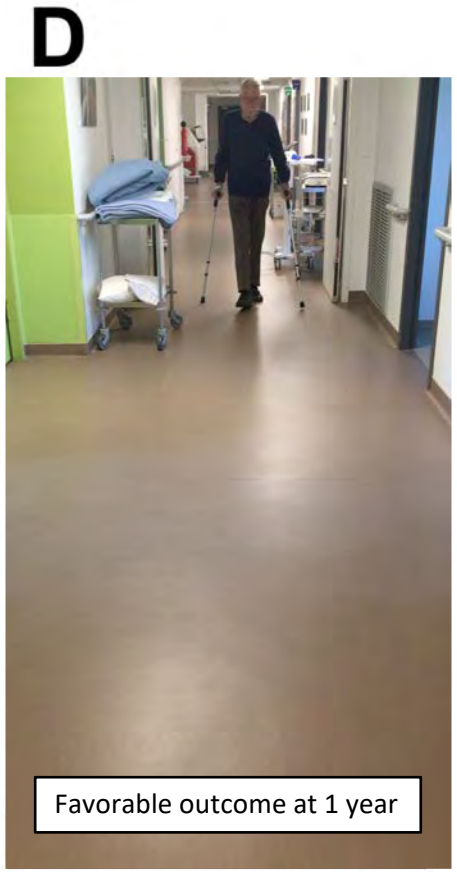
88-year-old man

Relapsing *P. aeruginosa* prosthetic left knee infection

End-stage cardiac failure

Contraindicated to open DAIR





RIOAc LYON

HCL Hospices Civils de Lyon

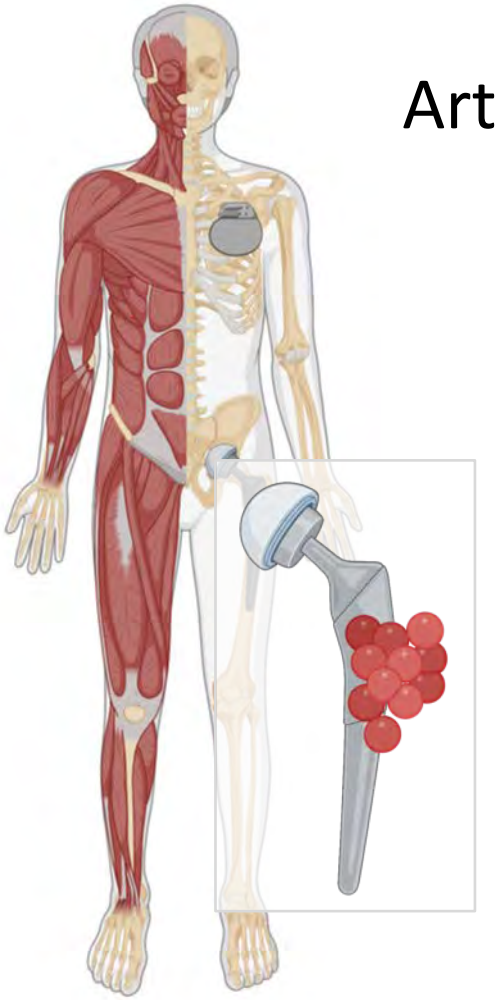
Université Lyon 1

PHAGE*in*LYON

ciri Centre International de Recherche en Infectiologie

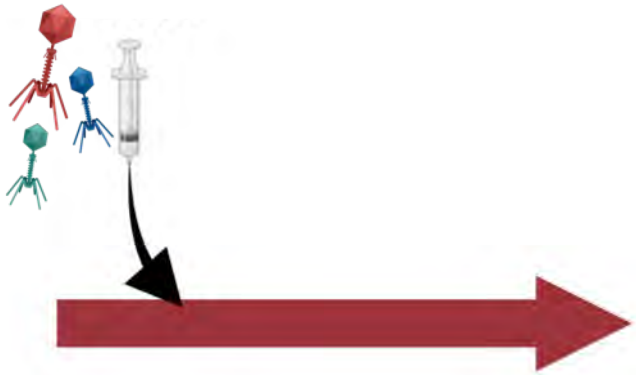
Fondation HCL Hospices Civils de Lyon

PHAGE *in* LYON
Clinic

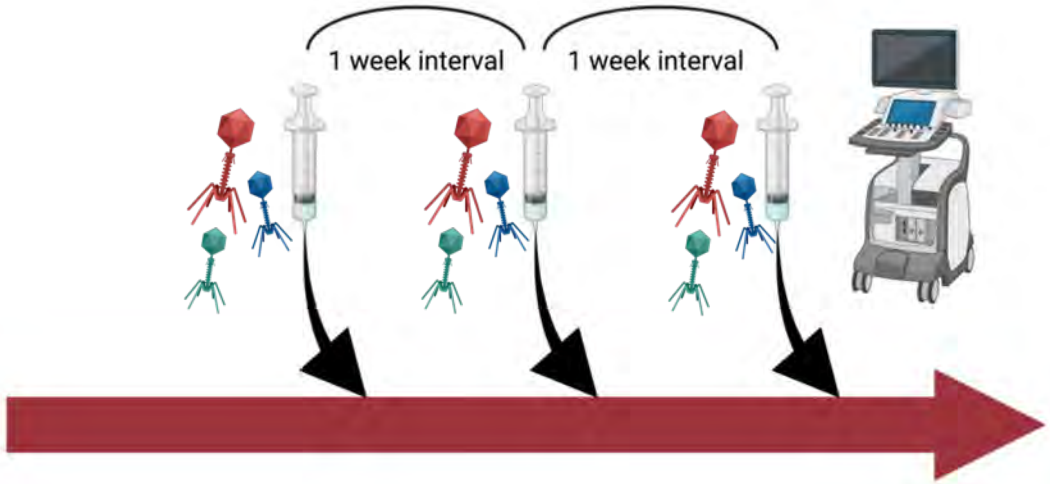


Arthroscopic or open

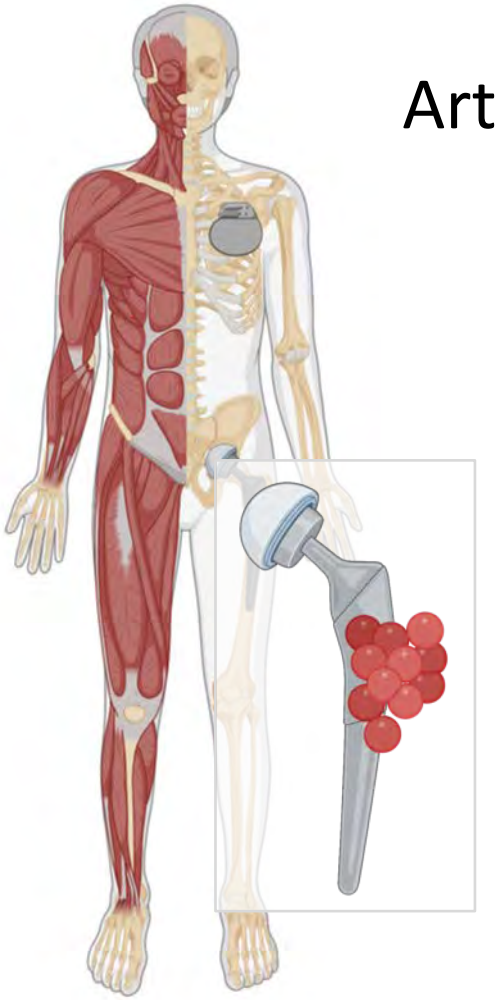
DAIR



in case of **relapse**
OR if **no DAIR** could be performed
OR **after DAIR** if no phages were available at the time of the DAIR



PHAGE *in* LYON
Clinic



Arthroscopic or open

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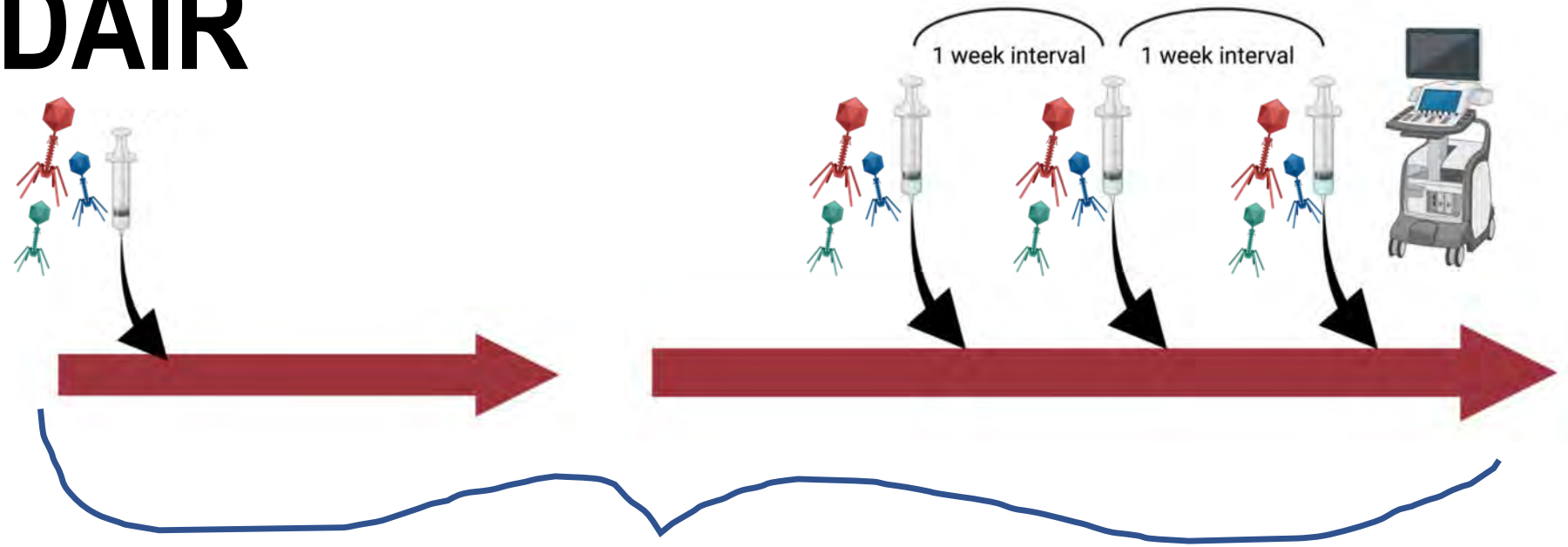
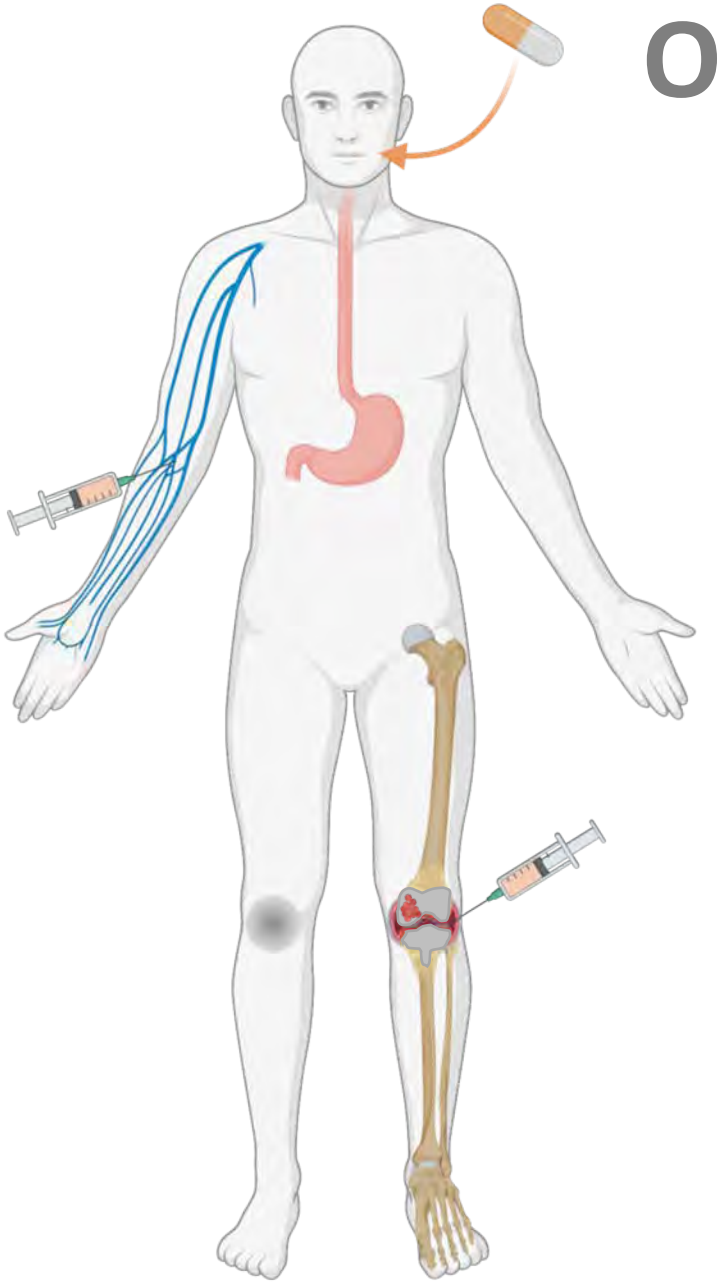


Combination of both
+ daily intravenous injections

Is PJI treatment a threesom?

Oral antibiotics



IV antibiotics

IV phages

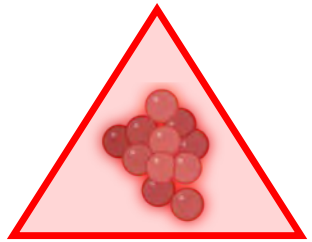
Local therapy

Surgery

No surgery
Arthroscopic DAIR
Open DAIR (SoC)
Prosthesis exchange (SoC)

Local phages

A large panel of **severe** bacterial infections



Central nervous system infections

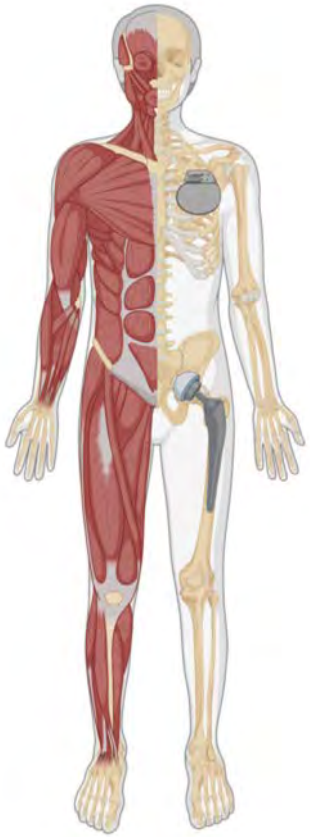
Implant-associated meningitis

Lung infections

Ventilator-associated pneumonia
Exacerbation in cystic fibrosis
Exacerbations in bronchiectasis

Urinary tract infections

Pyelonephritis
Ureteral stent-associated infection



Cardiovascular infections

Endocarditis
Cardiac electronic device infection
Prosthetic-valve endocarditis
Vascular graft infection

Muskuloskeletal infections

Wound infection
Osteomyelitis, fracture-related infection
Implant-associated bone and joint infection
Prosthetic joint infection

Digestive-tract infection

Typhoid fever, shigellosis
Cholera

Clinical case (12th treated patient)

74-year-old man

Melanoma treated with anti-PD1

Catheter-related *P. aeruginosa* bacteriemia in January 2018

Spinal pain summer 2018

Spondylodiscitis with **spinal abscess**

Pandrug-resistant *P. aeruginosa* in culture!

Clinical case (12th treated patient)

74-year-old man

Melanoma treated with anti-PD1

Catheter-related *P. aeruginosa* bacteriemia in January 2018

Spinal pain summer 2018

Spondylodiscitis with **spina**

Pandrug-resist

	Pseudomonas aeruginosa CMI (mg/l)
Ticarcilline + Ac. Clav	R (> 64)
Pipéracilline	R (> 64)
Pipéracilline + Tazobactam	R (> 64)
Ceftazidime	R (> 32)
Céfépime	R (> 32)
Aztréonam	R (> 32)
Imipénème	R (> 8)
Meropeneme	R (> 8)
Gentamicine	R (> 8)
Tobramycine	R (> 8)
Amikacine	R (> 32)
Ciprofloxacine	R (> 2)
[illegible]xacine	R (> 4)
[illegible]oxazole	R
[illegible]e	S (8) ⇨ R
	S E-test : 1 ⇨ R
	R E-test : > 256
	R E-test : 64

PHERECYDES PHARMA

AMPLIPHI BIOSCIENCES CORPORATION

The strain was also spontaneously resistant to bacteriophages !!!

HCL HOSPICES CIVILS DE LYON

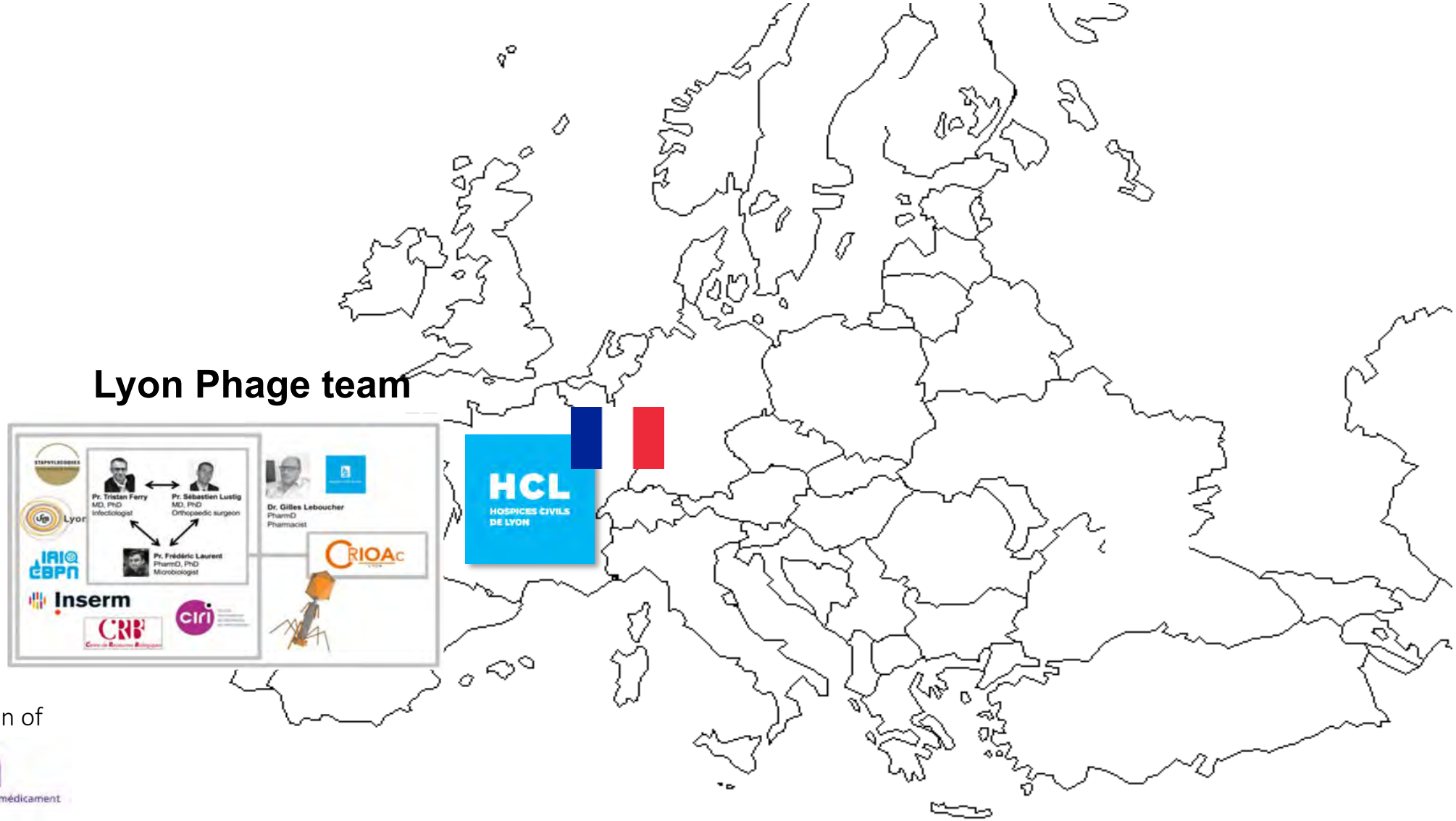
Lyon 1

PHAGE*in*LYON

ciri Centre International de Recherche en Infectiologie

FONDATION HCL HOSPICES CIVILS DE LYON

Unique European academic collaboration

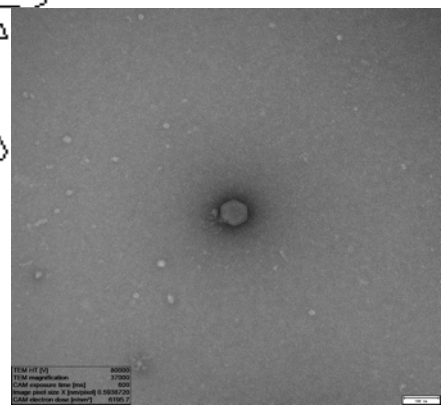


Under the supervision of

ansm
Agence nationale de sécurité du médicament et des produits de santé

French Health Authority

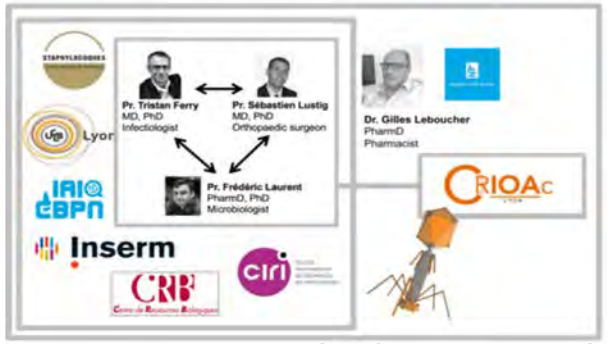
Unique European academic collaboration



Jean-Paul Pirnay

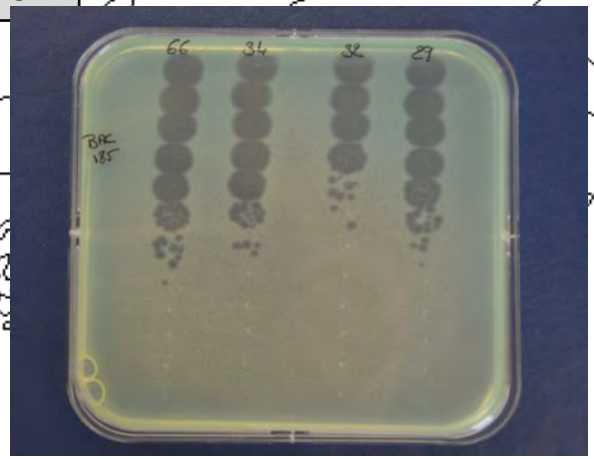
Gregory Resch

Lyon Phage tea



HCL
HOSPICES CIVILS DE LYON

Unil
UNIL | Université de



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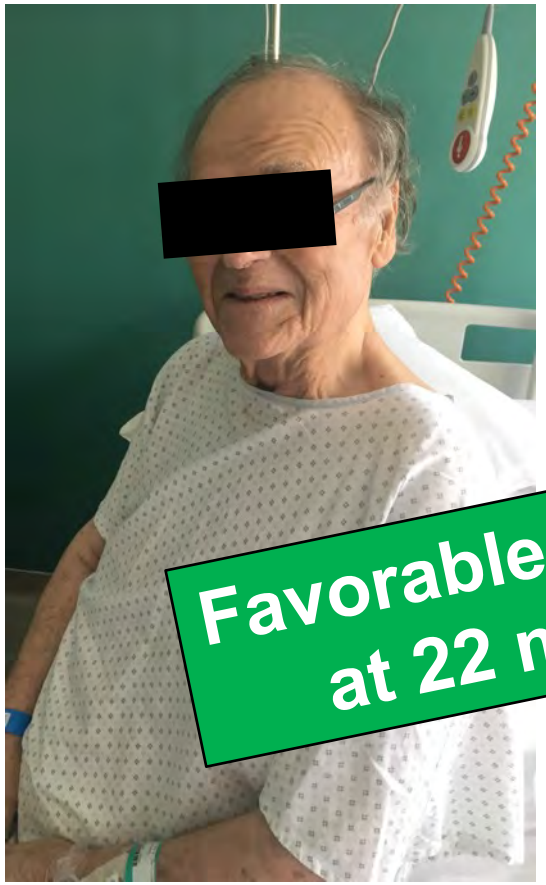
HCL HOSPICES CIVILS DE LYON

MHKA HMRA

UNIL | Université de Lausanne



Favorable outcome at 22 months

nature COMMUNICATIONS

T. FERRY et al. 2022

HCL PHAGE*in*LYON HCL

Lyon 1 CRIOAc ciri

Under the supervision of

ansm Agence nationale de sécurité du médicament et des produits de santé

French Health Authority

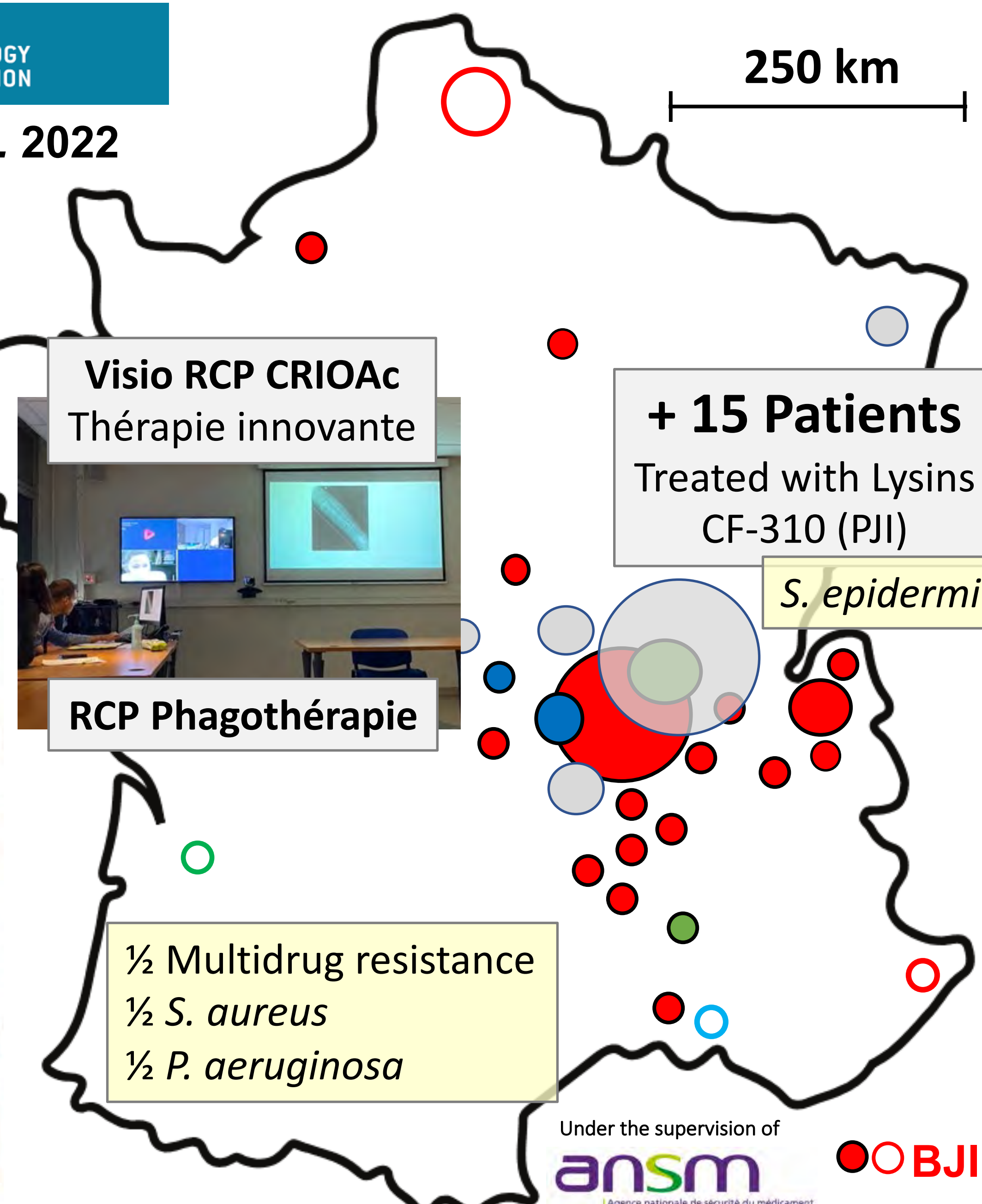
Conclusions: Personalized phage therapy is a potential adjuvant treatment for patients with complex BJI due to pandrug-resistant bacteria. **In addition to industrial phages under development, academic collaborative research is crucial to develop personalized phage therapy.**

Implementation of a **Phage Therapy Center** in a CRIOAc

CMI CLINICAL MICROBIOLOGY AND INFECTION

FERRY T. *et al.* 2022

Updated



Visio RCP CRIOAc
Thérapie innovante

RCP Phagothérapie

+ 15 Patients
Treated with Lysins
CF-310 (PJI)

S. epidermidis

½ Multidrug resistance
½ *S. aureus*
½ *P. aeruginosa*

Under the supervision of ansm

PHAGE in LYON

53 patients in Lyon since 2017
~80% of the whole patients treated in France

- 50 with phages from PHERECYDES PHARMA
- 3 with phages from MHKA HMRA

- 42 **BJI** (including **34 PJI**)
- 8 **endocarditis/vascular graft/ cardiac electronic device infection**
- 3 **lung infections** (VAP + bacteremia, pneumonia in lung graft bronchectasia, cystic fibrosis exacerbation)

+ 11 patients managed outside Lyon ○
including 1 in [Sweden] and 1 in [Switzerland]

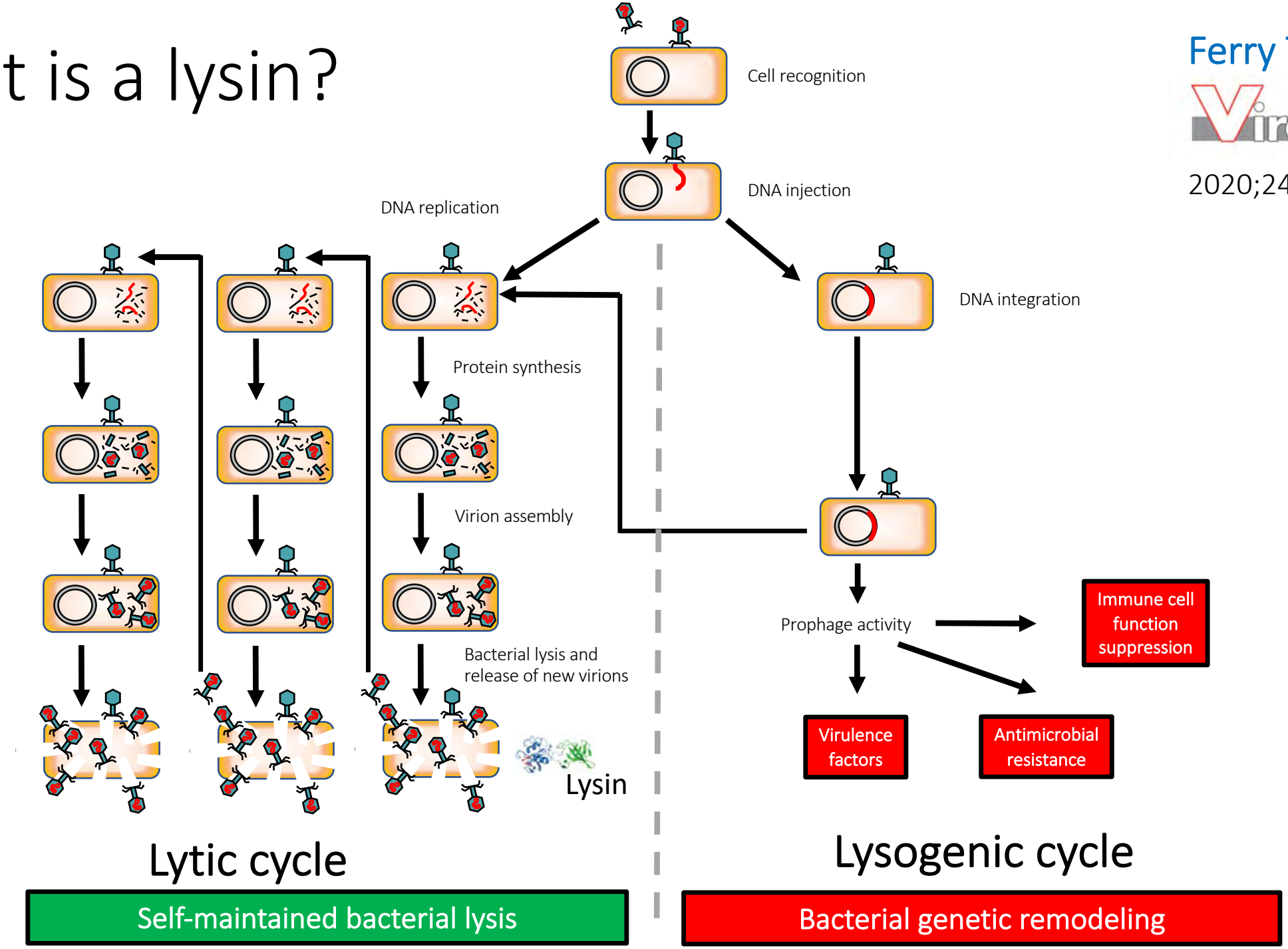
●○ **BJI** ●○ **Endocarditis** ●○ **Pneumonia** ●○ **Burn**

What is a lysin?

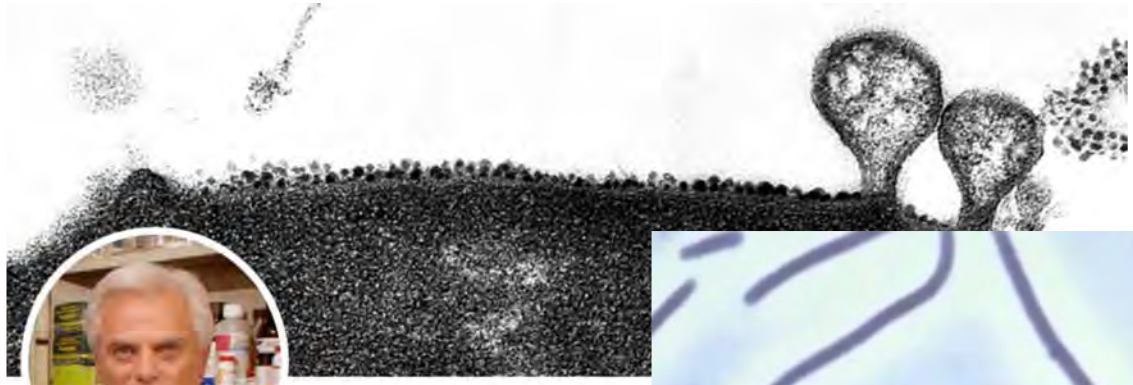
Ferry T. et al.

Virologie

2020;24(1):49-56



What is a lysin?



Vincent A Fischetti
@microbephage

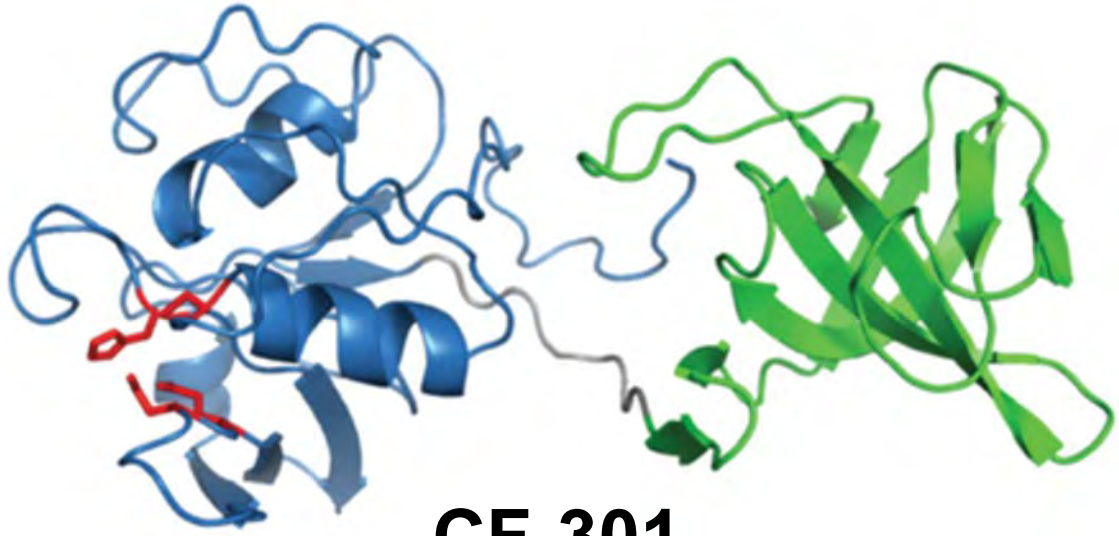
Tristan Ferry Lyon University Hospitals
@FerryLyon

Incredible talk of Pr. Vincent A. Fischetti @microbephage @IDWeek2019 about the great potential of #bacteriophage #lysins to induce bacterial explosion... and disappearance! It's good to hear that he discovered lysins that are active against #multidrugresistant #ESKAPE pathogens!

Combination Therapy With Lysin CF-301 and Antibiotic Is Superior to Antibiotic Alone for Treating Methicillin-Resistant *Staphylococcus aureus*–Induced Murine Bacteremia

Raymond Schuch,[1] Han M. Lee,[1] Brent C. Schneider,[1] Karen L. Sauve,[1] Christina Law,[1] Babar K. Khan,[1] Jimmy A. Rotolo,[1] Yuki Horiuchi,[1] Daniel E. Couto,[1] Assaf Raz,[2] Vincent A. Fischetti,[2] David B. Huang,[1] Robert C. Nowinski,[1] and Michael Wittekind[1]

[1]ContraFect Corporation, Yonkers, NY, and [2]Department of Bacterial Pathogenesis and Immunology, The Rockefeller University, New York, New York



CF-301

CF-301 is a lysin from a *S. aureus* phage
Broader spectrum of activity: against *S. aureus*, but also against coagulase-negative staphylococci

Combination Therapy With Lysin CF-301 and Antibiotic Is Superior to Antibiotic Alone for Treating Methicillin-Resistant *Staphylococcus aureus*–Induced Murine Bacteremia

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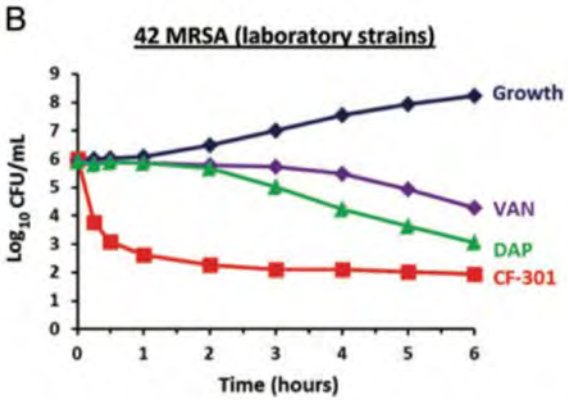
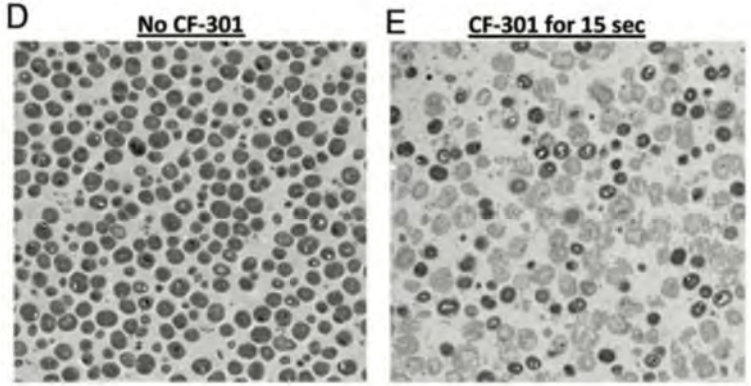
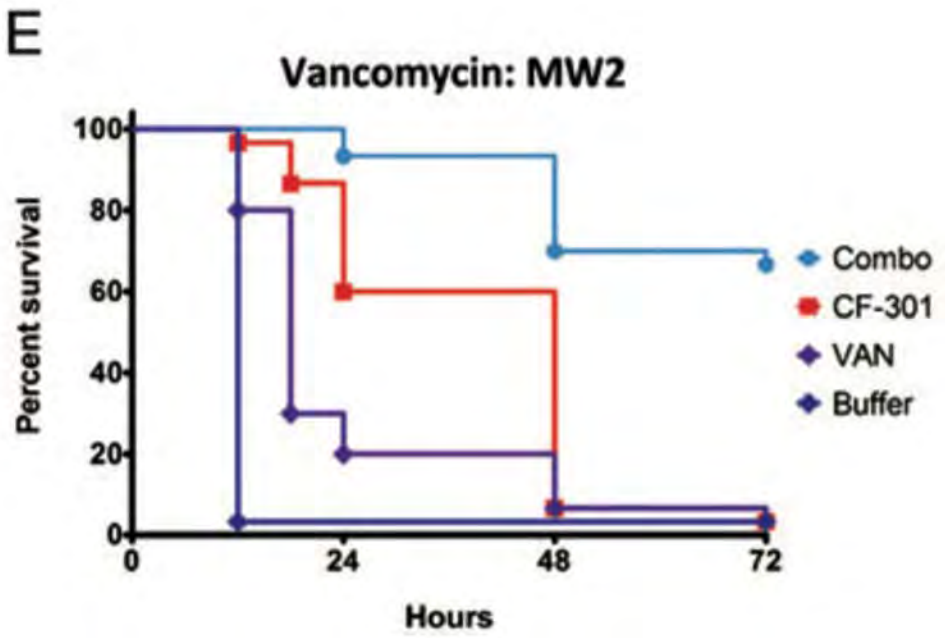




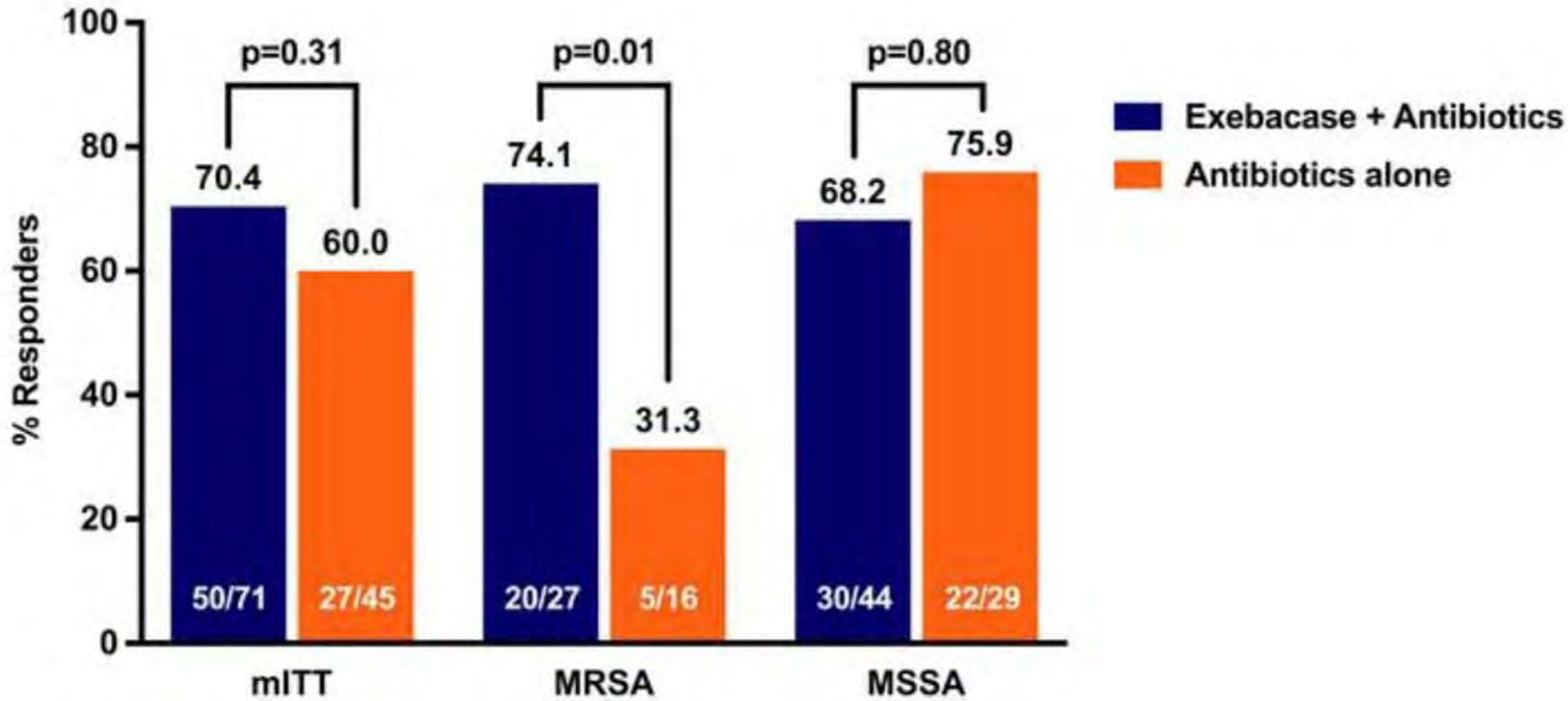


J Infect Dis 2014

The Journal of Clinical Investigation
2020

Exebacase for patients with *Staphylococcus aureus* bloodstream infection and endocarditis

Vance G. Fowler Jr.,[1,2] Anita F. Das,[3] Joy Lipka-Diamond,[4] Raymond Schuch,[5] Roger Pomerantz,[5] Luis Jáuregui-Peredo,[6] Adam Bressler,[7] David Evans,[8] Gregory J. Moran,[9] Mark E. Rupp,[10] Robert Wise,[11] G. Ralph Corey,[1] Marcus Zervos,[12] Pamela S. Douglas,[1,2] and Cara Cassino[5]



Arthroscopic debridement, antibiotic and implant retention (DAIR) with local administration of Exebacase (Lysin CF-301) (LysinDAIR) followed by suppressive tedizolid as salvage therapy in elderly patients for relapsing multidrug-resistant *Staphylococcus epidermidis* prosthetic knee infection

Conclusions: Exebacase has the potential to be used as salvage therapy during arthroscopic DAIR in patients with relapsing MDR *S. epidermidis* PKI, to improve the efficacy of suppressive antibiotics, and to avoid considerable loss of function.

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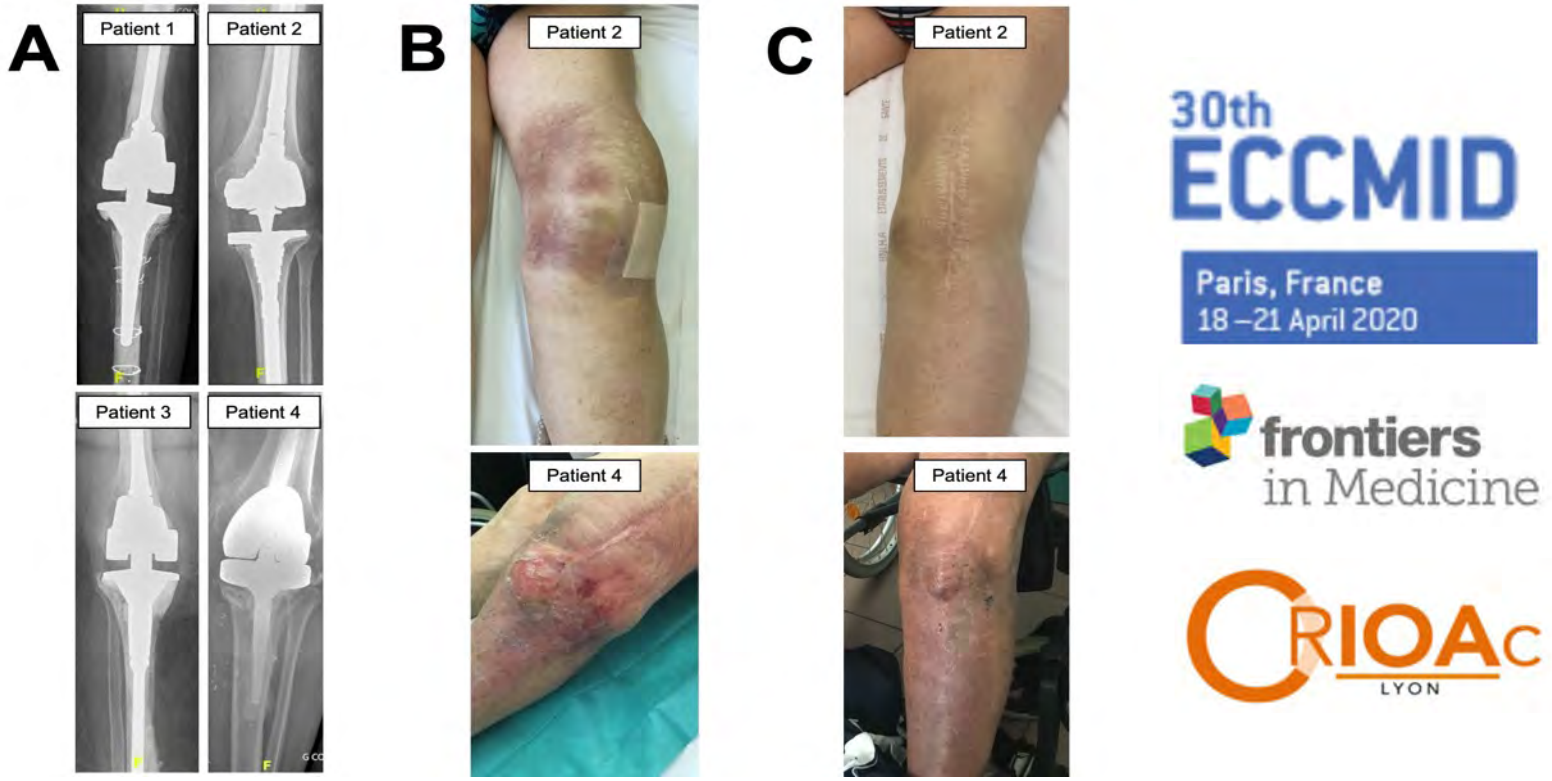

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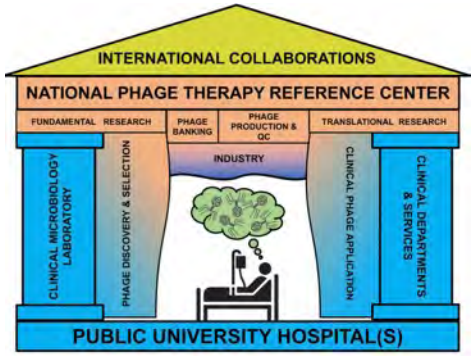


Phage therapy center

+

RIOAc LYON

HCL HOSPICES CIVILS DE LYON

Referral center complex BJI

Phages from the industry
Phages from academic
Lysins from the industry

Dedicated referral activity
Significant number of patients
Relevant clinical situations

Significant level of Scientific evidence

Disruptive approach

Individual patient benefit

The pyramid of bacterial infectious diseases

life- or limb- threatening infections

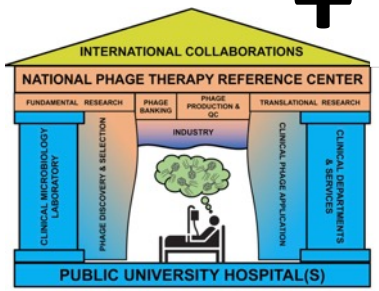
Relapsing severe bacterial infections

Severe bacterial infections

Nonsevere bacterial infections

Frequency

+



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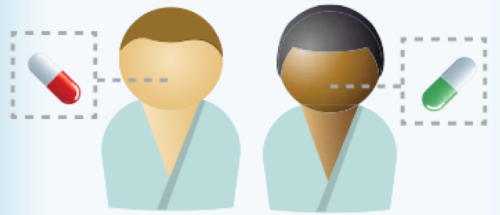
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Clinical trials

U.S. Food and Drug Administration
FDA **Drug Approval Process**



Phase 1 (n ≈ 20-80)
Phase 2 (n ≈ 100)
Phase 3 (n ≈ 1000)

Bone and joint infections: Lyon becomes the national expert center for phage therapy

HCR.REFERENCE-IOA@chu-lyon.fr

The reference center for complex bone and joint infections, based at the Hospices Civils de Lyon, will centralize all requests concerning this last resort treatment, using viruses against resistant bacteria.

Le Progrès - 23 Feb. 2023 at 17:51 | updated 23 Feb. 2023 at 18:08 - Reading time: 2 min

National online multidisciplinar meetings

MINISTÈRE DE LA SANTÉ ET DE LA PRÉVENTION
Liberté Égalité Fraternité

Dedicated to innovative anti-infective therapies

PHAGE*in*LYON
Clinic

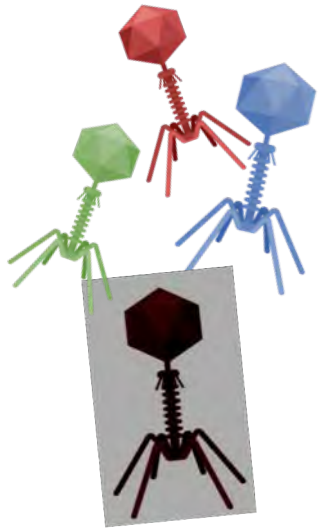


Photo: Tristan Ferry

Infectious diseases department

Clinical developement

Multidisciplinar meetings

Identifying relevant indications

Managing the patient

Compassionate use

Cohort studies

Pharmacokinetic in humans

Clinical trials

Phage requests

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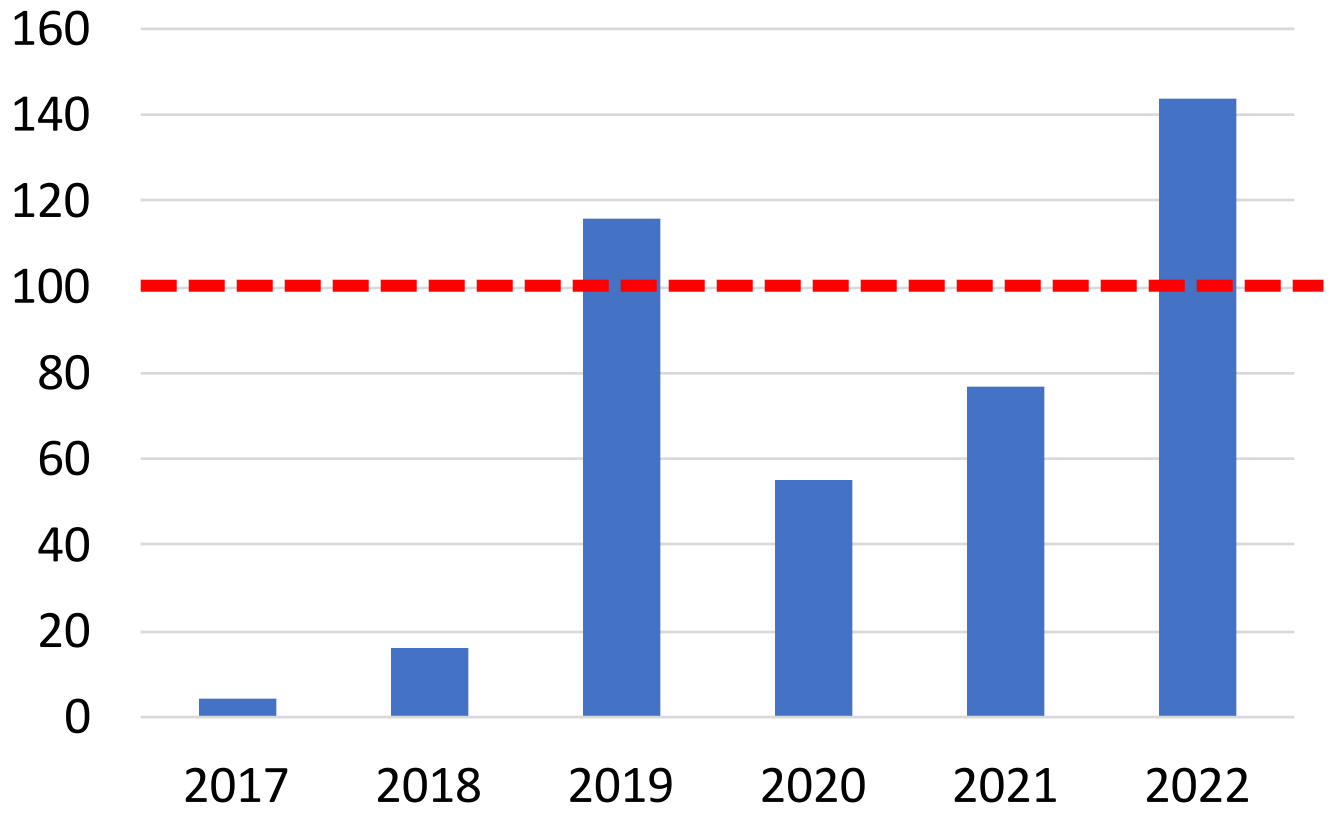

Involved bacteria

32 % *Staphylococcus aureus*

16 % *Pseudomonas aeruginosa*

6 % *Staphylococcus epidermidis*

Type of infction

37% Prosthetic-joint infection

27% Other bone and joint infection

8% Lung infection

Source : T. Ferry

Lyon 1 · RIOAc LYON · ciri Centre International de Recherche en Infectiologie · Fondation HCL Hospices Civils de Lyon · HCL Hospices Civils de Lyon

Treated patients

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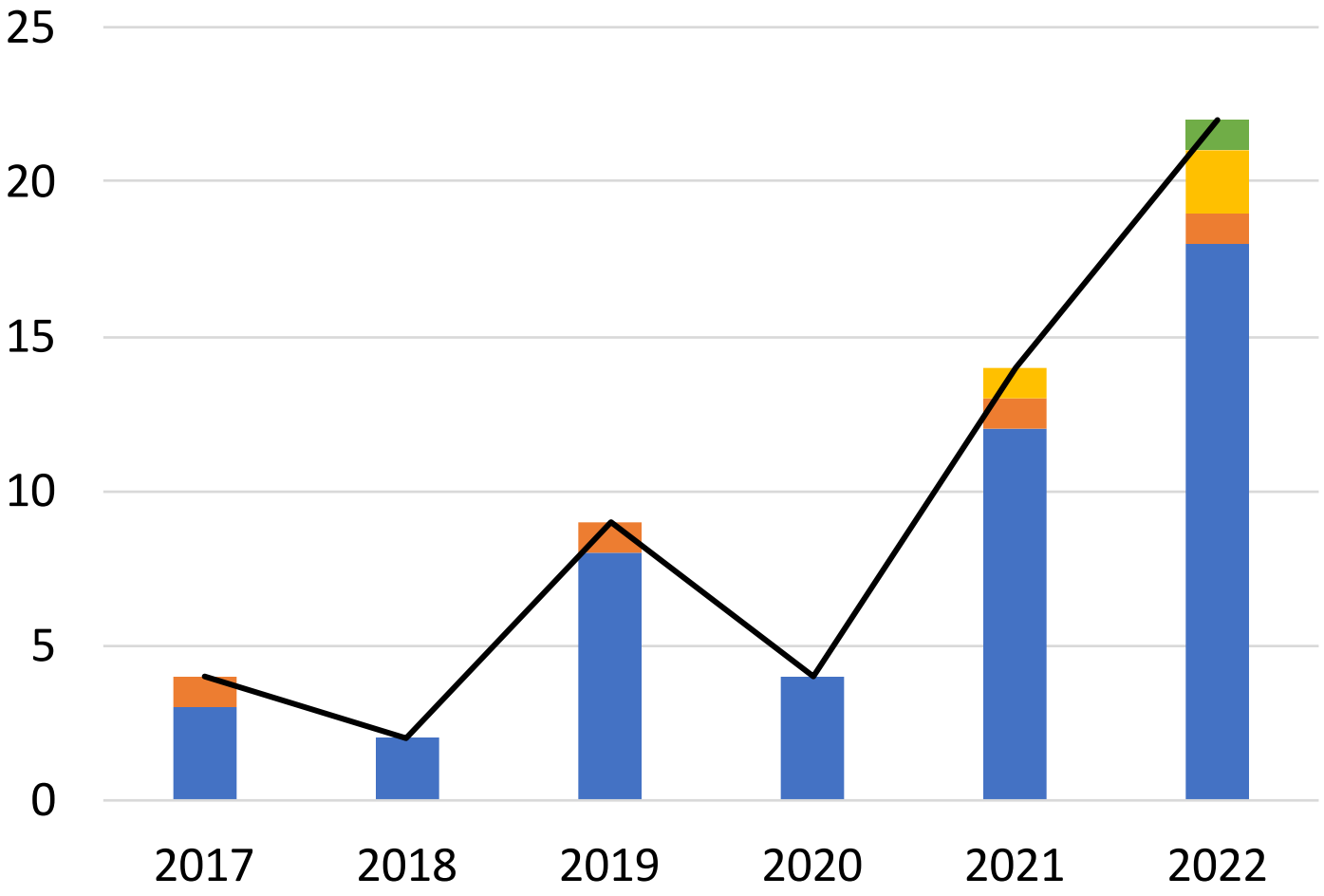

- Bone and joint
- Endocarditis
- Other
- Lung
- Vascular graft infection

Source : T. Ferry

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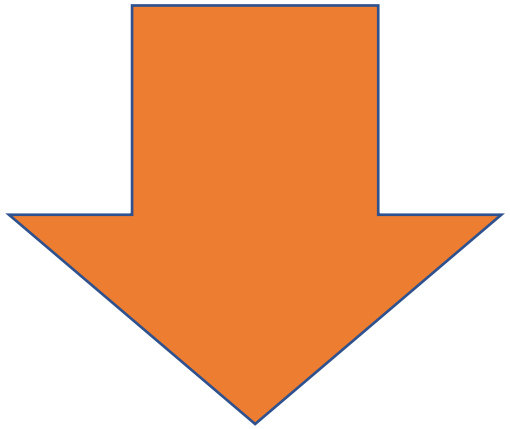
https://www.chu-lyon.fr/phagotherapie-bacteriophage

HCL
HOSPICES CIVILS DE LYON

Les HCL | Offre de soins



Accueil > *Fiches Santé* > *Phagothérapie (Bactériophage)*

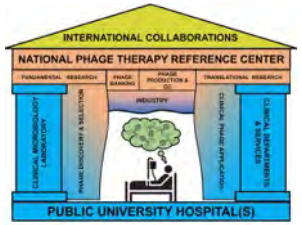
Phagothérapie (Bactériophage)

La phagothérapie consiste à produire des bactériophages spécifiques et à les utiliser pour une infection bactérienne.

- **Vous êtes professionnel de santé** et souhaitez faire une demande d'avis pour un patient, les demandes d'avis s'effectuent via la **messagerie sécurisée de santé MonSisra**.
- **Vous êtes patient** et souhaitez faire une demande d'avis, **compléter le formulaire de demande sur myHCL**.

Conclusion

- La phagothérapie est une **thérapie innovante et réémergente**
- **Indications paraissant pertinentes : infections pulmonaires, encodardites sur prothèse valvulaire, IOAc dont les infections de prothèse articulaire**
- **En ADJUVANT à l'antibiothérapie (et potentiellement la chirurgie)**
- **Modalités d'administration doivent être personnalisées en fonction de l'expérience clinique, des phages à disposition et de la présentation clinique**



- Nécessité d'une **mission nationale « CRIOAc thérapie innovante »**
  - Pour valider les **indications pertinentes** de phages/lysines dans les IOA
  - Pour orienter les prises en charge vers les **essais thérapeutiques**
  - Ou enfin pour **orienter et accompagner** le recours à des phages en « compassionnel » (nécessité d'une mission nationale **« RCP Phagothérapie »** pour préciser les modalités)

GHN.avis-phagotherapie@chu-lyon.fr

- Poser les jalons d'un **centre national de phagothérapie**
- Conception et réalisation d'**essais thérapeutiques**

ESGNTA
ESCMID STUDY GROUP FOR NON-TRADITIONAL ANTIBACTERIAL THERAPY
European Society of Clinical Microbiology and Infectious Diseases

THE MYTHOLOGY
OF PHAGE THERAPY

T. FERRY

T. FERRY

Lyon BJI Study group

Coordinator: Tristan Ferry

Infectious Diseases Specialists – Tristan Ferry, Florent Valour, Thomas Perpoint, Florence Ader, Sandrine Roux, Agathe Becker, Claire Triffault-Fillit, Anne Conrad, Cécile Pouderoux, Pierre Chauvelot, Paul Chabert, Johanna Lippman, Evelyne Braun

Surgeons – Sébastien Lustig, Elvire Servien, Cécile Batailler, Stanislas Gunst, Axel Schmidt, Elliot Sappey-Marinier, Quentin Ode, Michel-Henry Fessy, Anthony Viste, Jean-Luc Besse, Philippe Chaudier, Lucie Louboutin, Adrien Van Haecke, Marcelle Mercier, Vincent Belgaid, Aram Gazarian, Arnaud Walch, Antoine Bertani, Frédéric Rongieras, Sébastien Martres, Franck Trouillet, Cédric Barrey, Ali Mojallal, Sophie Brosset, Camille Hanriat, Hélène Person, Samuel Prive, Philippe Céruse, Carine Fuchsmann, Arnaud Gleizal;

Anesthesiologists – Frédéric Aubrun, Mikhail Dziadzko, Caroline Macabéo, Dana Patrascu;

Microbiologists – Laetitia Beraud, Tiphaine Roussel-Gaillard, Céline Dupieux, Camille Kolenda, Jérôme Josse;

Imaging – Fabien Craighero, Loic Boussel, Jean-Baptiste Pialat, Isabelle Morelec;

PK/PD specialists – Michel Tod, Marie-Claude Gagnieu, Sylvain Goutelle;

Clinical research assistant and database manager– Eugénie Mabrut

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Coordinator: Tristan Ferry

Tristan Ferry, Myrtille Le Bouar, Gilles Leboucher, Thomas Briot, Camille Kolenda, Tiphaine Roussel-Gaillard, Karine Dallosto

ESGNTA

ESCMID STUDY GROUP FOR NON-TRADITIONAL ANTIBACTERIAL THERAPY

European Society of Clinical Microbiology and Infectious Diseases

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Clinical officer: **Tristan Ferry, France**

Shawna Mc Callin, **Switzerland**

Zuzanna Drulis-kawa, **Poland**

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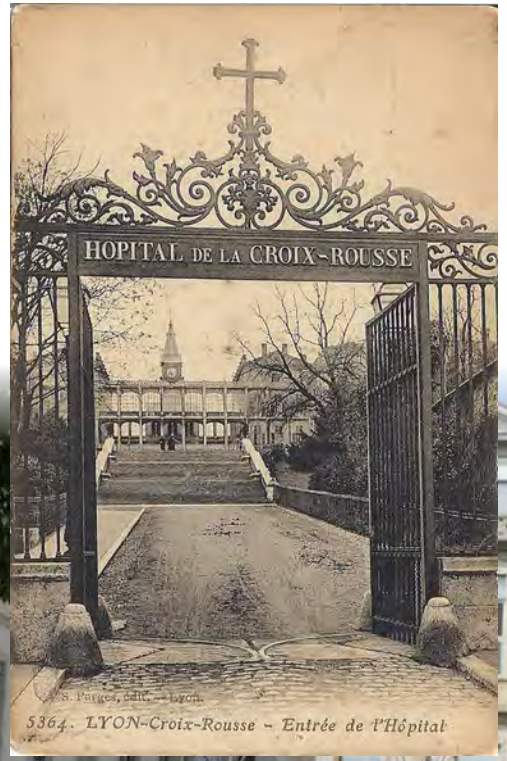
MANAGING INFECTIONS PROMOTING SCIENCE

Croix-Rousse Hospital



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