The webinar will start shortly

The recording of this webinar will soon be made available on revive.gardp.org/webinars via the GARDP YouTube channel.

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Innovating for impact: Tackling chronic lung infections in cystic fibrosis through new antimicrobials

Guest speakers: Jane Davies, Neill Gingles & David Richards

Moderator: Deborah O'Neil

Host: Shirine Derakhshani

19 February 2026

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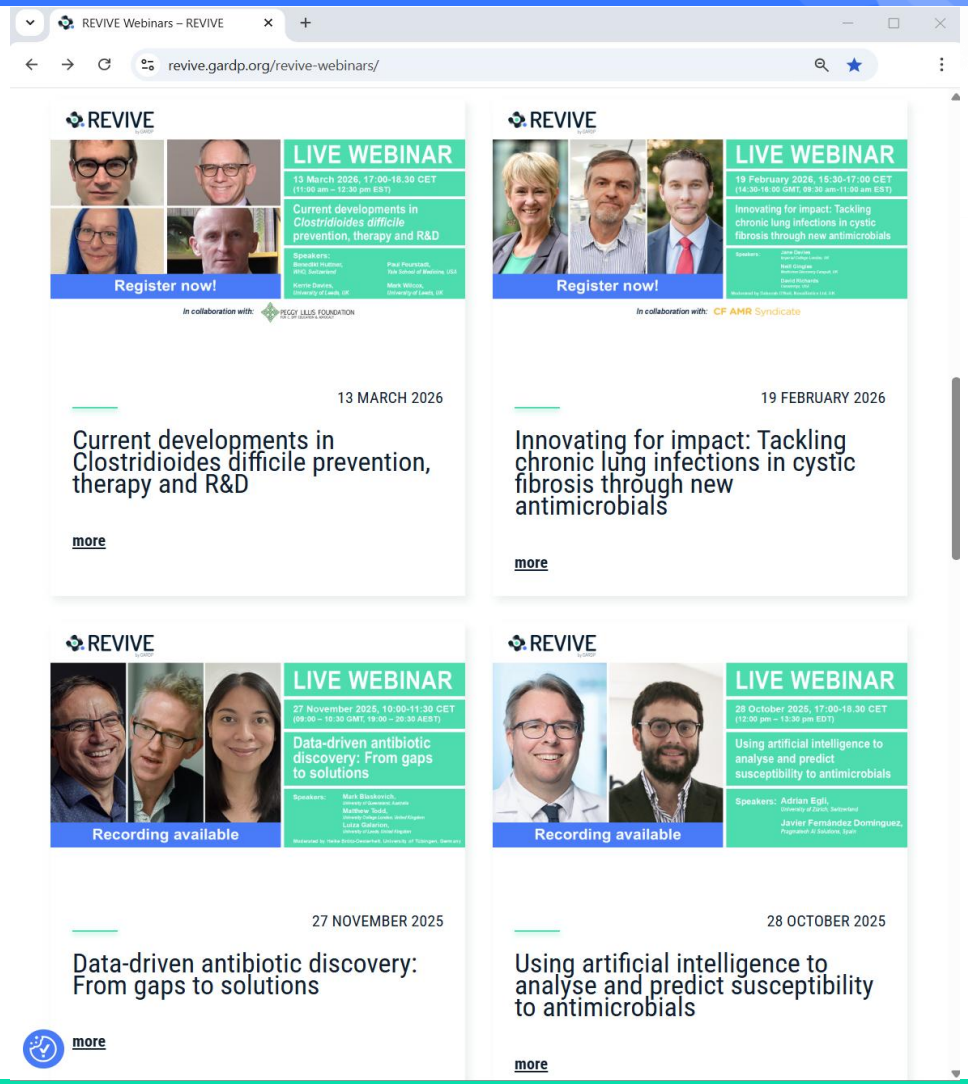

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Antimicrobial Viewpoints

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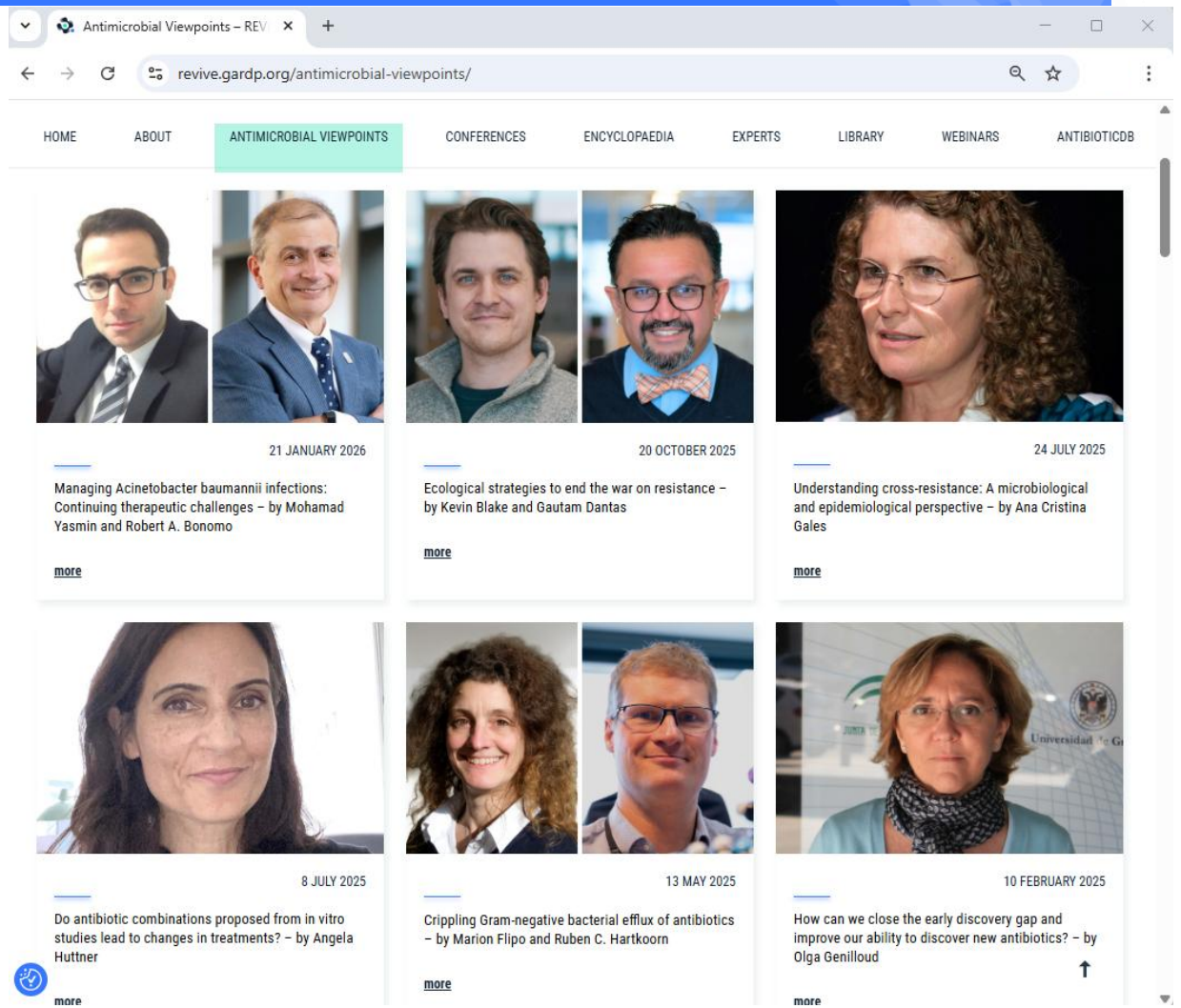

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Antimicrobial Encyclopaedia

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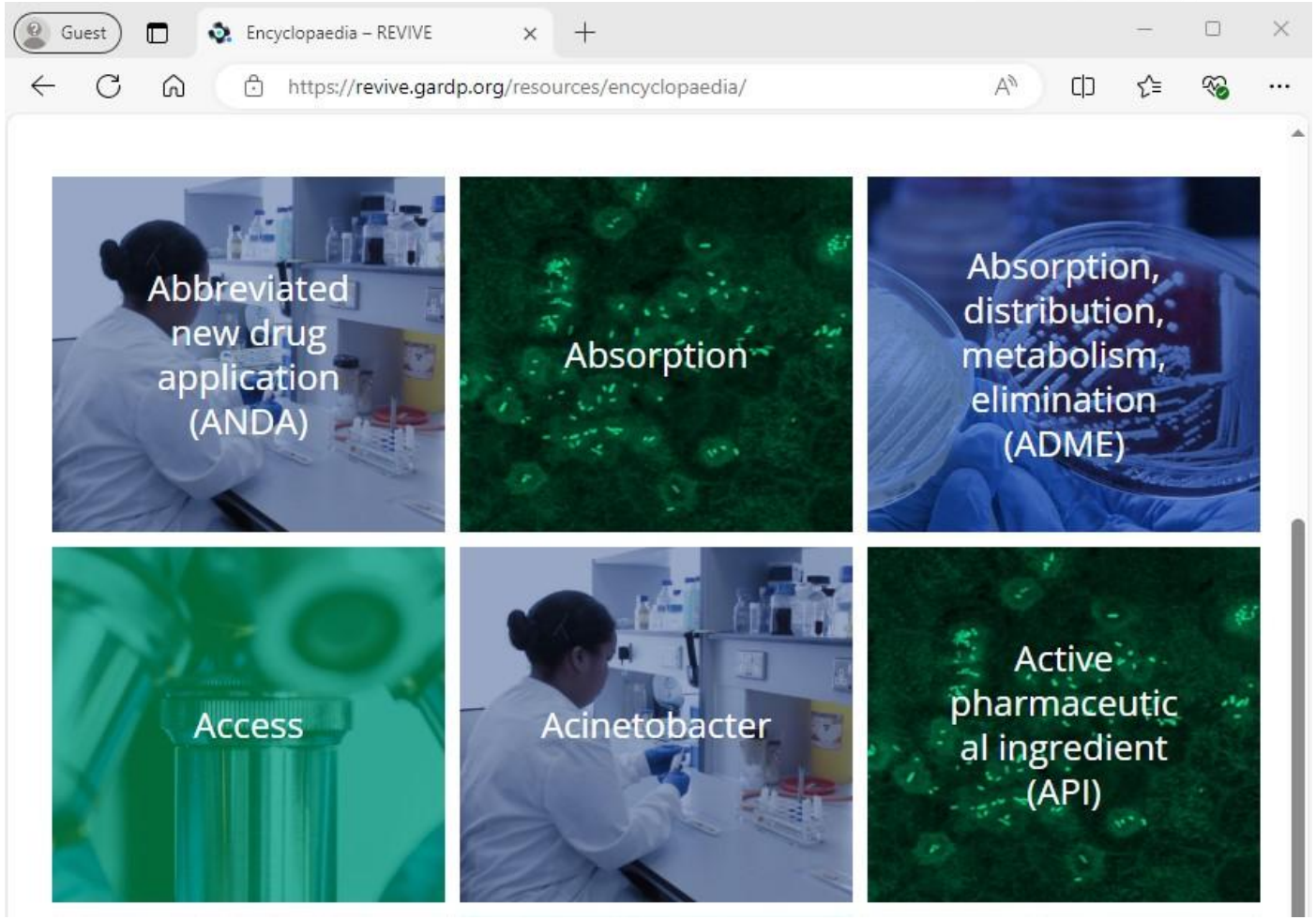

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How to submit your questions

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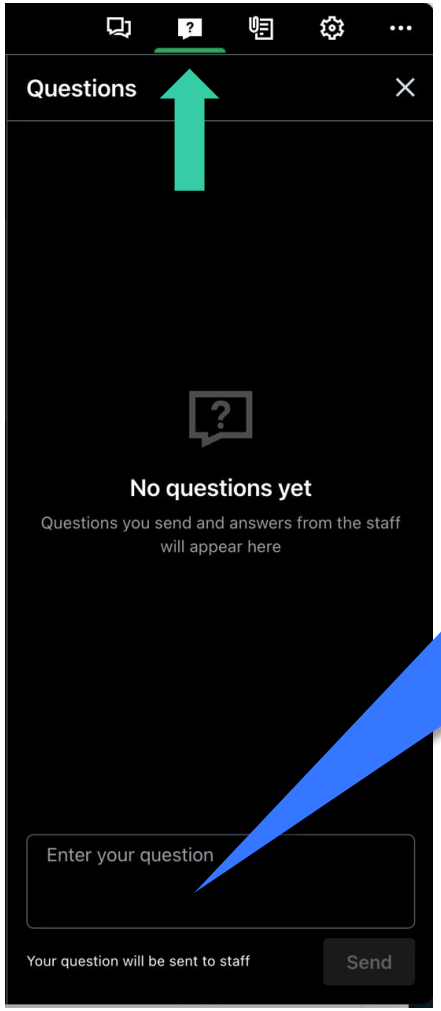


Please submit your questions through the box provided after clicking the ‘questions’ button. We will review all questions and respond to as many as possible after the presentation.

Today's speakers

REVIVE by GARDP

Innovating for impact: Tackling chronic lung infections in cystic fibrosis through new antimicrobials

Moderator:
Deborah O'Neil
NovaBiotics Ltd, UK

Jane Davies
Imperial College
London, UK

Neill Gingles
Medicines Discovery
Catapult, UK

David Richards
Clarametyx, USA

Jane Davies

Jane Davies is Professor of Paediatric Respirology & Experimental Medicine at the National Heart and Lung Institute, Imperial College London and an Honorary Consultant at the Royal Brompton Hospital, one of the largest cystic fibrosis (CF) clinics in Europe.
Her areas of research expertise are CF chronic lung infection and clinical trial design. Jane has directed two Strategic Research Centres focused on Pseudomonas aeruginosa, training future clinical and scientific researchers in CF infection. These laid the foundation for the successful bid to lead one of the new CFT/LifeArc Innovation Hubs, PRECISION, a multimillion collaboration focused on polymicrobial interactions and novel approaches to infection detection.

Jane has been global & national lead investigator on over 30 trials of CFTR modulator drugs, including in children and infants. She co-leads the multicentre observational studies, RECOVER and ENHANCE, and the MATRIARCH Strategic Research Centre, investigating maternal and infant health in the CFTR modulator era. She is clinical lead/ Strategy Group member of the UK CF Gene Therapy Consortium, currently conducting a phase 1/2 study of lentiviral mediated gene therapy in adults unable to benefit from modulators. She is President of the European CF Society, directs the European Lung Clearance Core Facility and chairs the UK NIHR National Research Strategy Group in CF. She sits on Advisory Boards for LifeArc, CF Trust and multiple pharma/ biotech companies developing new therapies for CF and lung infections. Jane is a Fellow of the Academy of Medical Sciences, an NIHR Senior Investigator and was made an Officer of the Order of the British Empire (OBE) in 2024.

https://www.imperial.ac.uk/stories/ref21-jane/

Neill Gingles

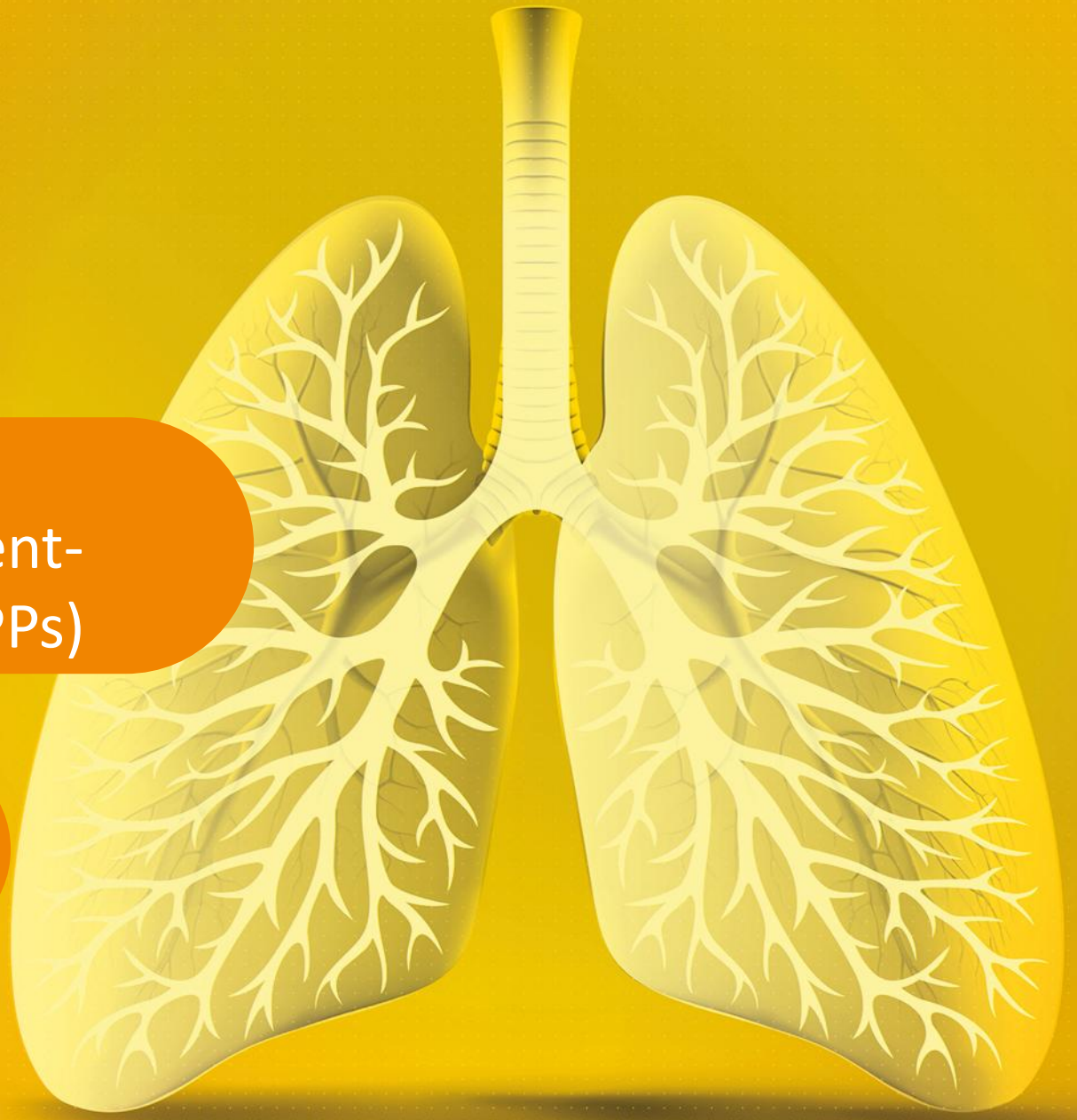
Neill Gingles, PhD, is a lead scientist with over 20 years of experience across academia, biotech, and pharmaceutical R&D, specialising in infectious disease, antimicrobial resistance, and translational drug discovery.

He currently serves as a Scientific Lead within the CF AMR Syndicate and PACE programmes, where he helps shape scientific strategy and supports early-stage innovation to accelerate new antimicrobial therapies and diagnostics.

CF AMR Syndicate

Shaping Innovation Together: Designing and implementing Patient-Centric Target Product Profiles (TPPs)

Neill Gingles, Medicines Discovery Catapult



CATAPULT Medicines Discovery

Cystic Fibrosis Trust

LifeArc

CF AMR Syndicate Mission & Strategic Goals

Promote and advance translational science to bring new antimicrobials & diagnostics to the clinic, faster.

Explore the Opportunity

New insights through network engagement

Enable Discovery

Enabling capabilities to address barriers

Accelerate the solution

Collaborative programmes to drive the pipeline

CATAPULT Medicines Discovery

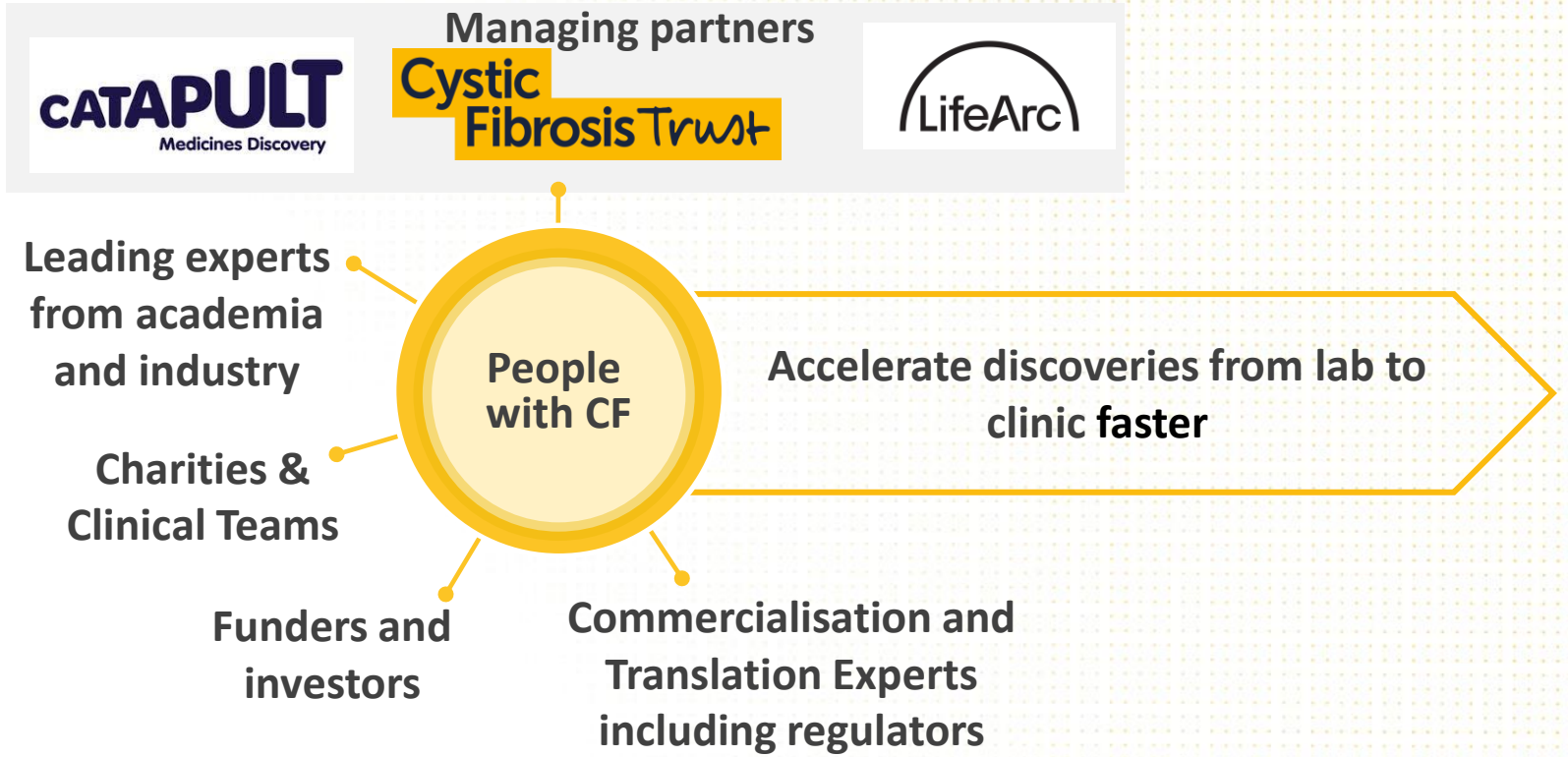
Cystic Fibrosis Trust

LifeArc

cfamr.org.uk

A connected community with a collaborative approach

- Identifying areas of unmet need
- Leveraging cross-sector expertise
- Catalysing drug discovery efforts
- Involving patients



Engagement

>980 cross sector stakeholders engaged within the CF AMR Syndicate community

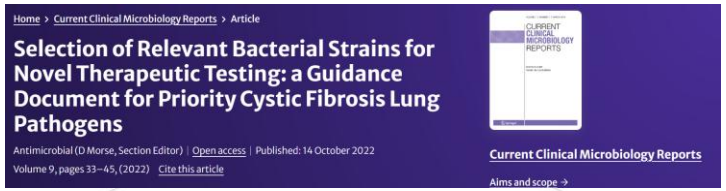
Our network

CF AMR Syndicate

The Syndicate has formed the CF AMR Network to help the community to work together to address the challenges

Website & Newsletter

Blogs **Reports** **Resources**

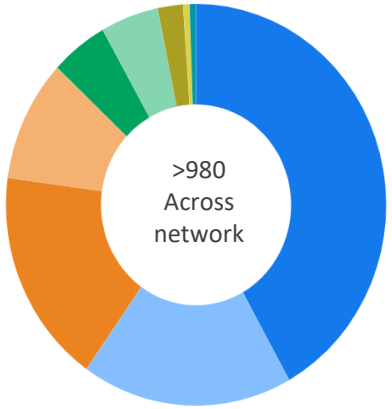


Workshops & Events

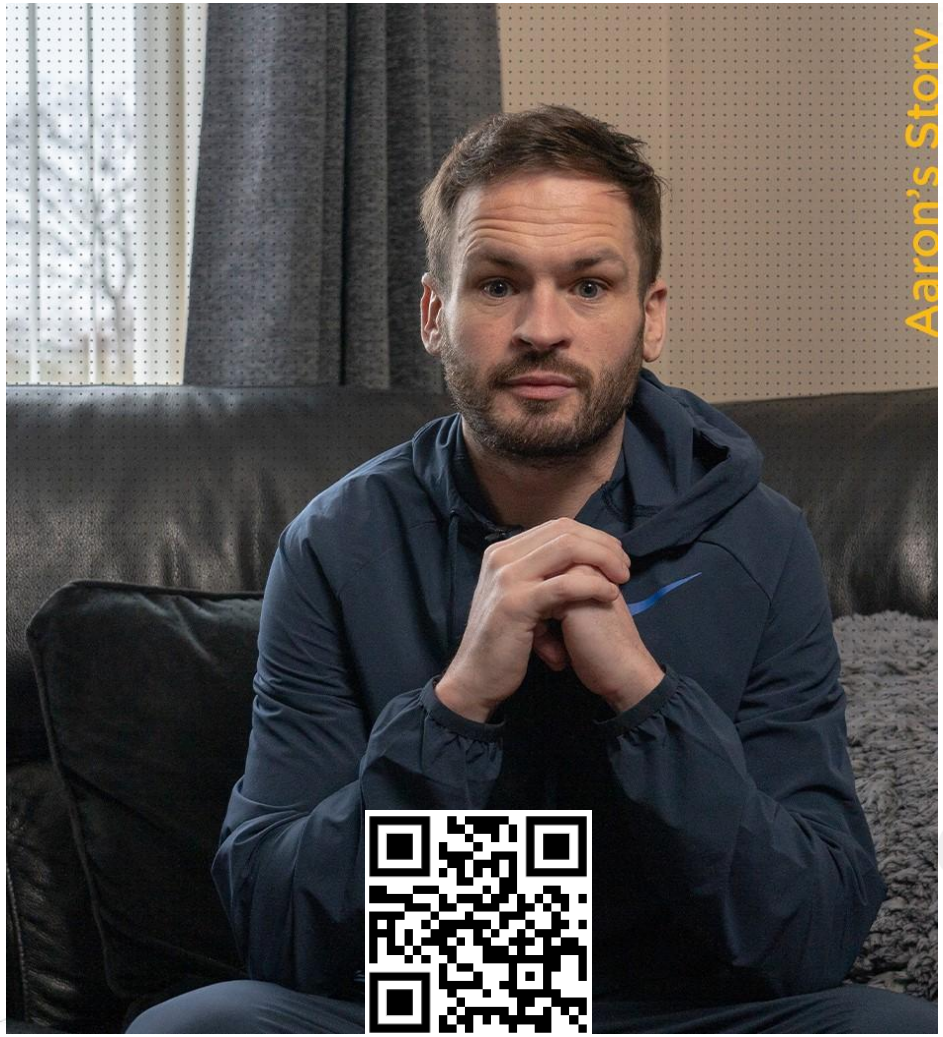
Knowledge exchange & problem solving

Networking & Signposting

Catalysing collaborations

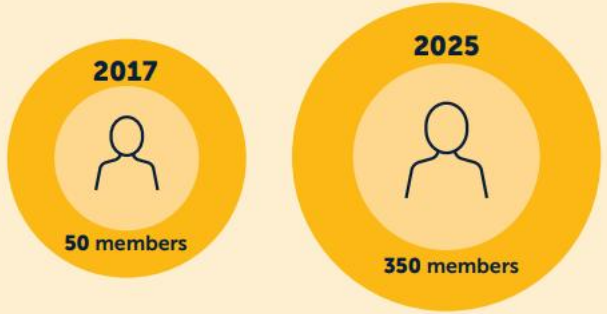


Connecting people with lived experience to the R&D community



- Focus groups
- Document reviews
- Event presentations
- Advisory group representatives
- Insight reports

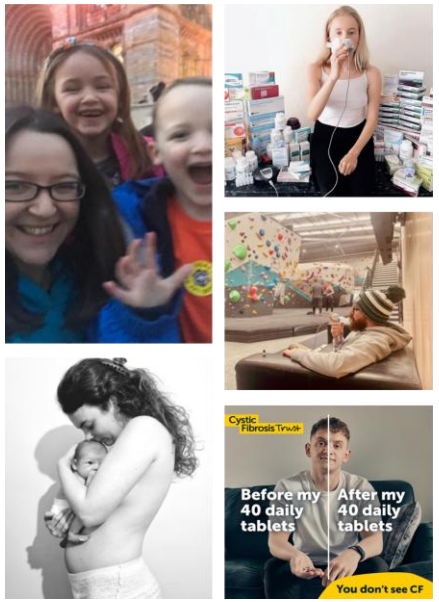
Involvement Group membership growth



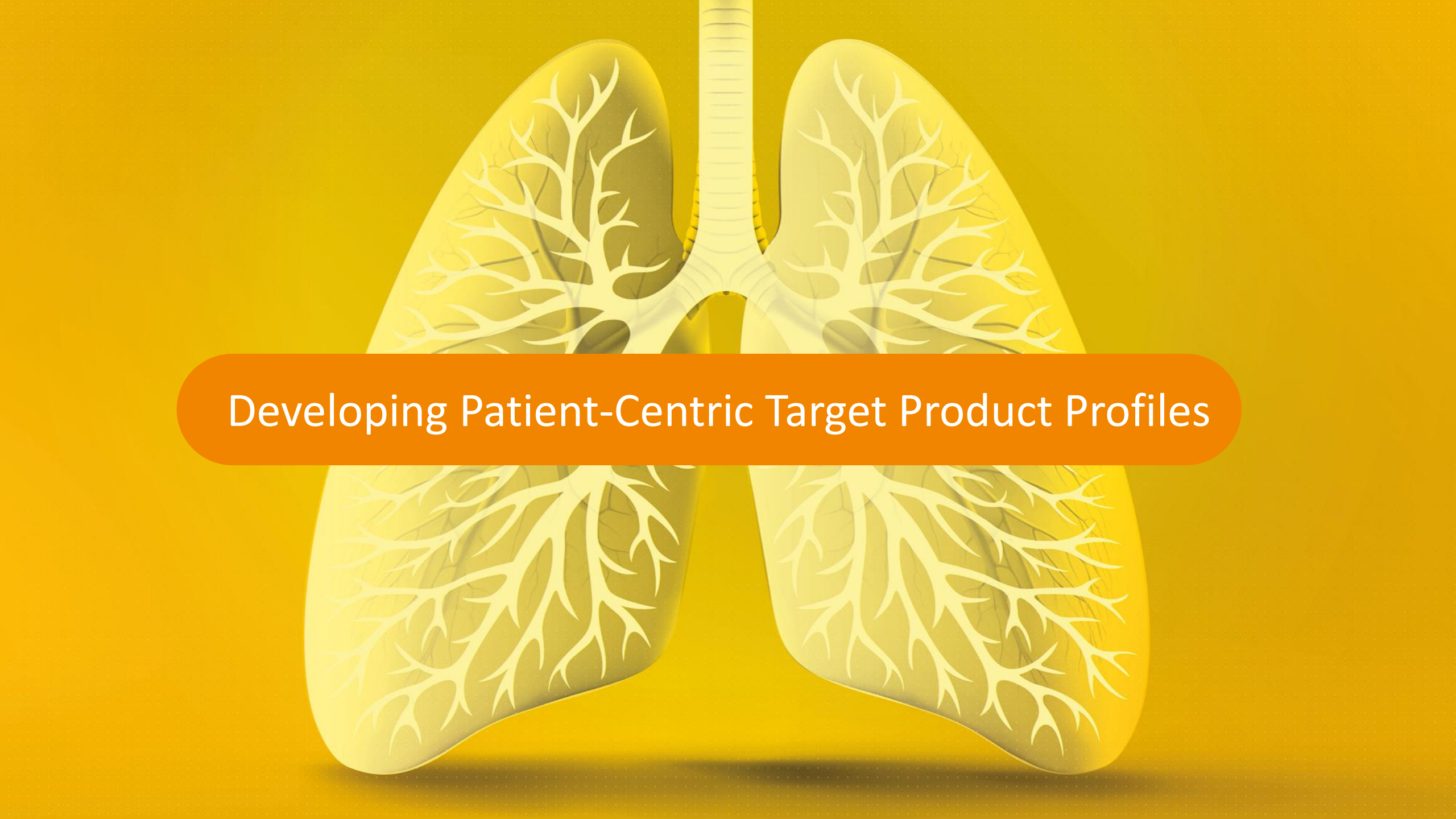
Antibiotics have literally helped me my whole life.
Now going from having six or seven options, I think I've only got three.

Aaron's Story

The power of community insight



- ***Aligning drug and diagnostic development with real patient needs***
- **Living** with a chronic, life-long condition leads to great expertise beyond **textbook clinical** knowledge
- **Potential participants** as opposed to patients
- Identify **relevance –** products, outcomes, measures, formulation
- **Critical insights** – polypharmacy, burden of care, tolerability
- Prevents development in isolation without addressing real unmet need



Developing Patient-Centric Target Product Profiles

Developing patient-centric target product profiles (TPPs)

What is a TPP and why develop them?

- A TPP outlines key characteristics a product should have in order to address a specific patient need. They can act to;
  - Guide innovation where it is needed the most
  - Accelerate the development and translation of novel therapeutics and diagnostics

Why Patient-Centric TPPs Matter

- Patients are experts in their own disease experience
- Integrates unmet needs and quality-of-life priorities
- Reduces clinical trial recruitment issues/failures due to patient burden concerns
- Accelerates regulatory acceptance and market uptake
- Ensures innovations address what patients truly need

Development of TPPs for CF related lung infections

Expert advisory group

- Focus group of people with CF
- Clinical focus group
- 1:1s with Industry & KOLs
- Survey for consensus
- Virtual Symposium
- Publication and Dissemination

Patient-centric priorities

Identified key unmet needs as defined by those with lived experience.

Multi-stakeholder engagement

Discussions within mixed expert groups, facilitating shared learnings and open conversations.

Iterative 'Sense checking'

Lived experience input throughout to ensure R&D efforts address patient needs/priorities.

Shaping the TPPs – some key insights

Therapeutic insights: Treatment Burden and tolerability

- **Burden Matters:** Shorter regimens with lower toxicity beat marginal efficacy gains
- Preparation, administration, and device cleaning are major burdens
- **Treatment complexity** increases with age—critical for adult CF - No cumulative toxicity with repeated dosing key
- **DDI Awareness:** Drug-drug interactions are deal-breakers in CF's complex landscape - Compatibility with existing CF therapies including CFTRm
- **Patient Voice First:** Priorities beyond clinically defined efficacy - Patient-reported outcomes should be primary, not secondary

" We're almost certainly very frequently overtreating, which is obvious that it has consequences…." Clinical team participant

"With the new modulators, a lot of people aren't actually producing any sputum anymore" Clinical team participant

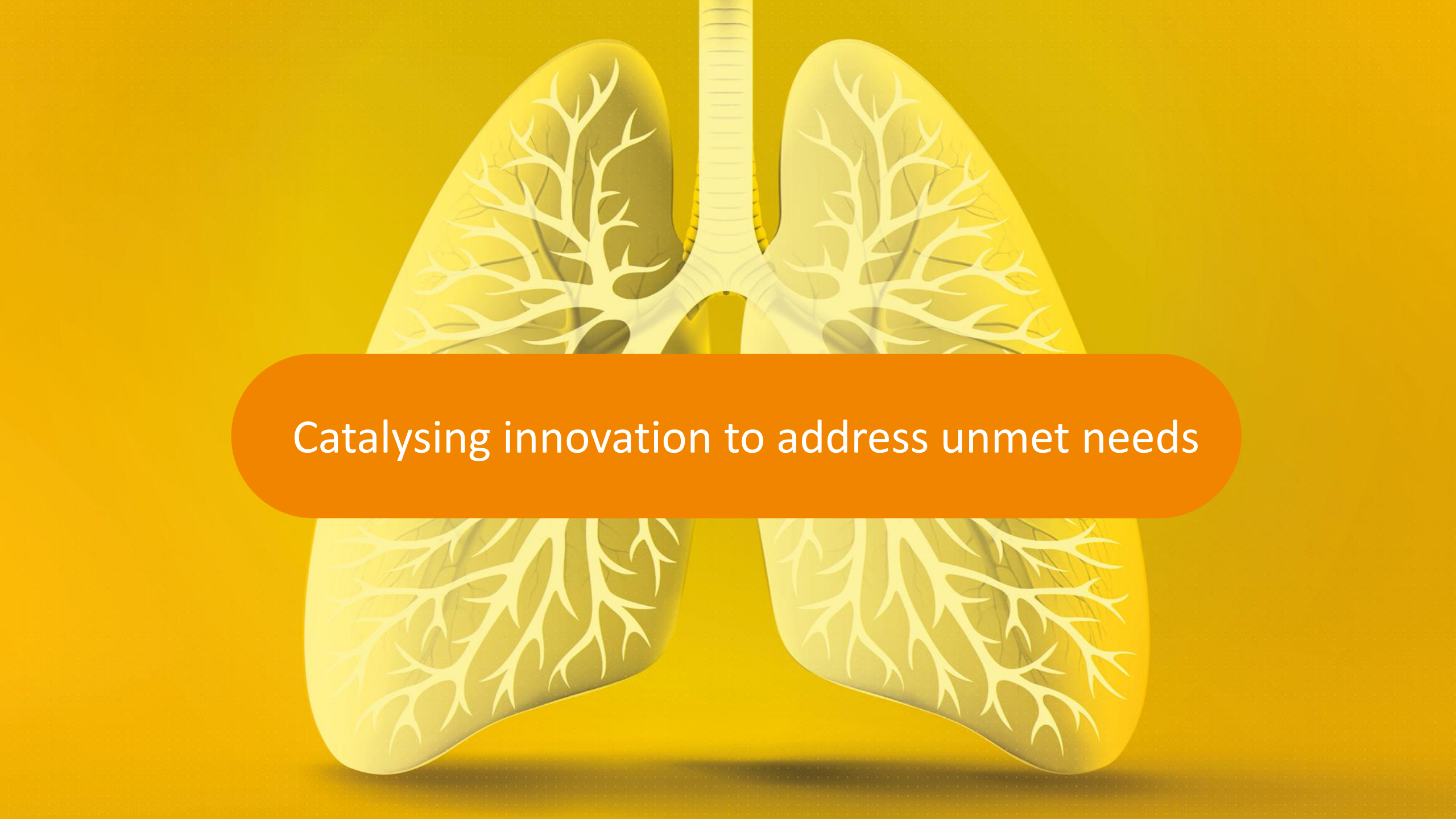
Shaping the TPPs – some key insights

Diagnostic development considerations

- There's an urgent need for technologies that utilise **novel sample types**
- New diagnostics should resolve issues with existing approaches (e.g. **non-invasive, rapidity**)
- Defining when/what to treat remains a key challenge (when does detection of pathogen require intervention, how should you treat, and for what duration)
- With an increasingly diverse population of people with CF, there is a growing need for personalised approaches to care

"…5-7 days + growing sputum in a lab is scary when your loved one is going downhill". Parent of person with CF

"With NTM you're waiting like six, eight weeks for results. So by the time you get those, you've already had this infection for possibly two, three months" pwCF


Catalysing innovation to address unmet needs

Catalysing innovation to address unmet needs

- **The CF AMR Syndicate's Collaborative Discovery Programme provides funding and wrap-around support to help advance projects towards patient impact**

EOI

Catalyser stage and full application

Project initiation

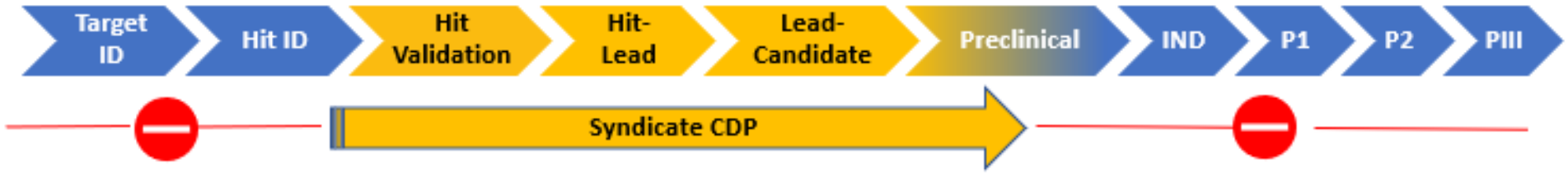
Enhance the pipeline of preclinical antimicrobials for treating lung infections in CF

£3M funding call

6 projects selected
Aligned to therapeutic TPP

Wraparound support and advice

Involvement of **pwCF**



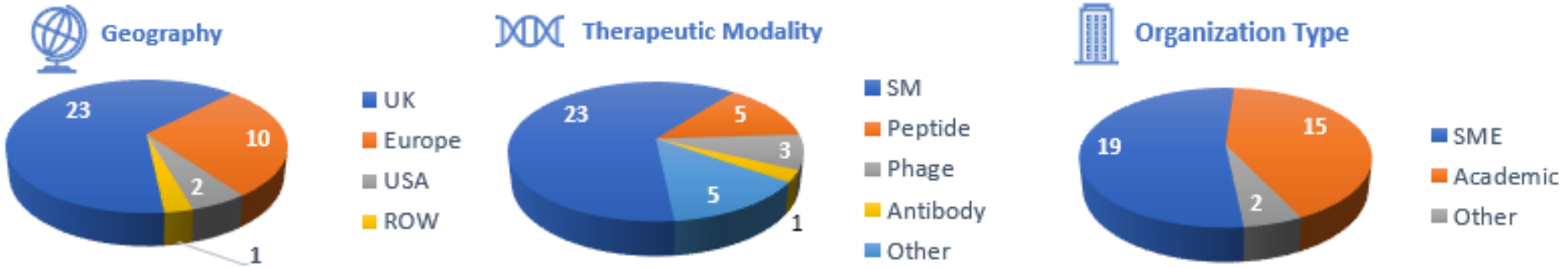
Collaborative discovery programme – metrics and outcomes

- Mar-May 23

Q1 2024-onwards

- **Collaboration right from the start:** Ongoing support and advice was provided by the syndicate through all stages of the application process through 1-1 meetings, workshops and webinars
- ***Engagement with pwCF was a key part of the review process***

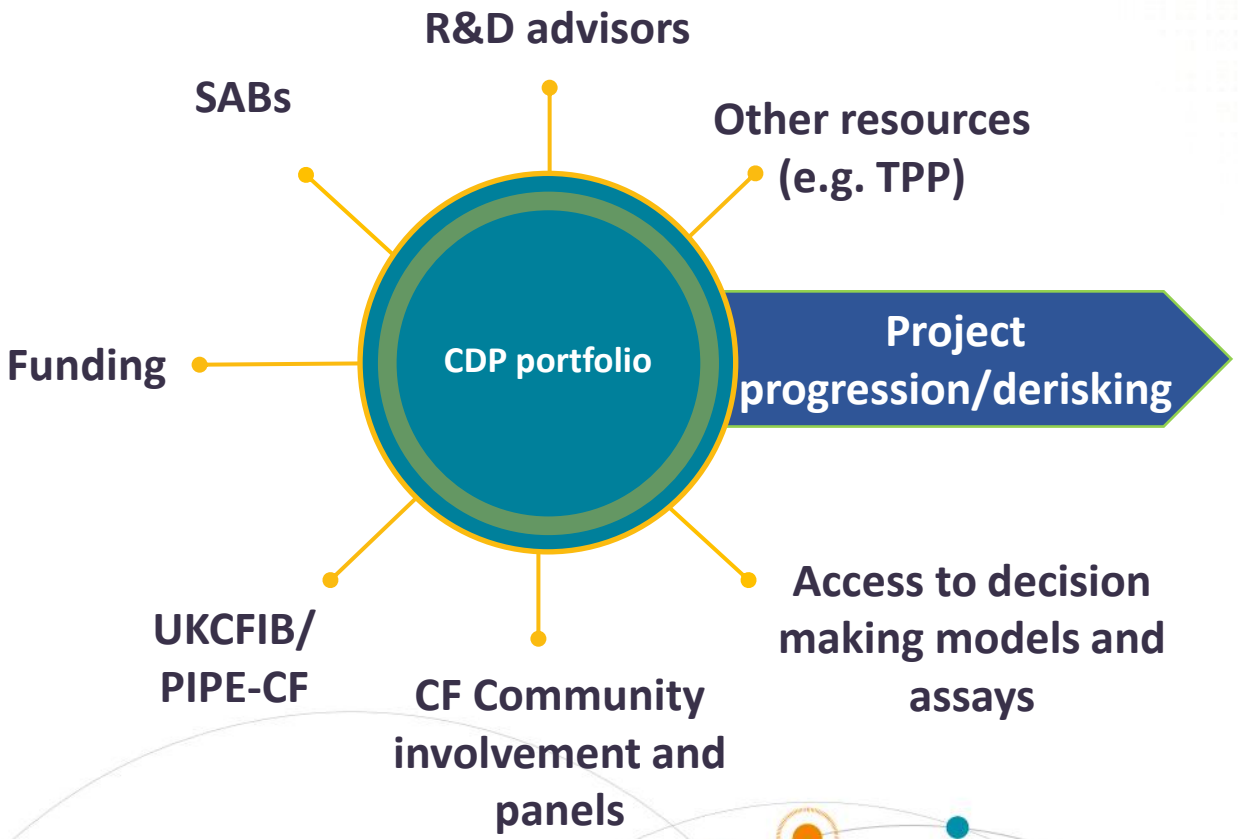
Breakdown of applications



- 36 Applications were received from 11 countries across the globe
- Broad range of therapeutic modalities

Collaborative discovery programme – *progress through collaboration*

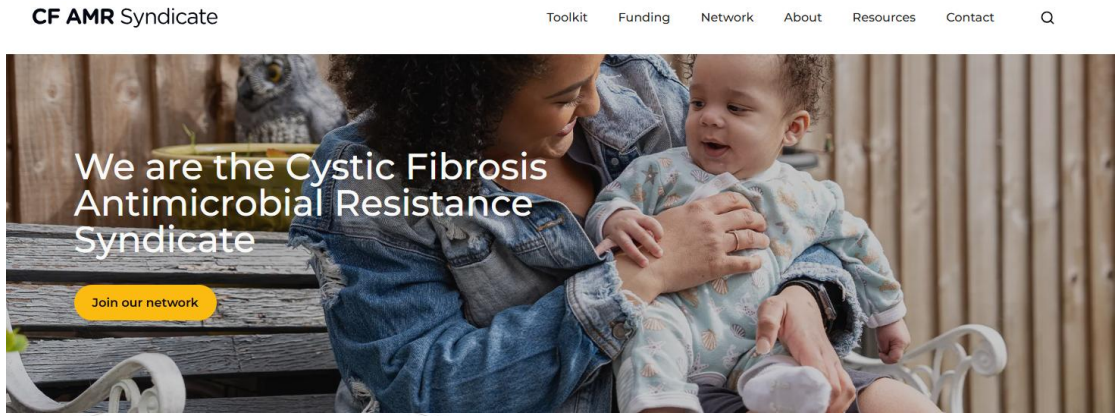
- **Wrap around support from abstract to tangible collaboration:** Programs like the CF AMR Syndicate encourage collaboration between biotech, academia, and clinical researchers to address translational barriers.



CDP Portfolio	Hit Validation	H2L	LO	Modality	Primary Pathogen
Bicycle				Peptide	*P. aeruginosa*
BIOVERSYS				Small molecule	NTM
GLOX THERAPEUTICS				Other (Protein)	*P. aeruginosa*
OXFORD DRUG DESIGN				Small molecule	*P. aeruginosa*
ROSTRA THERAPEUTICS				Small molecule	*Aspergillus spp.*
UK Health Security Agency / KING'S College LONDON				Small molecule	*P. aeruginosa* *B. cepacia*

Summary

- **Patients at the heart of discovery:** Patient-centric TPPs embed patient needs directly into R&D strategy
- **Delivering R&D success through collaboration:** Targeted, multifaceted support (both funding and non-funding inputs support successful project delivery and investment readiness
- **Community as a catalyst:** a uniquely coordinated and concentrated CF AMR environment drives meaningful patient outcomes



Thank you to people living with CF, their clinical care teams, our diverse network and collaborators who have helped support the activities and projects within the CF AMR Syndicate.

Visit our website to join the network **Or get in touch to find out more:** *cfamr@md.catapult.org.uk*

David Richards

David Richards is a life sciences executive, serving as Chief Executive Officer of Clarametyx Biosiences since 2020.

Prior to Clarametyx, he served in operational and general counsel roles for Aclipse Therapeutics, focusing in neurodegenerative and gastrointestinal disease areas; and N8 Biosciences, Inc., which is commercializing novel small molecule antimicrobial therapeutics and device coatings that mimic naturally occurring antimicrobial peptides.

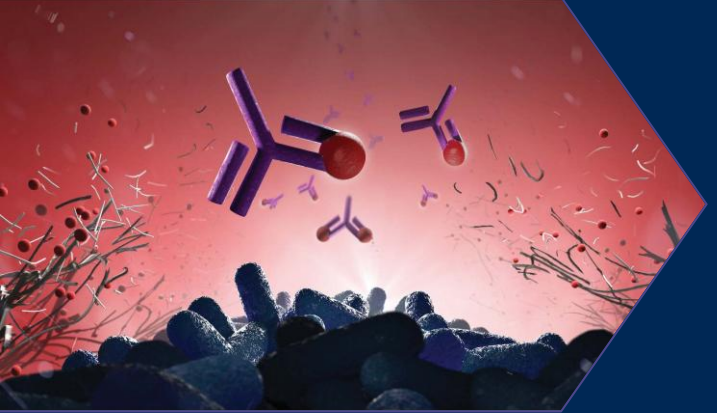
Prior to these roles, David served in operational and legal capacities for various startups, family office funds and was an associate at a large multinational law firm Latham & Watkins LLP. David received a bachelor's degree in economics from Vanderbilt University and his JD from the University of Texas School of Law.

https://clarametyx.com/

February 2026
Non-Confidential Presentation

CLARAMETYX biosciences

Innovating for Impact: Novel Therapeutic Strategies to Address Chronic Lung Infections and Inflammation in Cystic Fibrosis



Targeting Biofilms to Address Chronic Respiratory Disease

Get to know Clarametyx

David V. Richards
Chief Executive Officer

Charles McOsker, PhD
Co-founder & Chief Scientific Officer

Veronica L. Hall, PhD
Chief Operating Officer

Steve St. Onge, PharmD, MBA
Chief Business Officer

Brendan Doran, PharmD
SVP, Clinical Development

Teresa M. Byrne
VP of Clinical Operations

Thomas Hofmann, MD, PhD
Consulting CMO

George Arida, MBA
Consulting CFO

Nationwide Children's

Lauren Bakaletz, PhD
Inventor, Co-Founder, Co-Chair of our Scientific Advisory Board

Steve Goodman, PhD
Inventor, Co-Founder, Co-Chair of our Scientific Advisory Board

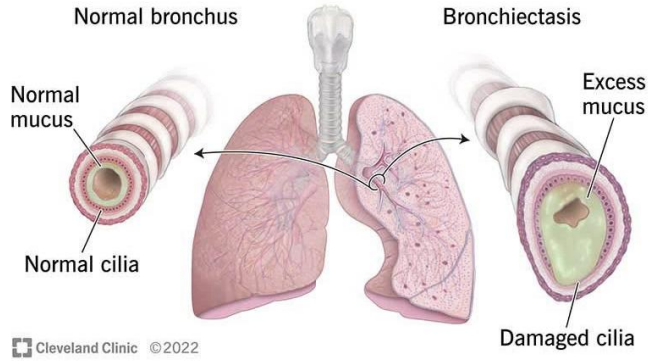
Urgent Unmet Needs in Chronic Respiratory Diseases

Bronchiectatic lung diseases driven by biofilms are associated with significant disease burden

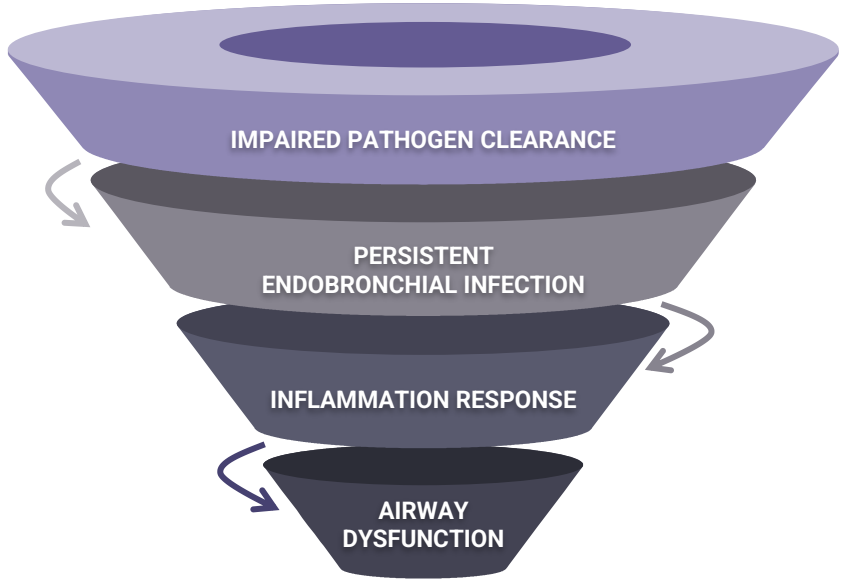
- **The "vicious vortex" of bronchiectatic lung disease:**
  - Chronic bacterial infection
  - Neutrophil-driven inflammation
  - Progressive airway damage and dilation resulting in lung function decline
- **Broad populations with common pathophysiology:**
  - US CF population: 25,000
  - Total US bronchiectasis population: ~500,000
- **Key unmet need: Counter the dominant upstream, pro-inflammatory role of the biofilm to prevent progressive lung function decline**
- **No current therapies directly target the biofilm**

1. Keir HR, Chalmers Semin Respir Crit Care Med (2021). doi: 10.1055/s-0041-1730891.
2. Flume PA, Chalmers JD, Olivier KN. Lancet (2018). doi: 10.1016/S0140-6736(18)31767-7.

BROCHIECTASIS



Biofilm burden drives progressive airway damage, declining lung function



We aim to reduce this burden with an anti-biofilm approach: CMTX-101

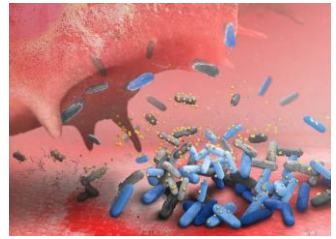
KEY DISCOVERY

Novel protein target that is a primary component of the biofilm scaffolding

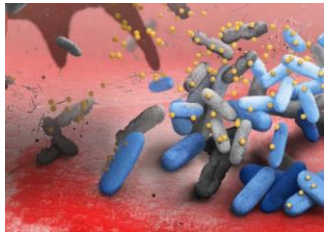
How does it work?

- Bacterial biofilm contains linchpin proteins (DNABII) that stabilize an extracellular DNA structure
- Clarametyx technology captures and removes these proteins, rapidly disrupting the biofilm or preventing it from properly forming
- Proteins are the same across bacteria – approach will support many types of infections

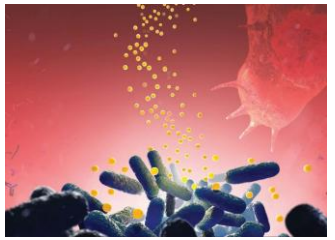
1 **Immune Cells Can Efficiently Clear Bacteria**



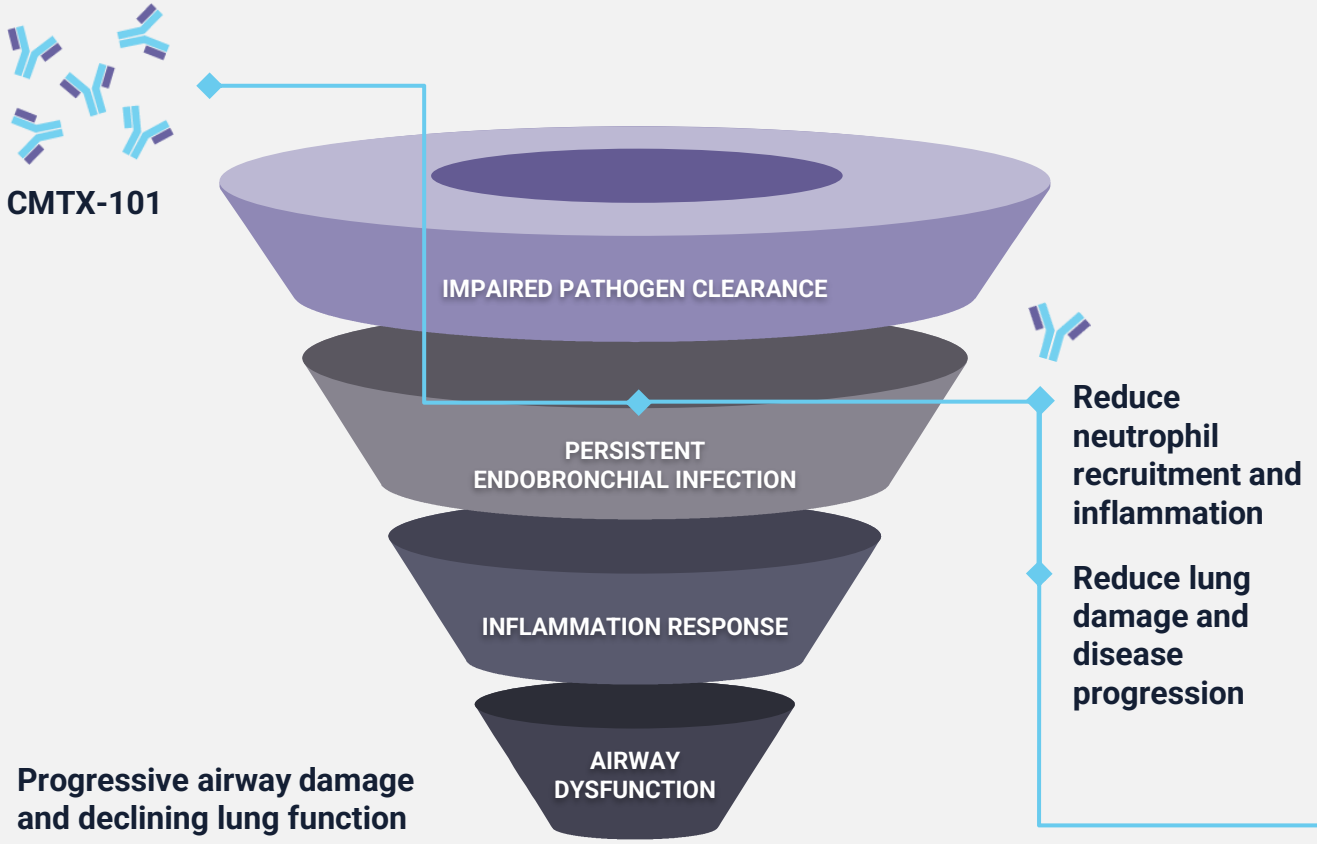
2 **Reduces inflammation to improve recovery**



3 **Makes today's antibiotics work better**



Novel upstream mechanism addresses multiple drivers of lung decline



Clarametyx Technology Intervenes Upstream to Preserve Pulmonary Function

Antibody targets novel protein target in the biofilm structure

- Linchpin DNABII proteins stabilize extracellular DNA structure and promote inflammation[1,2]
- Removing these DNABII proteins causes rapid disruption or prevention[3,4]
- Highly conserved target across biofilms, broad effect against regulatory pathogens

1. **Immune effectors can efficiently clear bacteria**
2. **Reduced inflammation prevents exacerbations, slows lung function decline**

1. Goodman SD et al. (2011) https://doi.org/10.1038/mi.2011.27 2. Kurbatfinski et al. (2022) https://doi.org/10.1128/AAC.01877-21.
2. Brockson et al (2014) https://doi.org/10.1111/mmi.12735. 4. Devaraj et al. (2018). https://doi.org/10.1002/mbo3.563.

Topline Analysis Supports CMTX-101 Development in Bronchiectasis

Results enable future studies in broader bronchiectasis population with similar disease physiology to CF

PRIMARY: SAFETY, PK AND IMMUNOGENICITY

Safety/Tolerability:

No safety signals in both 5 mg/kg and 30 mg/kg dosing levels

Pharmacokinetics (PK) and Immunogenicity in people with CF (pwCF):

PK appears linear, **negligible anti-drug antibodies** (ADAs) and **no neutralizing antibodies**

Detection of CMTX-101 in sputum:

CMTX-101 present in sputum of all dosed subjects with systemic administration

SECONDARY AND EXPLORATORY: EFFICACY TRENDS

Change in neutrophil elastase (NE) activity in sputum:

Reduction of NE activity in 5 mg/kg group through D28, with continuing downward trend

Change in *P. aeruginosa* (Pa) burden in sputum:

Reduction of Pa burden in 5 mg/kg group through D28, with continuing downward trend

Potential Lung Function Benefit

ppFEV1 maintained in 5 mg/kg group through D28, while placebo group declined

How We're Targeting Biofilm-Driven Disease

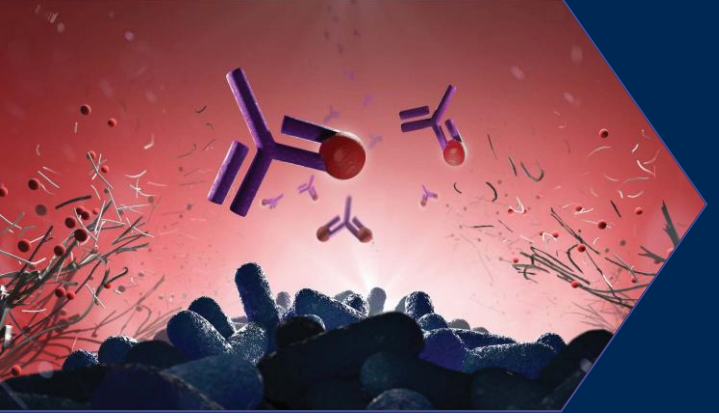
Planning mid-stage study commencing in 2H26, building upon CF Phase 2a trial data

PLATFORM PROGRAM	DRUG MECHANISM	TARGET INDICATION(S)	DEVELOPMENT STAGE	TARGETED MILESTONES
CMTX-101	Anti-**DNABII** mAb (Infusion)	**Bronchiectasis, including CF**	PRECLINICAL · PHASE 1 · PHASE 2A · PHASE 2 · PHASE 3	**Phase 2** ***Initiation 2H26***
CMTX-101	Anti-**DNABII** Subcutaneous mAb (IM)	**Bronchiectasis, including CF**		**Phase 1 Bridging Study** ***2027 Start***

Positive topline data supports progression to Phase 2 Bronchiectasis study

Our next steps

- **Phase 2 bronchiectasis study including CF subpopulation**
  - De-risks bronchiectasis registrational endpoints for CMTX-101
- **Phase 1 subcutaneous healthy volunteer bioavailability study**
  - Enabled with 5 mg/kg planned anchor dose for bronchiectasis Phase 2
  - *Potential to bring into Ph3 in combination or alternative to IV infusion*



Driving Innovation: Our Shared Path Forward

Clarametyx's Commitment

- ✓ **Focused** on measurable milestones to demonstrate scientific validation
- ✓ Invested in a **sustained effort** required for true transformation
- ✓ **Transparent about our roadmap** and the steps we are taking to reach our goals

The Role of This Community

- ❑ Remain **persistent** - pioneering new solutions is inherently difficult and every hurdle is a learning toward a future solution
- ❑ Actively engage in fostering an ecosystem that **encourages coordinated innovation** – let's be sure our "why" is clear

Insights, advocacy, and collaboration fuel our shared progress

Thank you!

- Trial participants and families
- CF Foundation Therapeutics Development Network
- Nationwide Children's Hospital
- CF Foundation
- CARB-X
- Site investigators and teams

How to submit your questions

REVIVE by GARDP

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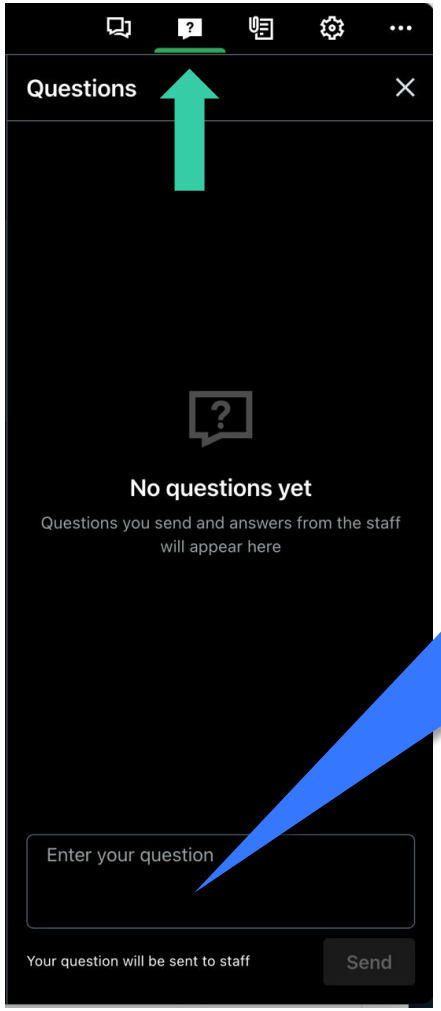

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Thank you to today's speakers

REVIVE by GARDP

Innovating for impact: Tackling chronic lung infections in cystic fibrosis through new antimicrobials

Moderator:
Deborah O'Neil
NovaBiotics Ltd, UK

Jane Davies
Imperial College
London, UK

Neill Gingles
Medicines Discovery
Catapult, UK

David Richards
Clarametyx, USA

Upcoming webinars

REVIVE by GARDP

Current developments in Clostridioides difficile prevention, therapy and R&D

With Benedikt Huttner, Paul Feurstadt, Kerrie Davies & Mark Wilcox

13 March 2026, 17:00-18:30 CET

Upcoming webinars

REVIVE by GARDP

Current developments in Clostridioides difficile prevention, therapy and R&D

- With Benedikt Huttner, Paul Feurstadt, Kerrie Davies & Mark Wilcox
- 13 March 2026, 17:00-18:30 CEST

Journal Club: Key findings from recent publications in antimicrobial R&D

- With Melis Anahtar, Nicole Scarangella-Oman, David Paterson & Nazgul Sakenova
- 26 March 2026, 17:00-18:30 CET

And more coming up!

Be the first to hear the latest REVIVE updates

- On the REVIVE website (revive.gardp.org/webinars)
- Our newsletter
- On BlueSky (@gardp.bsky.social), X (@gardp_amr) and LinkedIn

Thank you for joining us