

From discovery to IND: Roadmap to a successful antibacterial project

Guest speakers: Patricia A. Bradford, Alita Miller
Moderator: Michael Mourez
Host: Laura Piddock (GARDP)

25 February 2021



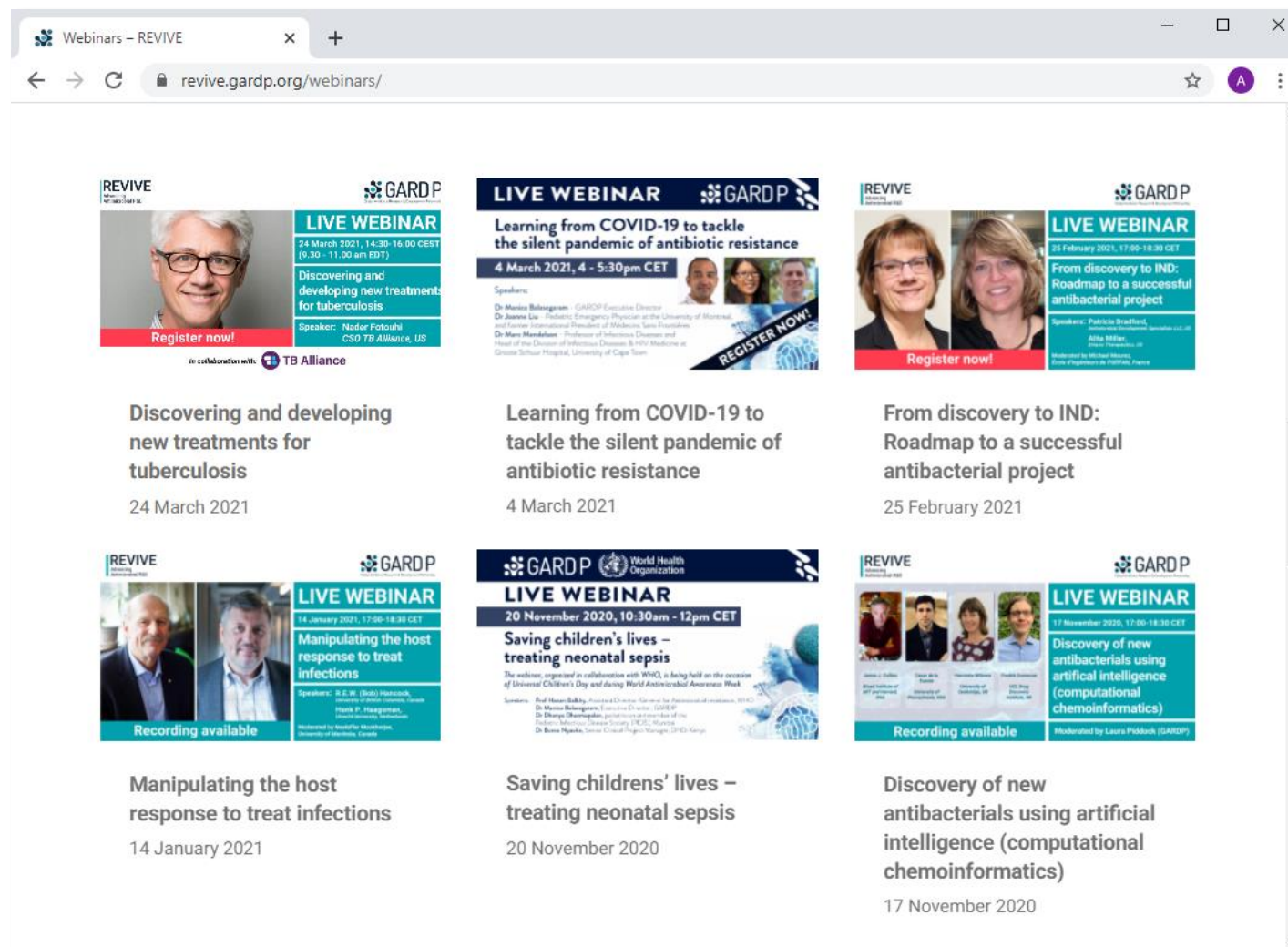
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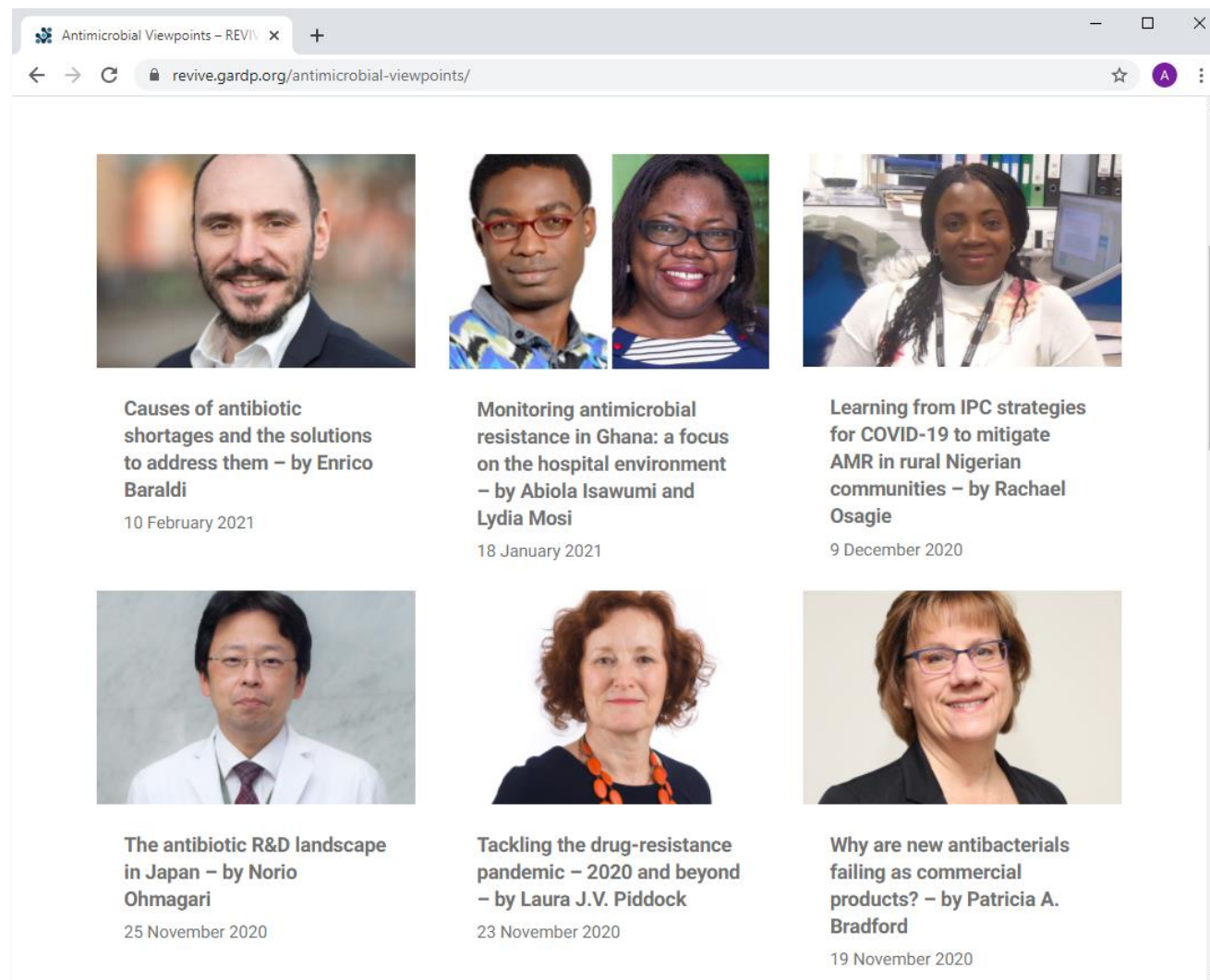


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Webinar Title	Date	Status
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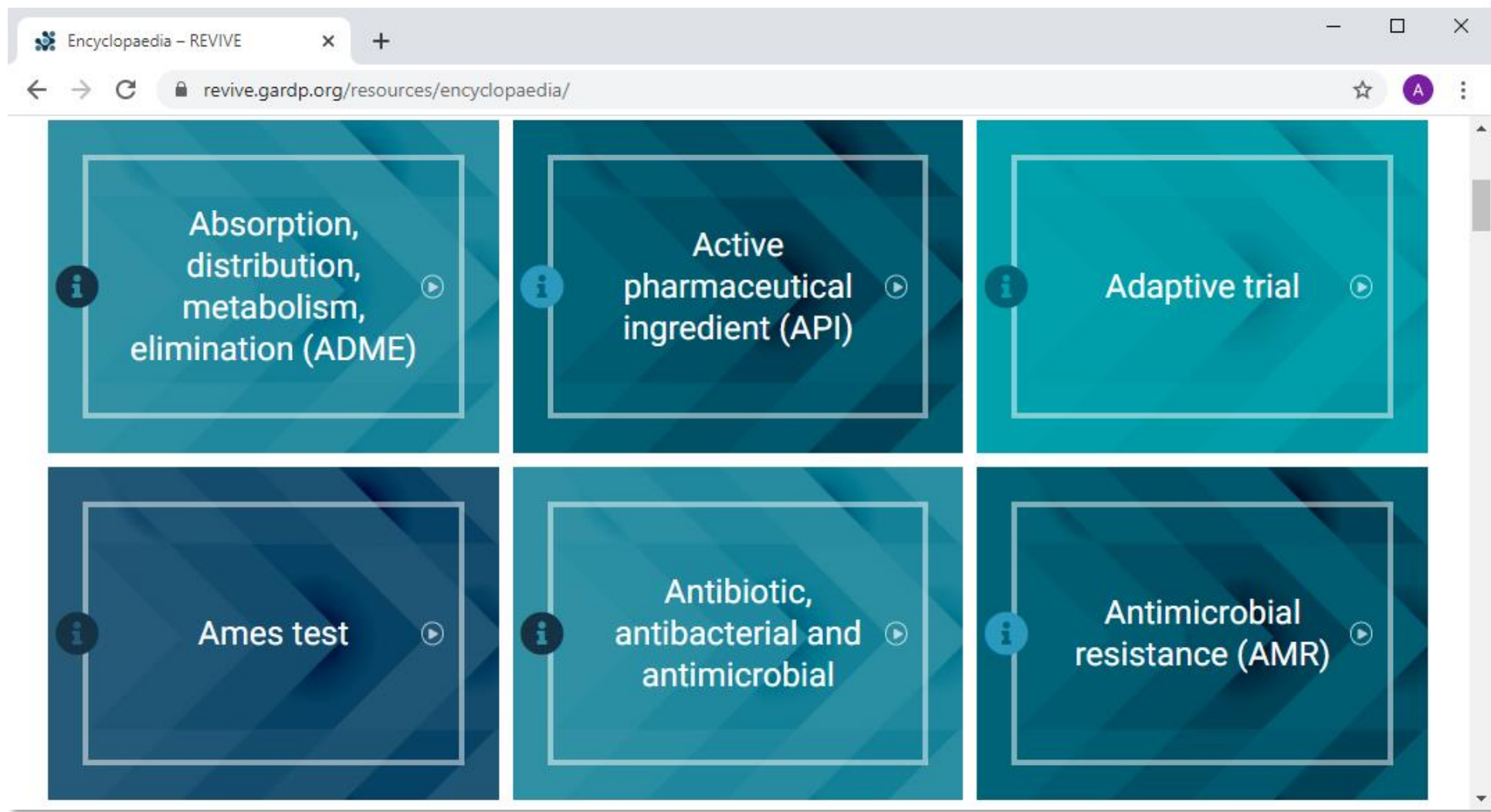
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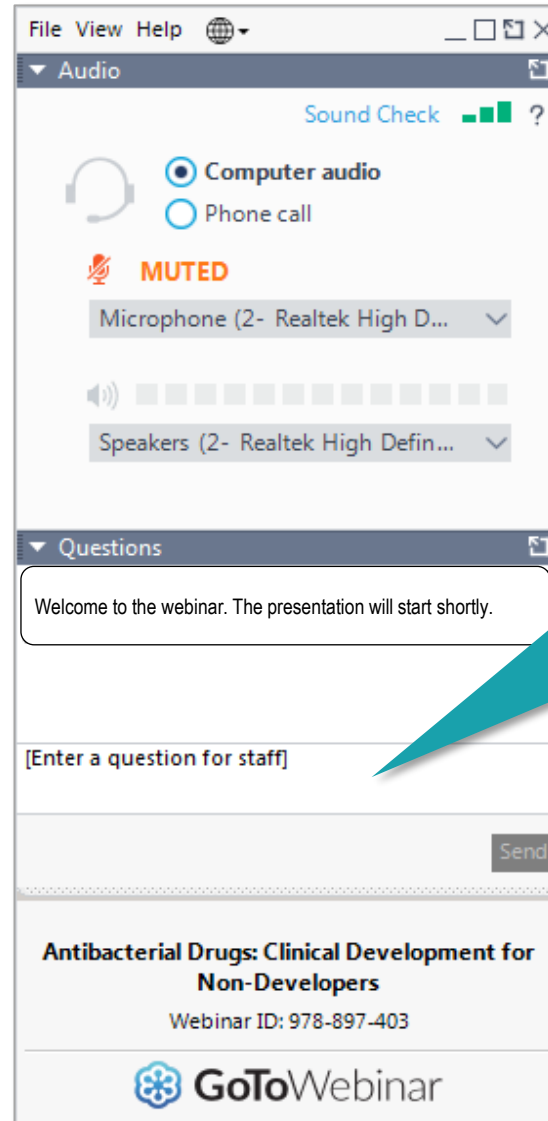
Antimicrobial Encyclopaedia



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At the bottom of the interface, the text 'Antibacterial Drugs: Clinical Development for Non-Developers' and 'Webinar ID: 978-897-403' is displayed. The GoToWebinar logo is at the very bottom.

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Please submit your questions via the 'questions' window. We will review all questions and respond to as many as possible after the presentation.

Today's speakers

From discovery to IND: Roadmap to a successful antibacterial project



Patricia A. Bradford
Independent consultant
Antimicrobial Development Specialists (US)



Alita Miller
Head of Biology
Entasis Therapeutics (US)



Moderator:
Michael Mourez
Head of Innovation
École d'Ingénieurs de PURPAN (France)

Alita Miller



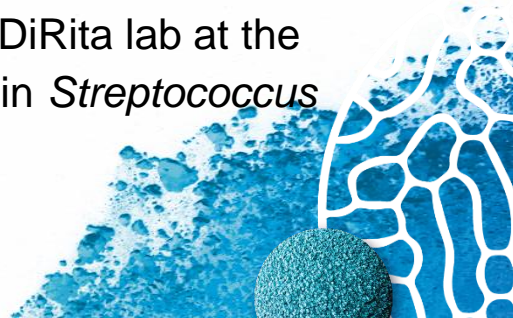
Alita Miller is a Vice President of Biology at Entasis Therapeutics, a small biotech outside of Boston, USA, dedicated to the discovery and development of novel antibacterial agents to treat serious infections by resistant Gram-negative bacteria.

At Entasis, Alita oversees both preclinical biology and developmental microbiology research. As a member of the senior leadership team, she is also involved in the strategic planning and execution of the company's long-term research objectives.

Alita has over 18 years' experience in antibacterial research, first at Pfizer where she led both large and small molecule discovery projects and then at AstraZeneca, where she was Head of Microbial Genetics and Genomics.

Alita's current research interests include novel approaches to antibacterial discovery, including new ways of characterizing small molecule permeation and accumulation in bacterial pathogens.

Alita obtained a BA in chemistry from Kalamazoo College and a PhD in biochemistry/molecular biology from the University of Chicago. Her postdoctoral training was in the DiRita lab at the University of Michigan characterizing the molecular drivers of pathogenesis in *Streptococcus pyogenes*.



Patricia A. Bradford



Patricia A. Bradford is the owner of Antimicrobial Development Specialists LLC, a consulting company that focuses on the late-stage development of antibiotics.

Prior to this, she was responsible for microbiology support at AstraZeneca, where she contributed to the successful development and approval of ceftazidime-avibactam. Before joining AstraZeneca, Patricia worked in antibiotic research for Novartis, Wyeth Pharmaceuticals and Lederle Laboratories. During her time at Wyeth Pharmaceuticals, she worked on a number of antibiotic projects and was instrumental in the team that wrote the dossier for the registration and approval of tigecycline. She was also heavily involved in the studies for several supplemental new drug applications (sNDA) for piperacillin-tazobactam.

Patricia is a fellow in the American Academy of Microbiology and has over 100 publications in peer-reviewed scientific journals. She is also an active member of the subcommittee on Antimicrobial Susceptibility Testing of the Clinical Laboratory Standards Institute (CLSI). Patricia received her bachelor's degree in Medical Technology from the University of Nebraska Medical Center (USA) and then went on to complete her PhD in Medical Microbiology from Creighton University (USA) and completed a post-doctoral fellowship in the laboratory of Karen Bush in beta-lactamase research.





From Discovery to IND: Roadmap to a Successful Antibacterial Project

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GARDP REVIVE webinar February 25, 2021



Bradford Financial Disclosures

- Allecra
- Boston Pharma
- ContraFect
- Entasis
- Genetech
- RecreoPharma
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- Sinovent
- SuperTrans Medical
- X-Biotix
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Miller Financial Disclosures

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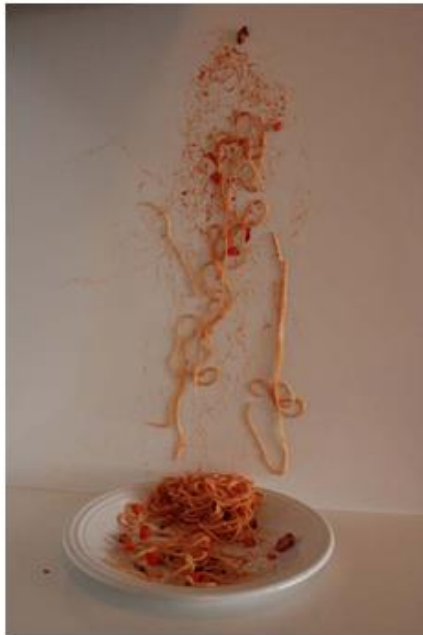
So You Have Some Promising Hits from a Screen to Discover a New Antibacterial...

Now What?

- **Introduction – Patricia Bradford**
 - Line of sight is key for success
- **Screen to Pre-clinical Candidate – Alita Miller**
 - Hit to Lead
 - Lead Optimization
- **Pre-clinical Candidate to IND – Patricia Bradford**
 - Non-clinical package requirements for FIH
 - Safety studies



Line of Sight: Where Are You Going With Your Project?



Throwing spaghetti at the wall: Lots of experiments to see what works

Or



Yellow brick road to the Emerald City: Focused experiments to generate decision making data

Line of Sight

- You have to know where you are going before you can make a plan to get there
 - What organisms are in scope for this compound?
 - What diseases do these organisms cause?
 - Is there an unmet medical need associated with those infections?
- Define Go/No go criteria at each stage of the project
 - What MIC do we need to achieve with med chem?
 - What MTD (maximum tolerated dose) would give a reasonable therapeutic window?
- Plans can change as data is generated, but the end goal remains constant



How Long Is the Road from Here to There?

- It's long.....
- A substantial amount of preclinical data must be generated before you can proceed into clinical trials.
 - Is the drug likely to be efficacious?
 - Is the drug safe?
 - Can you make the drug?



Agenda

- Introduction
- **Screen to Pre-clinical Candidate – Alita Miller**
 - Discovery strategies
 - Hit to lead generation
 - Hit validation
 - MOA studies
 - Resistance studies
 - Spectrum of activity
 - Lead optimization
 - *In vitro* toxicity assessments
 - PK/PD characterization
- Pre-clinical Candidate to IND

Related Resources:

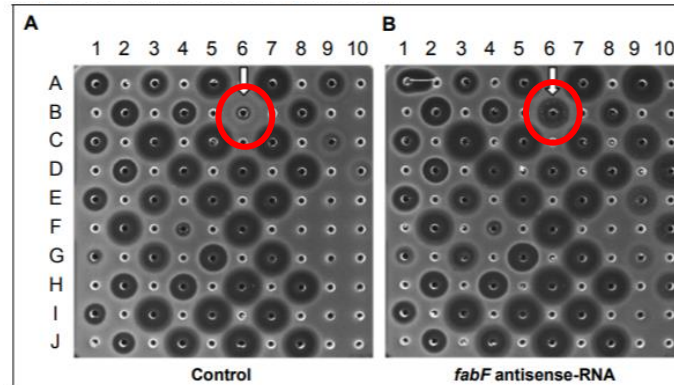
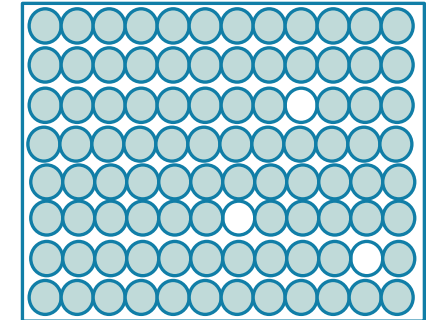
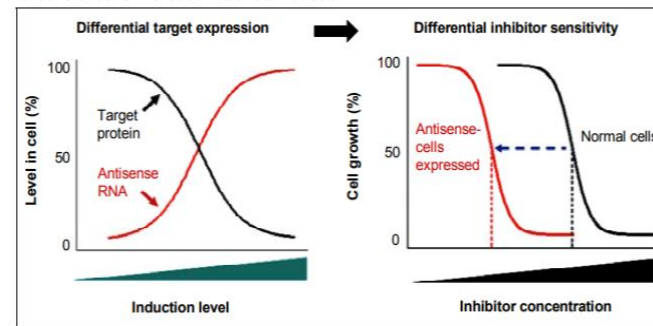
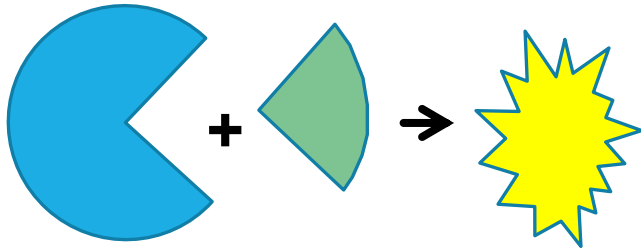
- iCARE (Interdisciplinary Course on Antibiotics and Resistance), Annecy, France Oct 16-21, 2021
<https://www.icarecourse.org/>
- <https://carb-x.org/resource/bootcamp-1-boston-hits-leads-and-tpps-escmid-asm-2017/>
- <https://revive.gardp.org/top-10-mistakes-in-antibacterial-development/>
- <https://www.fda.gov/drugs/news-events-human-drugs/meetings-conferences-workshops-drugs>

Discovery Screening Strategies

In vitro
target-based

Engineered Whole Cell
(target-directed)

Empiric Whole Cell
(target-agnostic)



"Discovery of platencin, a dual FabF and FabH inhibitor with *in vivo* antibiotic properties" Wang *et al.* 2007 PNAS 104:7612

What to Know About Your “Hits”

- Your screening library will dictate the number and quality of hits
- In almost any library, many samples are NOT:
 - the advertised structure or concentration
 - pure or even present

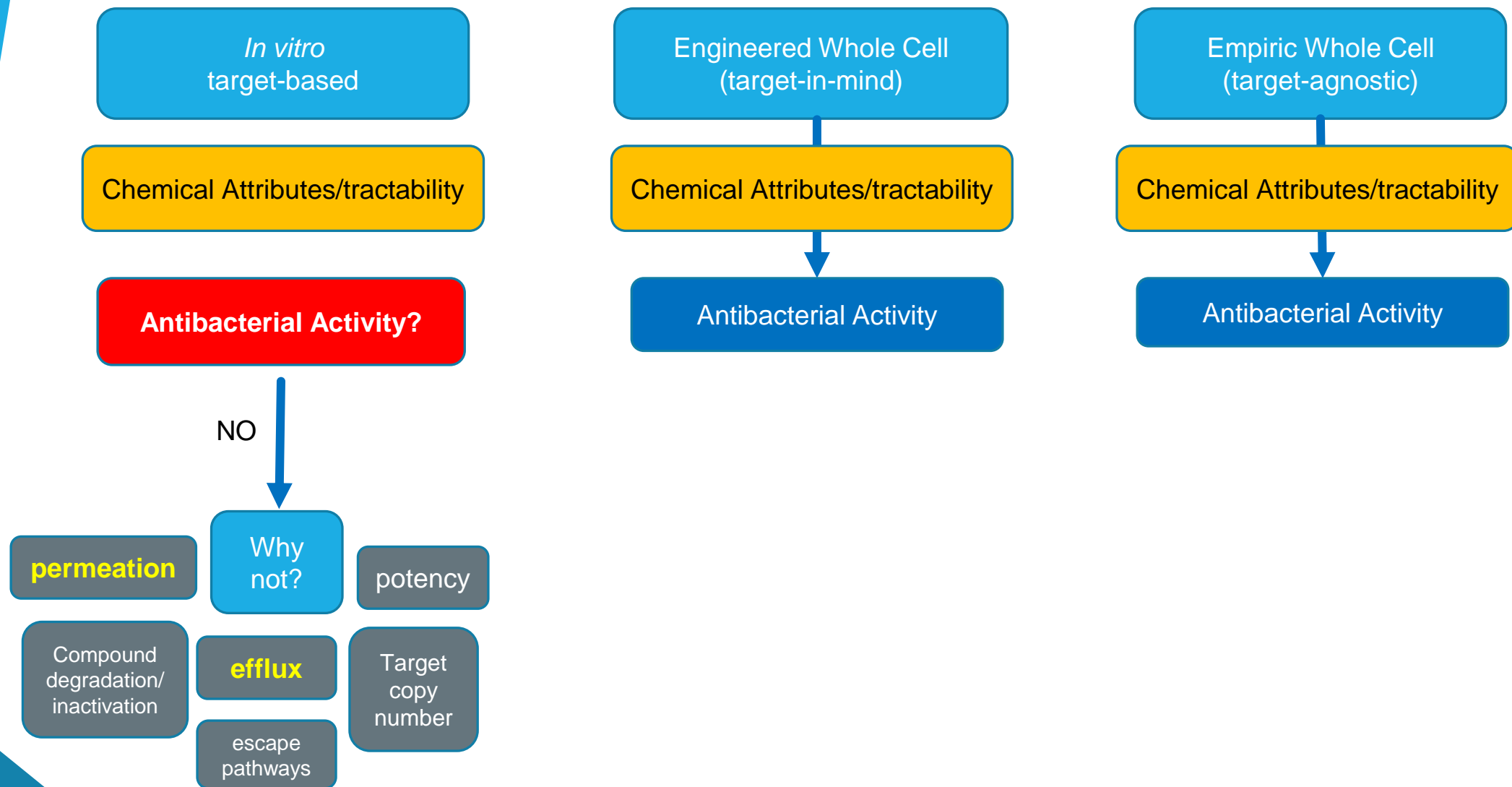
THEREFORE, it is prudent to:

- Beware of the PAINS
 - Pan-Assay Interference CompoundS
 - Promiscuous, non-specific hits
- Resynthesize as many hits as possible
- Retest with titration
- **Employ/collaborate with a medicinal chemist**



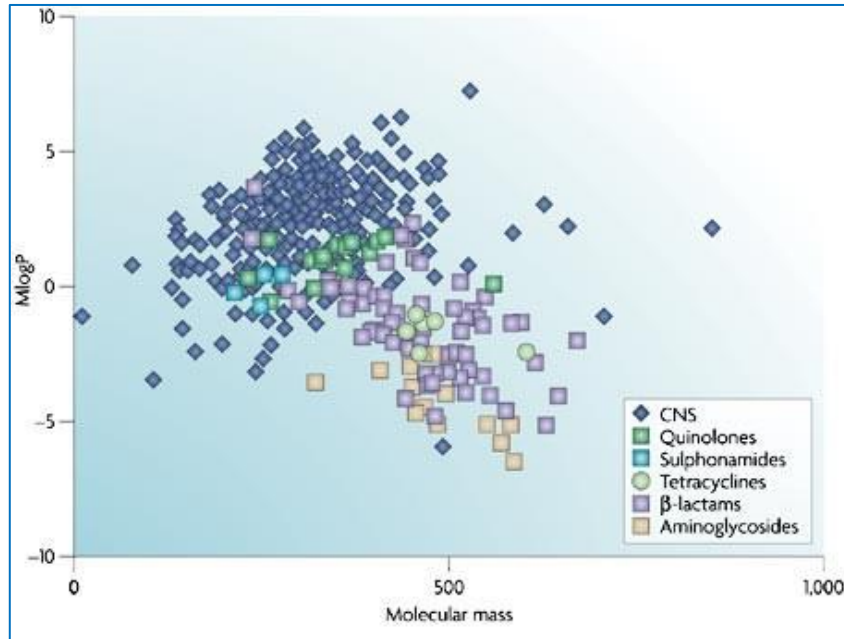
Baell and Walters (2014) *Nature* 513:481-483

Discovery Screening Strategies

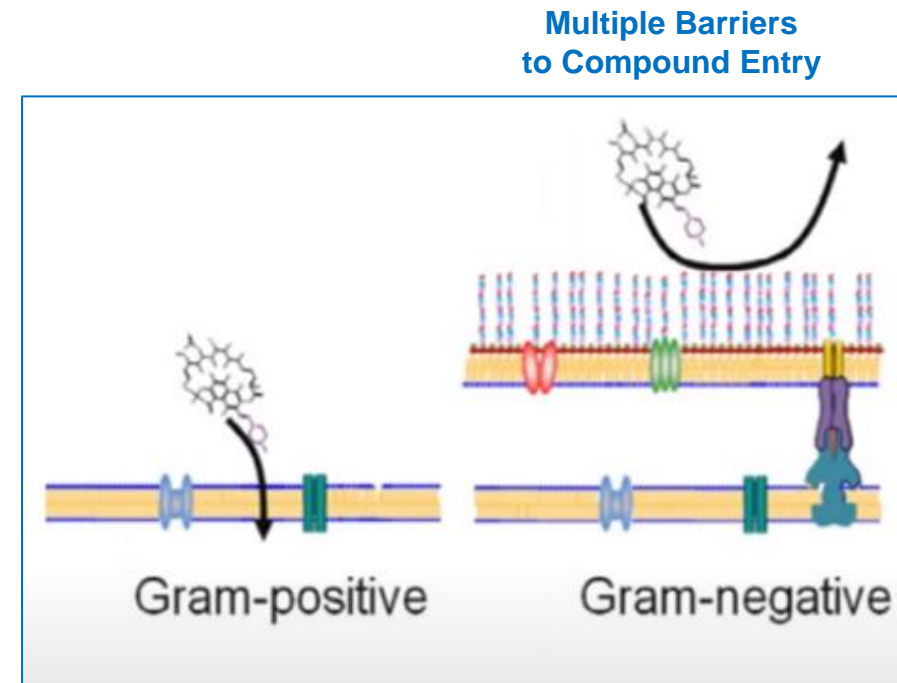


Challenges of “Engineering” in Whole Cell Activity

- Properties of antibacterials are different than other drug classes
- Gram-positive activity much easier to achieve than Gram-negative activity



- Payne *et al.* *Nature Rev. Drug Disc.* 2007
- Silver, LL *Bio Org Med Chem.* 2016
- Tommasi *et al.* *Nature Rev. Drug Disc.* 2015



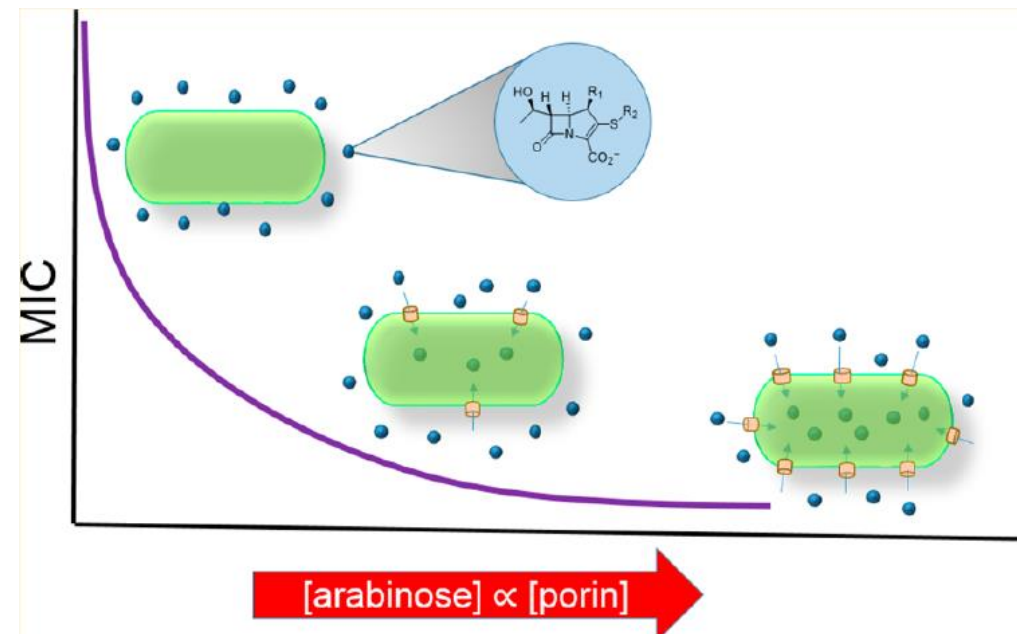
- Double membrane
- Multiple efflux pumps
- Selective porins

Emerging Science to 'Engineer In' Gram-Negative Activity

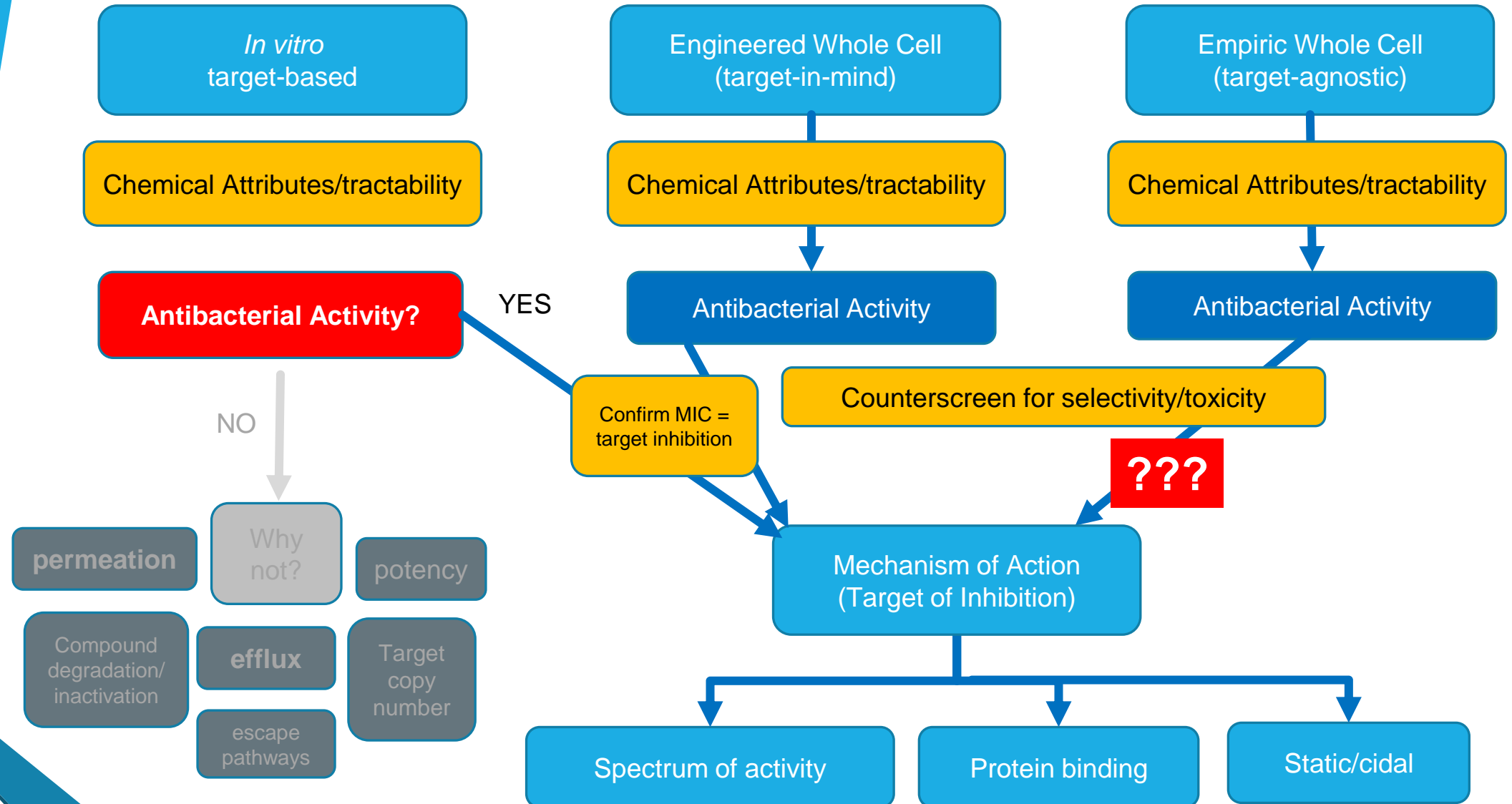
Some Examples:

- Iyer *et al.* (2017) ACS ID "Whole-Cell-Based Assay To Evaluate Structure Permeation"
- Relationships for Carbapenem Passage through the *P. aeruginosa* Porin OprD"
- Richter *et al.* (2017) *Nature* "Predictive Compound Accumulation Rules Yield a Broad-Spectrum Antibiotic" *Nature*
- Six *et al.* (2018) *Curr Opin Chem Biol.* "Advances and challenges in bacterial compound accumulation assays for drug discovery"
- Mehla *et al.* (2021) *mBio* "Predictive Rules of Efflux Inhibition and Avoidance in *P. aeruginosa*"

Structure-Porin Permeation Assay

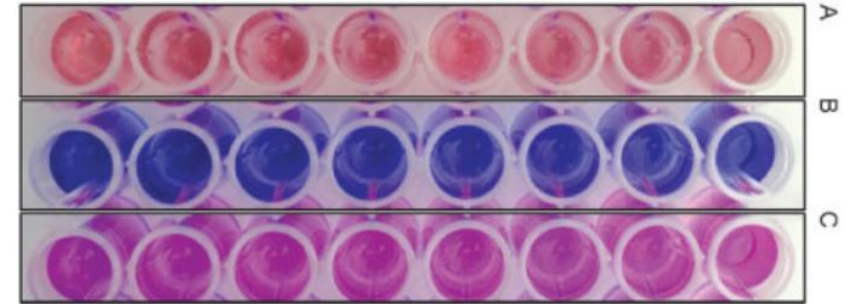


Discovery Screening Strategies



Hit Validation: Initial Toxicity Counterscreens

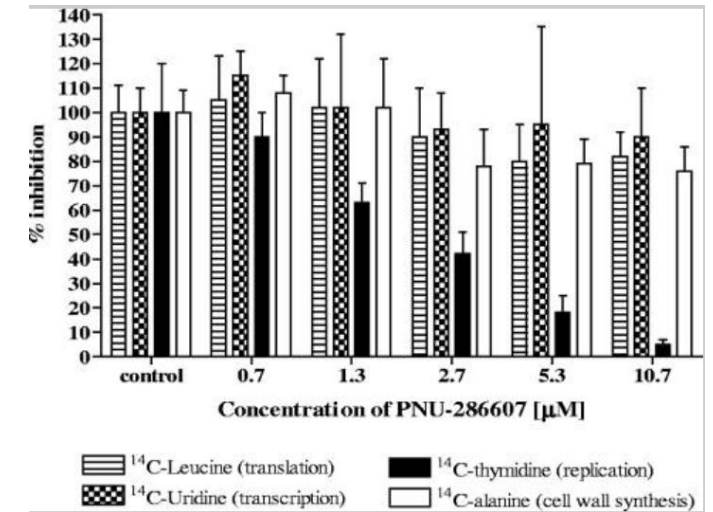
- Lytic activity
 - RBC (red blood cell) lysis
- Cytotoxicity in human cell lines
 - CC_{50} or MCC (minimum cytotoxic concentration)
 - LDH, MTT, SYTOX, Trypan Blue assays
 - Include positive and negative controls
 - Incubation time 48-72 h
- Many CROs perform these
- First 'Therapeutic Index' (TI) Assessment = ratio of cytotoxicity CC_{50} /MIC tested in comparable amount of serum
 - Plasma binding can influence toxicity readout



Hit Validation: Mechanism of Action studies

- Assays for evidence of pathway interference

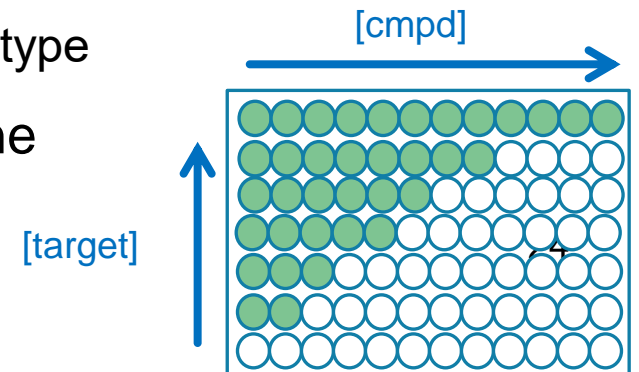
- Macromolecular Synthesis (MMS)
- Genomic approaches – RNAseq, TNseq



Miller *et al.* (2008) AAC

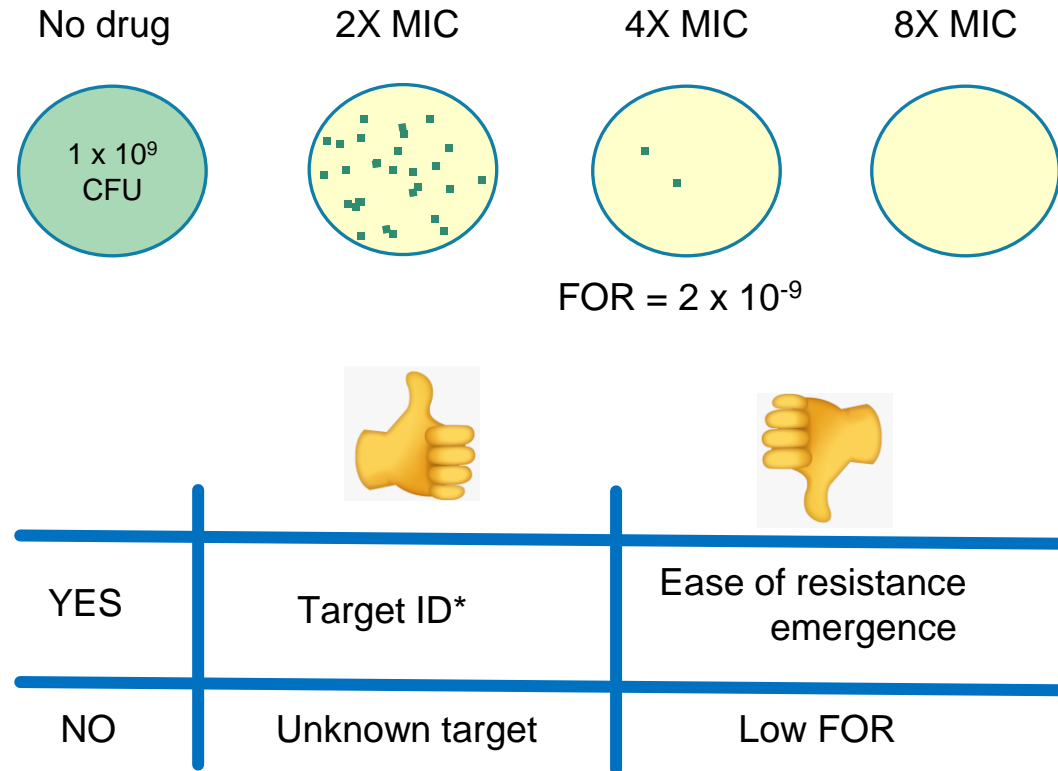
- Evidence that target inhibition is the cause of bacterial killing

- Resistance mapping
 - Compare genomes of wildtype parent vs. spontaneously resistant mutants
 - Backcross mutant in “clean” background to confirm phenotype
- Change in MIC upon under/overexpression of target gene



Resistance Studies

- Can you generate spontaneously resistant mutants to your compound?



- 24 & 48 hr incubation
- confirm stable resistance phenotype after drug-free passage

*can also map to resistance mechanism, not target

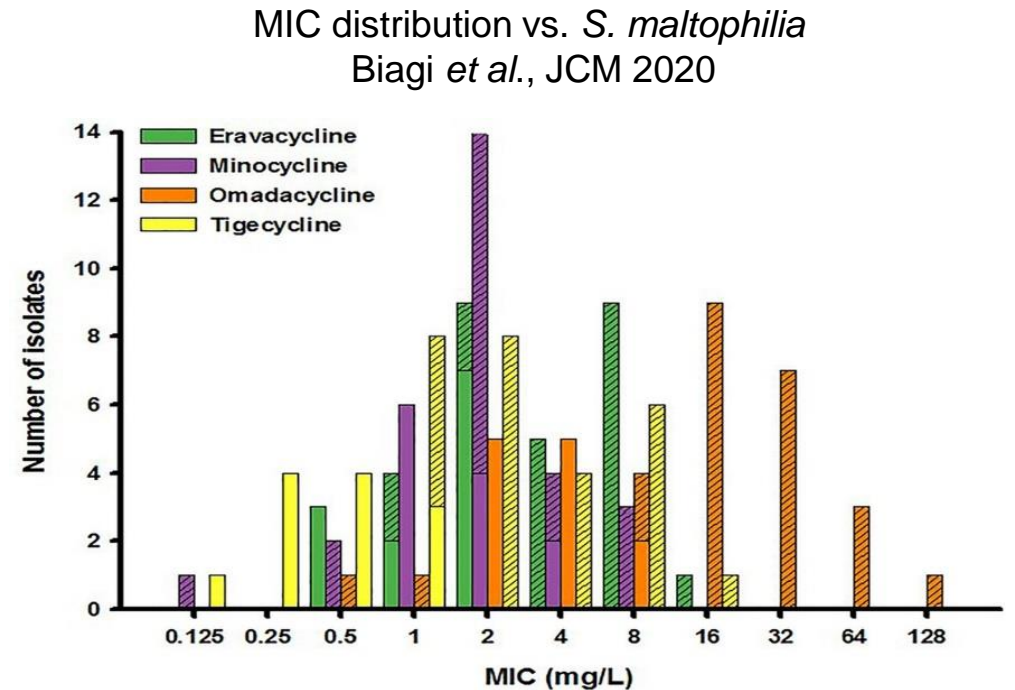
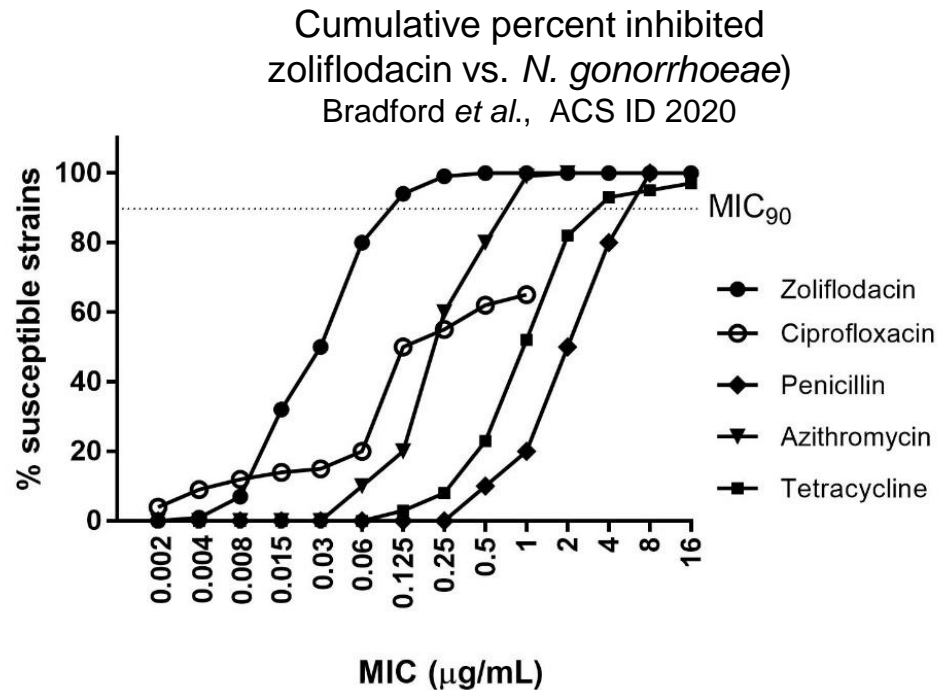
- 1 x 10⁻⁸ or lower FOR (frequency of resistance) is generally acceptable
- Must determine FOR in multiple clinical isolates (not just wimpy lab strains)
- In vitro* FOR does not necessarily predict/correlate to FOR *in vivo*

Spectrum of Activity

- How many and what kind of bacterial species are sensitive to your hit compounds
- Does this correlate with your target product profile (TPP)?
- Definition of a “good” MIC also depends on PK properties, as explained later
- Susceptibility studies must be performed against multiple clinical isolates of the target pathogen(s)
 - A low MIC against a lab strain does not guarantee similar activity against clinical isolates
 - 10-20 isolates should be tested in Hit-to-Lead
 - 50 - ≥ 100 isolates, including multi-drug resistant, in Lead Optimization
 - Look for cross-resistance to approved antibiotics

Spectrum of Activity

- $MIC_{50/90}$ = concentration at which growth of 50% and 90% of strains are inhibited
- MIC distribution = how many isolates are susceptible at each MIC
- Several CROs routinely perform these studies



Hit to Lead “Reality Check”

- Do Hits Meet Advancement Criteria?
 - Reasonable target potency and whole cell activity
 - Chemically attractive and tractable
 - Preferably multiple series/scaffolds
 - Tractability in lead optimization is the ultimate hit validation
 - Clear SAR* shows promise that it can be optimized
 - Low serum binding
 - Low cytotoxicity
 - Low frequency of resistance emergence
 - Evidence that desired spectrum is achievable

Make Data-Driven Decisions!



YES!
Lead Optimization

* SAR – Structure-activity relationship

Lead Optimization

Key features that need to be characterized/optimized to be able to justify advancement to IND*-enabling toxicity studies

- Drug-like compound attributes
- Potency
 - Spectrum of activity, esp. against drug-resistant clinical isolates
 - *In vivo* efficacy in preclinical models (Pharmacology)
- DMPK (Drug metabolism and pharmacokinetics)
 - Drug metabolism *in vitro* and *in vivo*
 - ADME = Absorption, Distribution, Metabolism and Excretion
 - Pharmacokinetic/Pharmacodynamic (PK/PD) properties
- Safety
 - Expanded *in vitro* testing

* IND – Investigational new drug

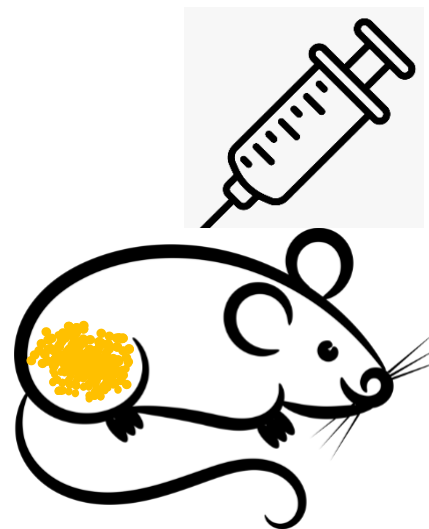
In vitro ADME and Toxicity Studies

- Solubility in various matrices
- Plasma binding (mouse, rat, dog, human)
- Compound metabolic stability in microsomes, plasma, hepatocytes
- *In vitro* safety/selectivity pharmacology panels
 - Screens for activity vs. human homologs (e.g. proteases), transporters, channels, GPCRs and other host proteins as a preliminary check for significant off-target interactions
- Caco-2 permeability
 - Predicts human intestinal permeability, efflux and uptake
- CYP (Cytochrome P450) induction/inhibition
 - Plays an important role in detoxification of foreign chemicals and the metabolism of drugs
 - Can potentially affect efficacy via effects on half-life or toxicity if elevated levels of toxic metabolites
- hERG inhibition
 - hERG = subunit of a potassium ion channel involved in cardiac function



Preclinical models of infection

- Used for evaluating preclinical *in vivo* efficacy and PK/PD
- Prioritize models that are most appropriate for your indication
- Often requires a high inoculum, immunocompromised animals and/or adjuvants
- Most common are acute, neutropenic rodent models of infection
 - Thigh
 - Lung/pneumonia
 - Skin and soft tissue
 - Bacteremia
- Less common infection models
 - Urinary Tract
 - Meningitis
 - Endocarditis

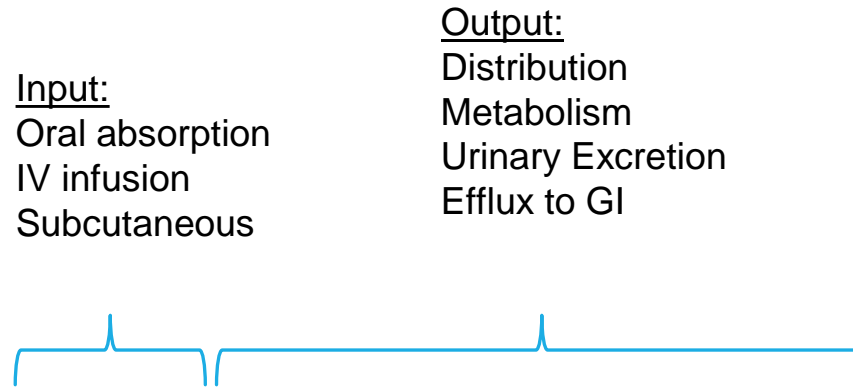


Zhao *et al.* (2016) *Bio Org Med Chem*
“Animal models in the PK/PD evaluation
of antimicrobial agents”

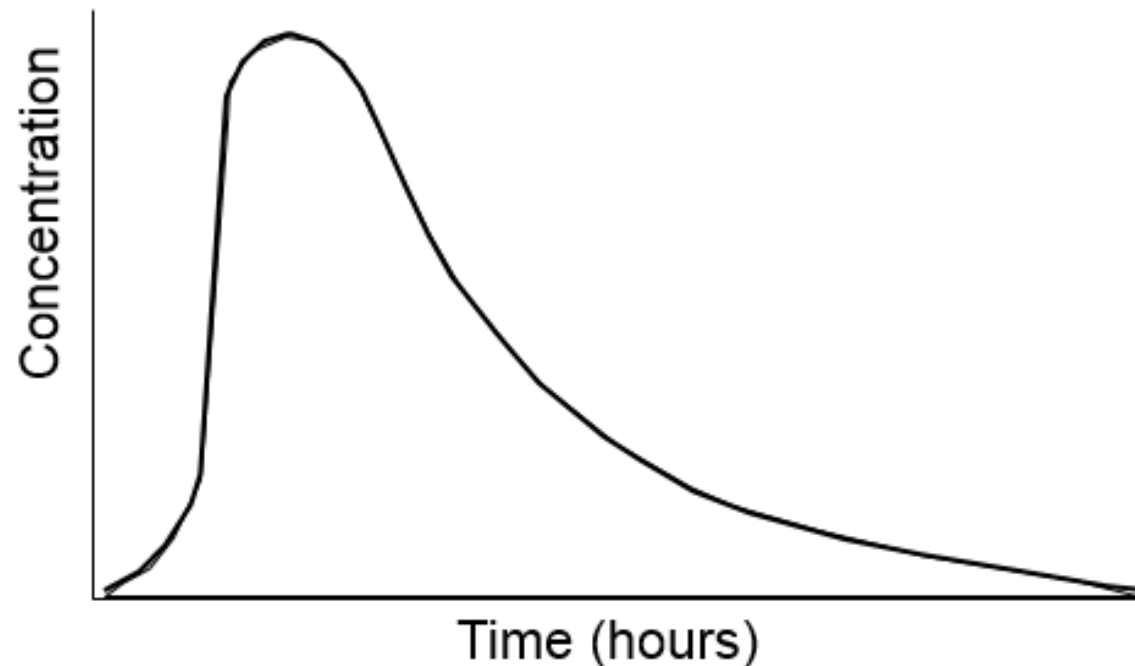
What is PK/PD?

- Pharmacokinetics: the study of the **movement** of drug in the body, including the processes of absorption, distribution, localization in tissues, biotransformation, and excretion
- Pharmacodynamics: the branch of pharmacology concerned with the **effects** of drugs and their mechanism of their action
- Fundamentally then PK/PD is the integrated study of the **movement** of drug in the body and their **effect** it exerts pharmacologically

The anatomy of a 'PK' profile (Time vs. Concentration)

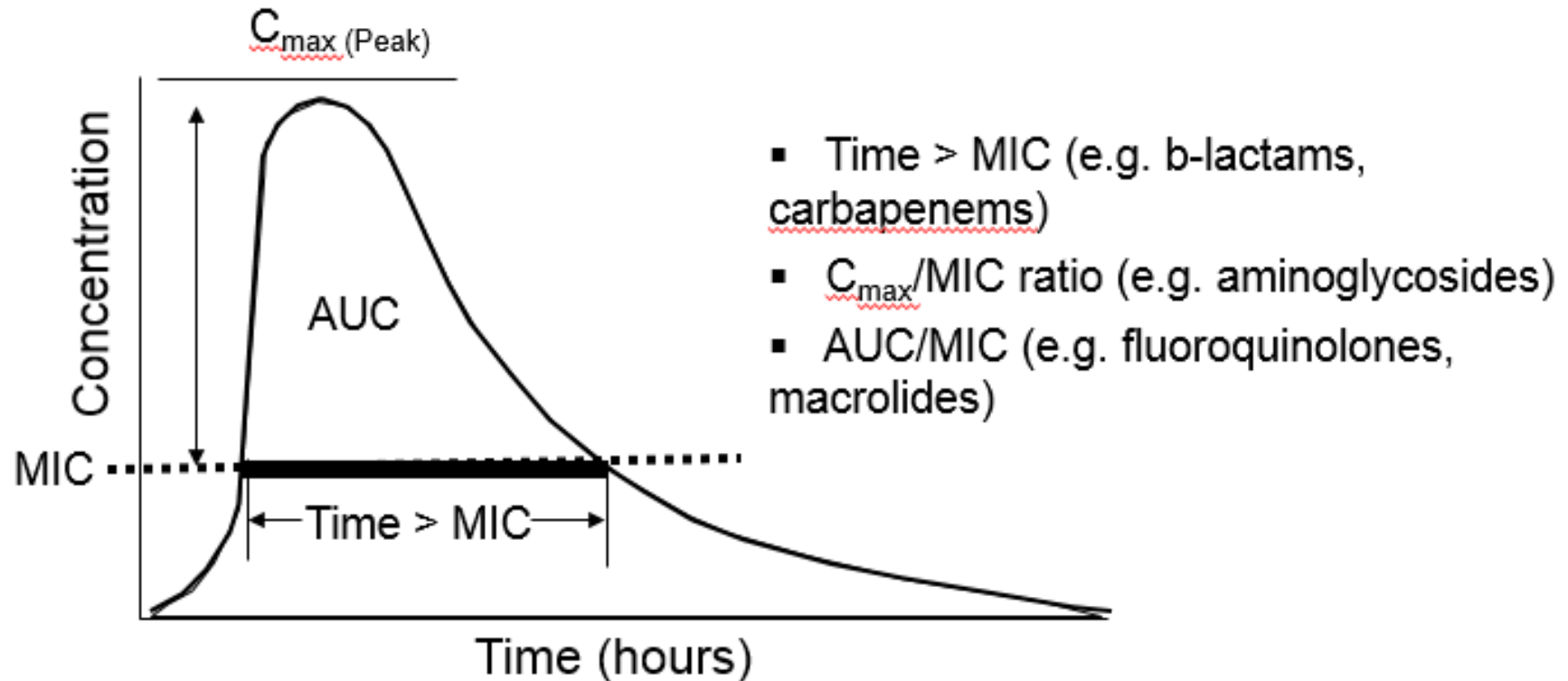


Blood
Plasma
Urine



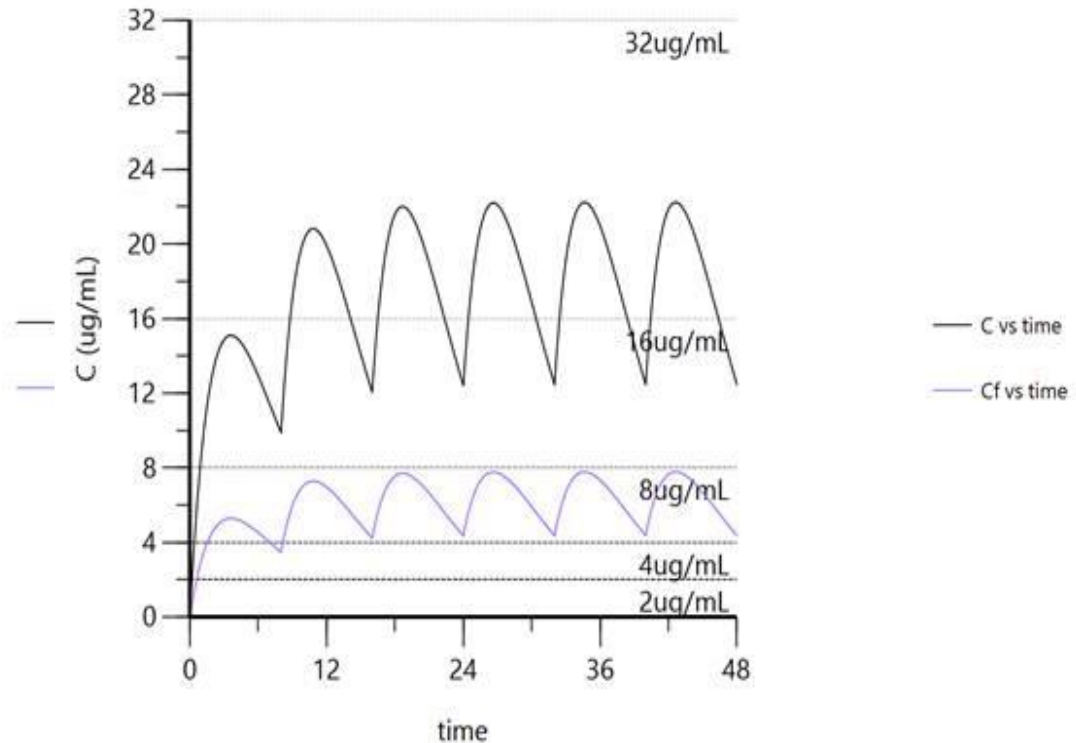
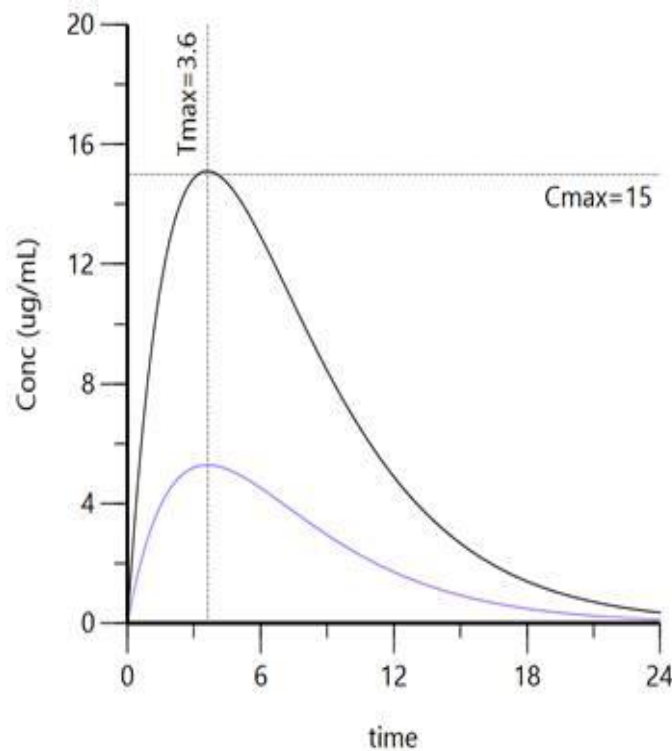
PK/PD driver determinations define exposure/effect relationships

- For antibiotics, the major killing effects are driven by either concentration (C_{\max}), or time dependent (%Time > Conc), or a mixture of both (AUC)

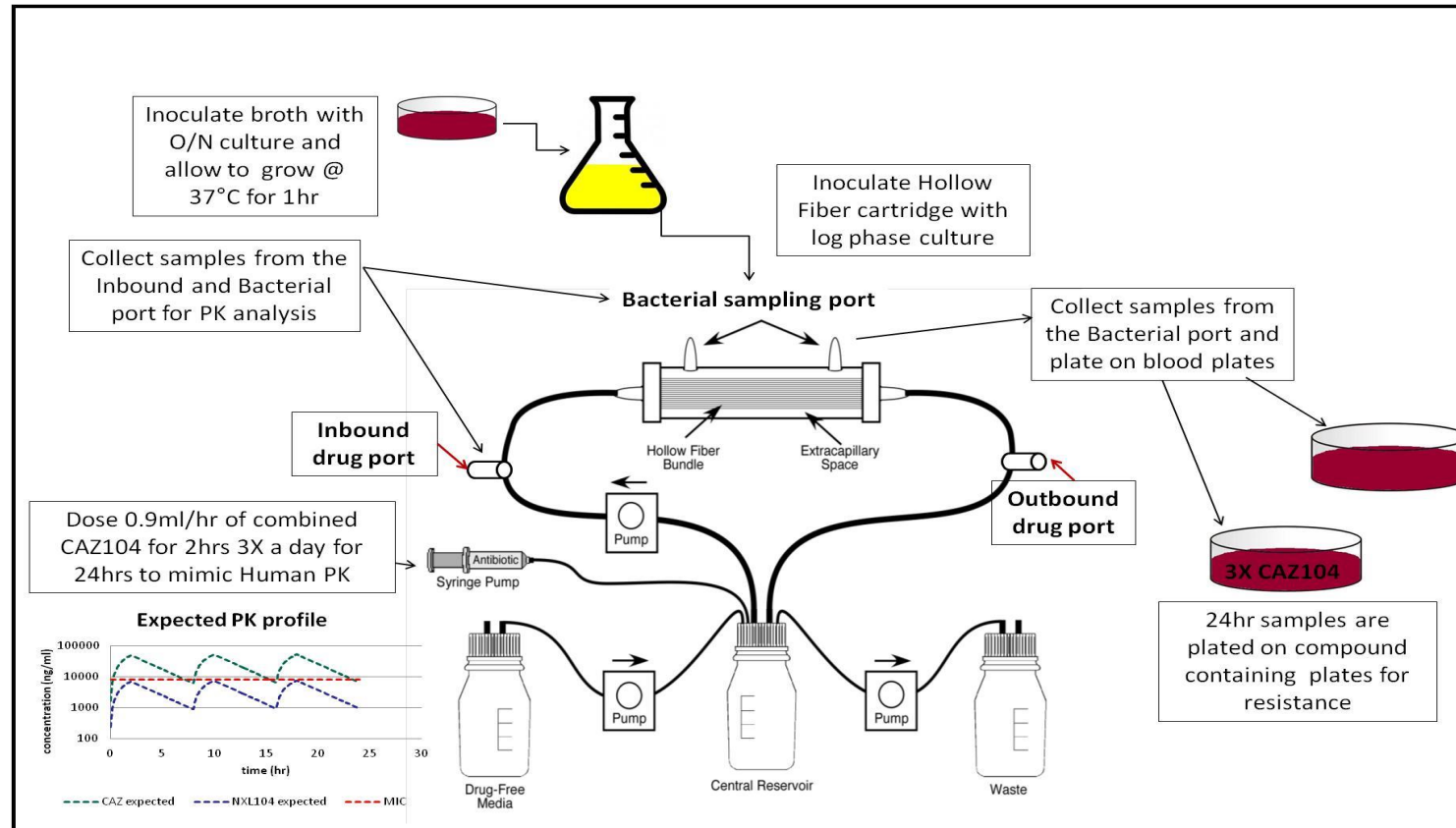


Half-life and dose frequency dictate PK/PD exposure

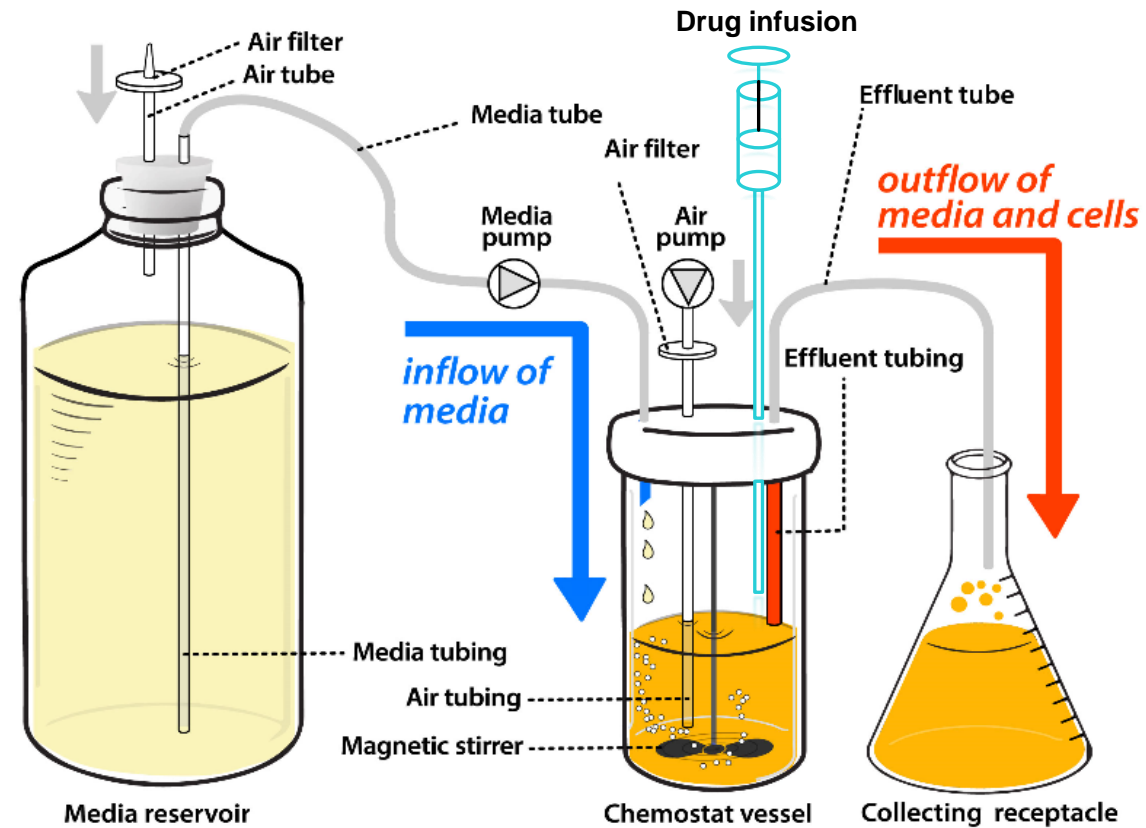
- Once a day (q24h) vs. 3X/day (q8h) administration → different PK/PD exposures



In vitro hollow-fiber infection model: a tool to understand PK/PD



The chemostat model: Low budget alternative to hollow-fiber



Advancing a preclinical candidate

- Many properties must be taken into account
- Target potency and antibacterial activities are important, but so are ease of synthesis, resistance potential, safety, physicochemical, ADME and PK properties
- Sometimes the choice is not obvious

Analog	Phys Prop	# Syn Steps	Target IC ₅₀	WCA, mg/L	MIC ₉₀	FOR	ADME	TOX	PK	efficacy
A	Green	Red	Green	Green	Yellow	Green	Green	Yellow	Green	Green
B	Yellow	Green	Yellow	Green	Yellow	Yellow	Green	Green	Green	Green
C	Red	Green	Yellow	Yellow	Yellow	Green	Green	Yellow	Yellow	Red
D	Yellow	Yellow	Green	Green	Green	Green	Yellow	Yellow	Yellow	Yellow
E	Green	Yellow	Yellow	Green	Yellow	Green	Yellow	Green	Green	Green

Agenda

- Introduction
- Screen to Pre-clinical Candidate
- **Pre-clinical Candidate to IND**
 - Non-clinical package requirements for FIH
 - Dose selection
 - Safety studies
 - CMC considerations
 - Regulatory process/pathways

Non-clinical package requirements for FIH*

Objective of IND: Show that the compound has a reasonable chance to work against the target infection indications AND that it is safe at projected human doses

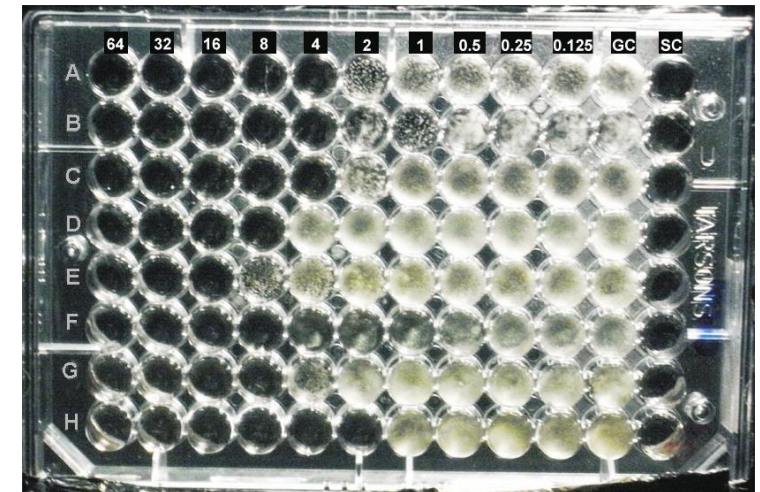
- No check list of requirements
- *In vitro* microbiology
 - Mechanism of action
 - Activity against relevant clinical isolates (50-100 isolates/organism)
 - Frequency of resistance
 - Static or cidal?
- Animal models of infection
 - Standard models for PK/PD (thigh, including dose fractionation)
 - Models that demonstrate efficacy at the site of infection for proposed indications (e.g. lung, UTI)

* FIH – First in human

Determining antimicrobial susceptibility testing conditions

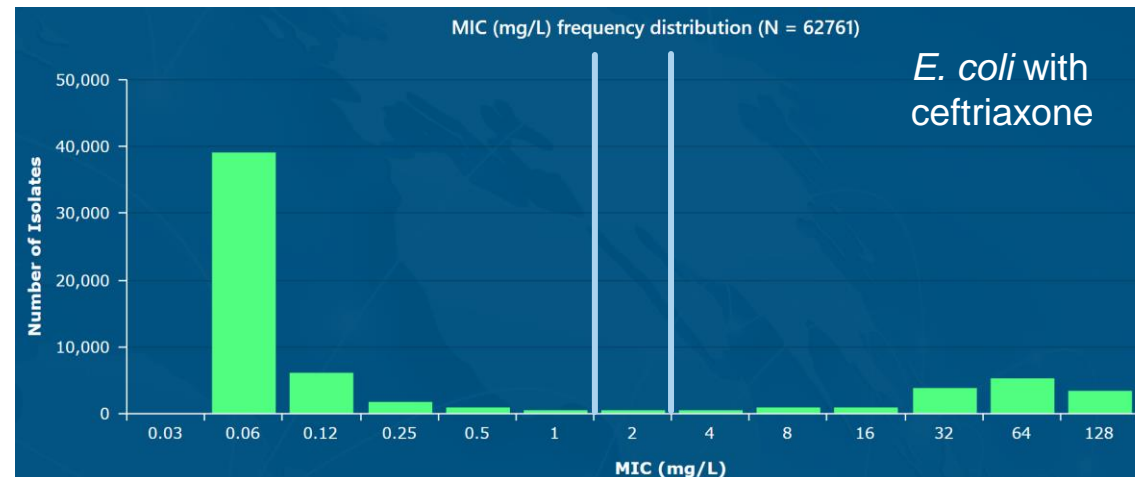
Knowing the correct MIC for an organism is essential for all facets of clinical development

- Do not assume CLSI (Clinical and Laboratory Standards Institute)/EUCAST (European Committee for Antimicrobial Susceptibility Testing) standard methodology is the best method for your drug
- Look for discordant results
 - Drug works better *in vivo* than MIC suggests
 - Discrepancies between organisms (e.g. low MIC for *S. aureus*, high MIC for *S. pneumoniae*)
- Examples of alterations in test methodology
 - Cation adjustment – daptomycin
 - Fresh media – tigecycline
 - Polysorbate 80 – telavancin, oritavancin, dalbavancin
 - Iron depleted media – cefiderocol
- BL/BLI combinations require justification for amount of inhibitor used
- Methods working group for CLSI is a good resource for feedback on alternative methods



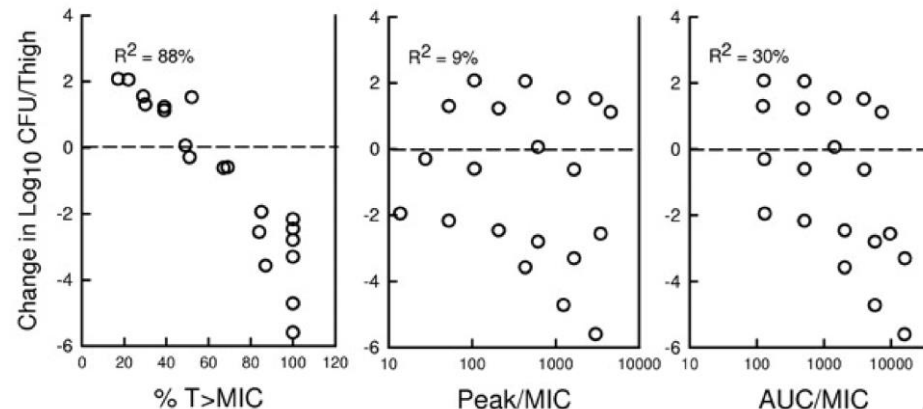
What is a breakpoint?

- Antimicrobial susceptibility test interpretive criteria: A classification of results based on the probability of *in vitro* response of an organism to an antibiotic at blood or tissue concentrations attainable with the most commonly prescribed dosing regimens
 - Most important to detect resistance = Do not use the drug for an organism
 - Second to establish MICs that are covered by PK exposure to the drug, or covered by clinical experience
- Information provided to physician as susceptible, intermediate or resistant (S/I/R)
- A preliminary breakpoint for a drug in development will be based on PK/PD

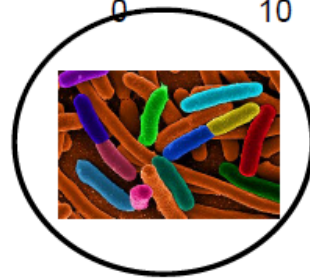
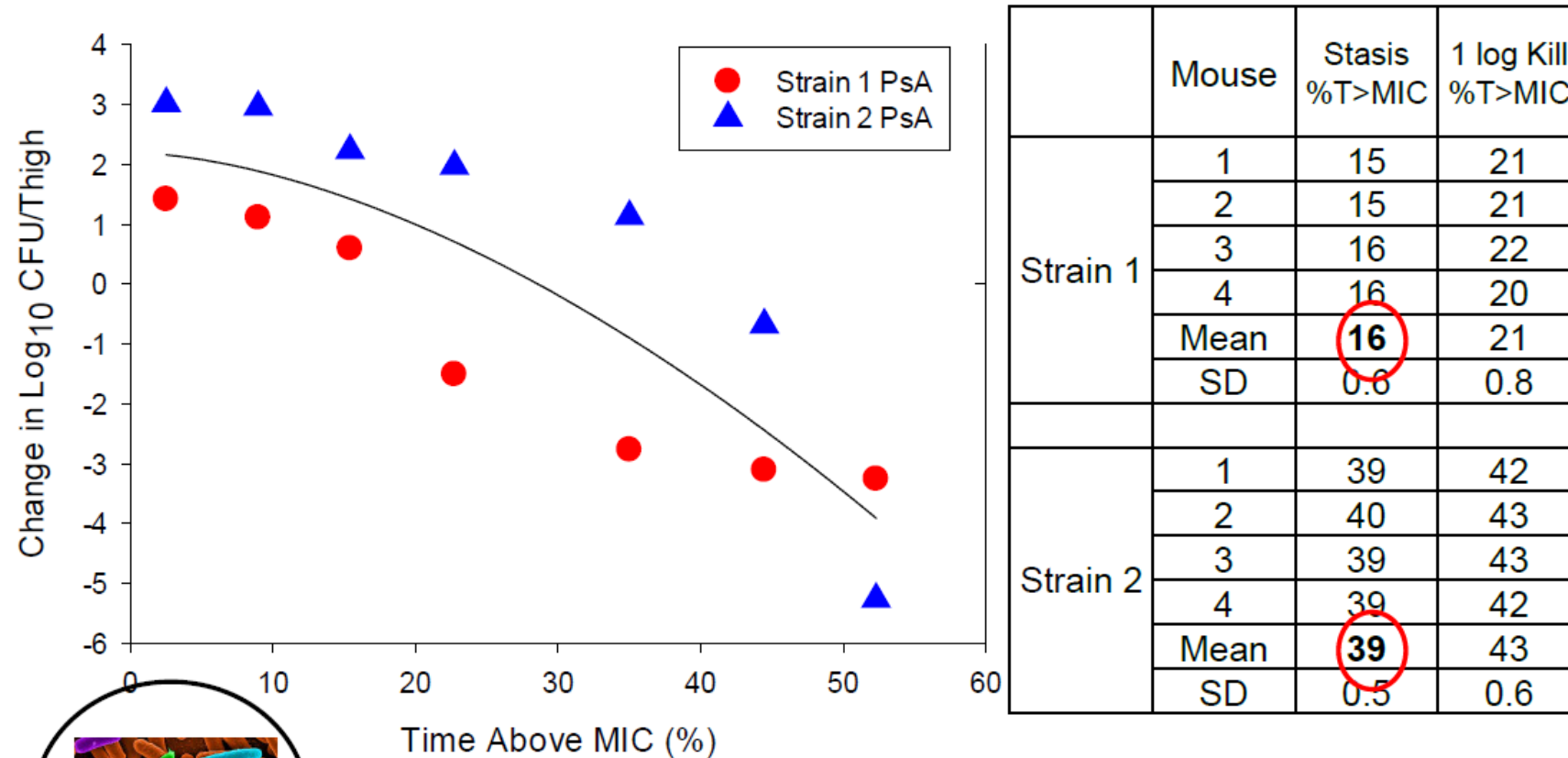


Dose fractionation studies to determine PK driver of efficacy

- Used to determine if the PK driver of efficacy is $fT > MIC$, $fAUC/MIC$, fC_{max}
 - $fT > MIC$ – should see better efficacy with more frequent dosing
 - $fAUC/MIC$ – all dosing intervals produce the same AUC – no difference in efficacy
 - fC_{max} – should see better efficacy with single high dose
- Identical total daily dose given as single or intermittent doses
 - Full dose given once, $\frac{1}{2}$ dose given q12 hr, $\frac{1}{3}$ dose given q8hr, $\frac{1}{4}$ dose given q6h
- The time course of the bacterial response to drug exposure is modeled



Strain to strain variability drives the need to utilize several clinical isolates across the targeted MIC range

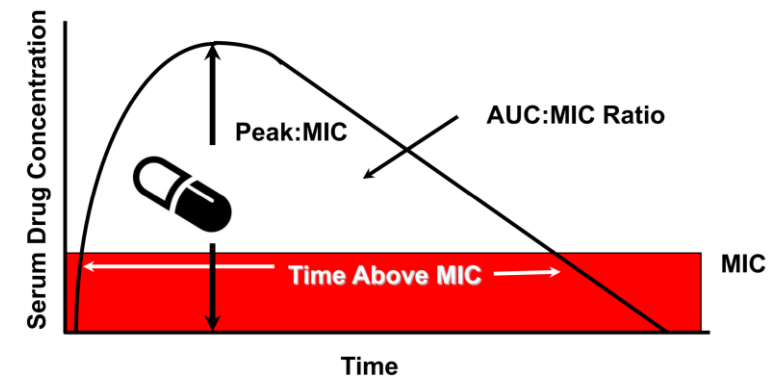


Strain Variability

Dose selection for first in human (FIH) studies

Requires a strong PK/PD package

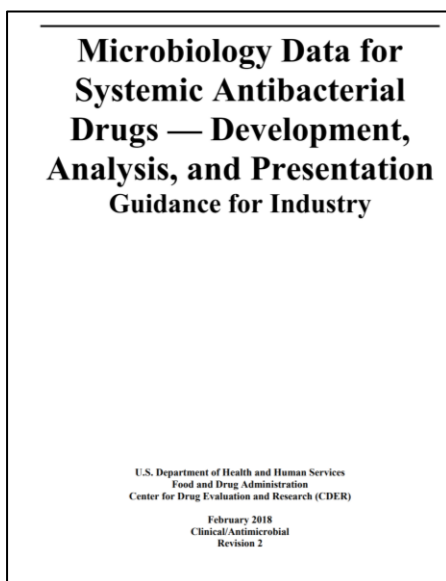
- *In vitro* microbiology
 - MIC frequency distribution for target organisms
 - Time-kill
- Hollow-fiber infection model
 - Dose fractionation to determine PK driver of efficacy ($fT > MIC$, AUC/MIC , C_{max})
 - Mutant prevention concentration
- Animal models of infection
 - Dose fractionation to confirm PK driver
- PK modeling to determine thresholds required to achieve efficacy
 - Allometric scaling to determine projected dose in humans
 - What MIC is covered by this threshold?



MIC = minimum inhibitory concentration; AUC = area under the curve; T = time

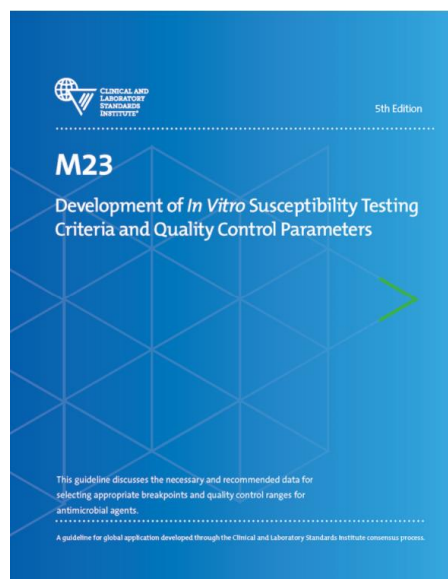
Some useful resources for preclinical pharmacology

FDA microbiology guidance



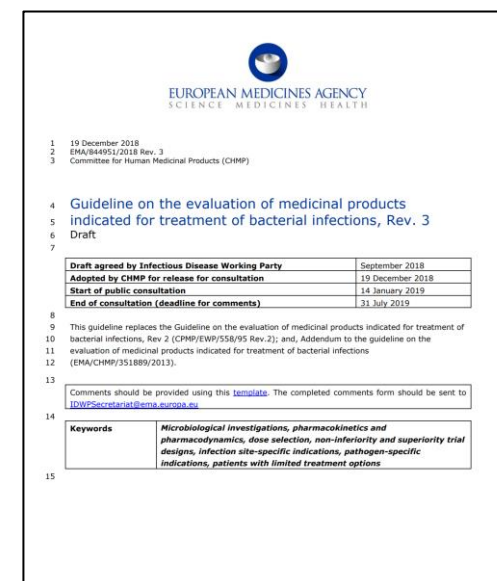
<https://www.fda.gov/media/77442/download>

CLSI document M23 on developing AST



<https://clsi.org/standards/products/microbiology/documents/m23/>

EMA antibacterial guidance



https://www.ema.europa.eu/en/documents/scientific-guideline/draft-guideline-evaluation-medicinal-products-indicated-treatment-bacterial-infections-revision-3_en.pdf

Non-clinical safety studies – Dose-ranging

- GLP (good laboratory practice) not required
- Often one species (mice or rats)
- Acute single dose – dose escalation to establish MTD (maximum tolerated dose)
- Multiple day dosing
 - 5 -14 days
 - Histopathology strongly encouraged



Guidance for Industry

M3(R2) Nonclinical Safety
Studies for the Conduct of
Human Clinical Trials and
Marketing Authorization for
Pharmaceuticals

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)

January 2010
ICH
Revision 1

<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/m3r2-nonclinical-safety-studies-conduct-human-clinical-trials-and-marketing-authorization>

Non-clinical safety studies – IND-enabling

- Must be done under GLP
- Often 3 doses to achieve multiples of AUC at projected clinical dose
 - Low: Sub-therapeutic
 - Estimated therapeutic dose
 - High: At or near MTD (target 50X therapeutic dose)
- One rodent (usually rats) and one non-rodent species (usually dogs)
- Duration of studies for antibacterials
 - 2 weeks dosing to support clinical trials
 - 4 weeks of dosing to support NDA/MAA* approval.
- Drug substance batch and formulation should be the same as what will be used for phase 1
- Include toxicokinetics
- Endpoint is NOAEL (No Observed Adverse Effect Level)
 - Ideal NOEAL provides 5-10x therapeutic window

Chemistry, Manufacturing and Controls (CMC) considerations

- Same batch for GLP studies and phase 1
 - Produced using GMP (good manufacturing practices)
 - Impurities characterized
- Bulk drug substance manufacturing and product packaging
 - Dedicated facility required for β -lactams
 - Formulations
 - Excipients
 - Dosing compatibility studies
 - Sterility and quality control measures
- Stability studies



Regulatory process/pathways

- Pre-IND meeting with FDA/EMA not required, but encouraged
- Before FIH studies, investigational applications must be filed
 - IND (Investigational New Drug Application) for US Food and Drug Administration (FDA)
 - CTA (Clinical Trial Application) for European Medicines Agency (EMA)
 - Documents follows the Common Technical Document (CTD) format.
- Initial IND/CTA filed in country where phase 1 study will be held
 - Subsequent filings with each of the major regulatory agencies

Conclusions: There is a lot to do!

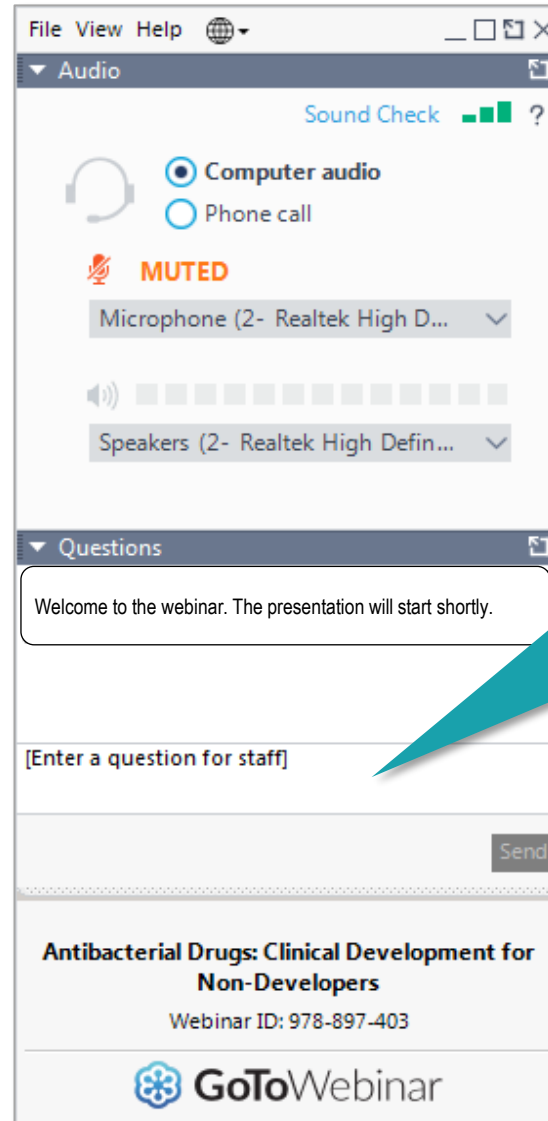
Tips to staying on the straight path

- Is there a practical use for this?
 - Given the spectrum of activity, what are the potential indications for this drug?
 - What is the unmet medical need?
- Don't generate data you don't need
 - For each experiment ask what is the purpose?
 - How will I use this data?
- Don't be afraid to generate data that might give you a negative result
 - Good leaders know when to end a project
- Plan for success
 - Write study reports as data is generated
 - Develop slide decks that will explain your rationale for proceeding



How to submit your questions

If your question is addressed to a specific speaker, please include their name when submitting the question.



The screenshot shows the GoToWebinar interface. At the top is a menu bar with 'File', 'View', and 'Help'. Below it is the 'Audio' section, which includes a 'Sound Check' status with a green bar and a question mark. There are two radio buttons: 'Computer audio' (selected) and 'Phone call'. A red microphone icon and the word 'MUTED' are displayed. Below this are dropdown menus for 'Microphone (2- Realtek High D...)' and 'Speakers (2- Realtek High Defin...)', with a volume slider in between. The 'Questions' section is below the audio controls. It contains a text box with the message 'Welcome to the webinar. The presentation will start shortly.' Below this is a text input field with the placeholder '[Enter a question for staff]'. To the right of the input field is a 'Send' button. At the bottom of the interface, the title 'Antibacterial Drugs: Clinical Development for Non-Developers' and the 'Webinar ID: 978-897-403' are displayed, followed by the GoToWebinar logo.

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Today's speakers

From discovery to IND: Roadmap to a successful antibacterial project



Patricia A. Bradford
Independent consultant
Antimicrobial Development Specialists (US)



Alita Miller
Head of Biology
Entasis Therapeutics (US)



Moderator:
Michael Mourez
Head of Innovation
École d'Ingénieurs de PURPAN (France)

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Learning from COVID-19 to tackle the silent pandemic of antibiotic resistance

Speakers:

- Manica Balasegaram, GARDP (Switzerland)
- Joanne Liu, University of Montreal (Canada)
- Marc Mendelson, University of Cape Town (South Africa)

24 March, 14:30-16:00 CET

Discovering and developing new treatments for tuberculosis

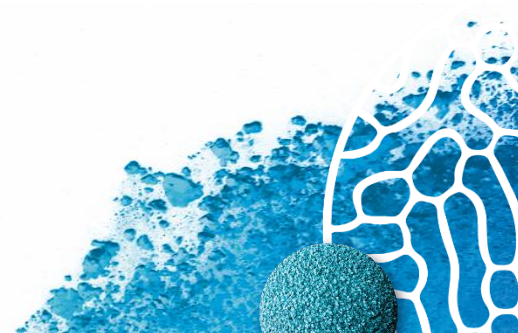
Speaker:

- Nader Fotouhi, TB Alliance (US)

Moderator:

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