PHIOGEN

Evolving biotherapeutics.

INCATE

TPP: When and why do you need one

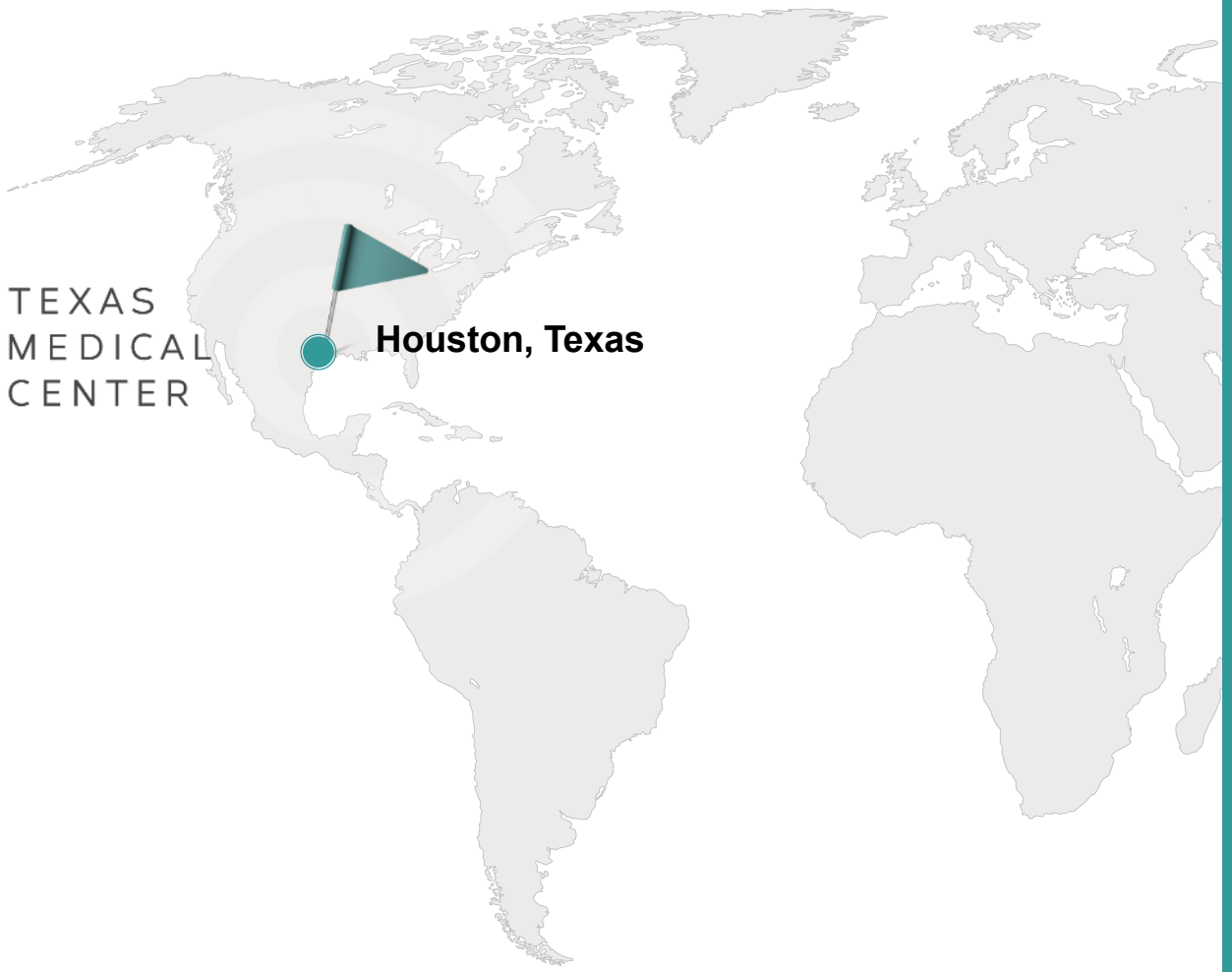
September 2025 | Amanda Burkardt | Virtual Presentation

Company profile

A Baylor College of Medicine biotech startup

Baylor College of Medicine

TMC | TEXAS MEDICAL CENTER



SXSW

CINCATE

CARB-X
Combating Antibiotic-Resistant Bacteria

BUILDERS + BACKERS

PHIOGEN™

Founded: Company launched in 2023

Headquarters: Texas Medical Center Innovation Hub (TMCi) in Houston

Facilities: 5,000 ft^2 in-house laboratory space at brand innovation district Helix Park

Team: A passionate team of 10 scientists, industry veterans and clinical advisors

Capabilities: Proprietary biotherapeutic technology platform

Assets: Robust pipeline of product candidates primed for clinical development

Biotherapeutic Product Pipeline

PHIOGEN™ PROGRAMS	DRUG TARGET	DISCOVERY	PRE-CLINICAL	PHASE I	PHASE II	PHASE III	Next Expected Milestone
PHI-UI-01 in recurrent Urinary Tract Infections (rUTIs)	*E. coli*						**Initiate Phase IB/IIA in 2026****
PHI-BI-02 in blood infections	*E. coli*						Preclinical development ongoing
PHI-SI-01 in dermatology	Staphylococcus spp.						Preclinical development ongoing

*Conventional Phase 1a safety study skipped – First in Human (FIH) achieved through FDA Emergency Investigational New Drug (EIND)
** Clinical timelines are subject to potential regulatory agency review and delays

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People with life-threatening infections have successfully been treated with PHIOGEN™ products

Emergency use was authorized by the FDA for human subjects with drug-resistant bacterial infections

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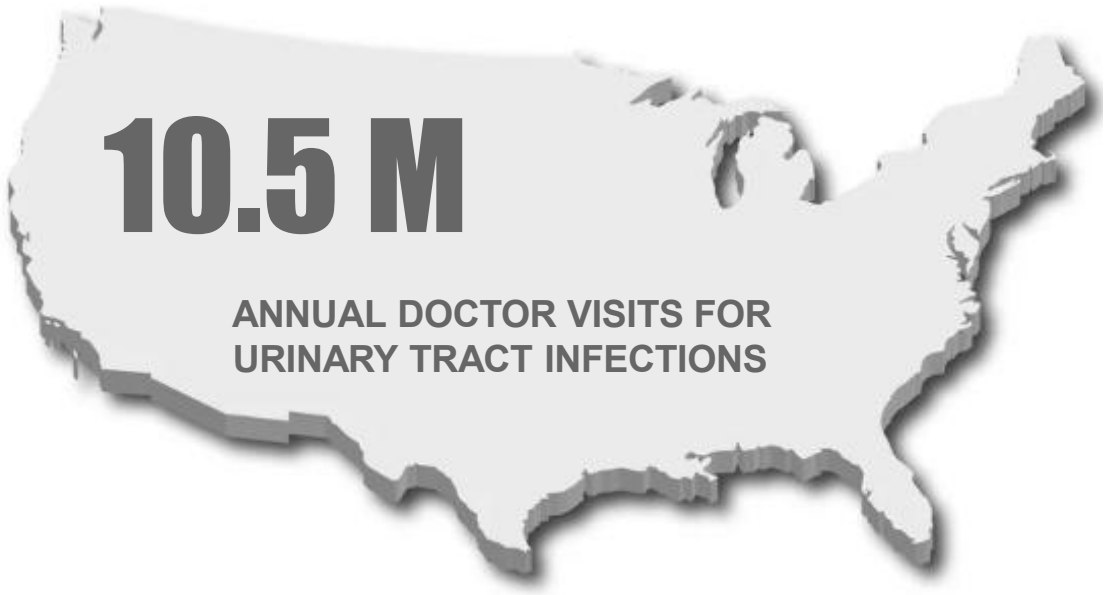
Recurrent UTIs are a **critical unmet medical need**, which can progress from **undruggable reoccurring** infections to **life-threatening invasive disease**



1.5 M **People in the United states who are suffering with chronic urinary tract infections**

Recurrent UTI is defined as 2 or more infections in 6 months or 3 or more infections in 12 months

- 90% rUTI treated in outpatient with women being disproportionally affected
- 57% of initial UTIs were resistant to one or more antibiotic classes
- 6-12 months low dose prophylactic antibiotics for managing rUTIs
- 31% of sepsis start as UTIs leading to 1.6 million deaths in the U.S. and Europe

Sources: Ku et al 2024, Huang et al 2018, Bonkat et al 2018

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First and only immunizing therapeutic to eliminate infection and prevent recurrence

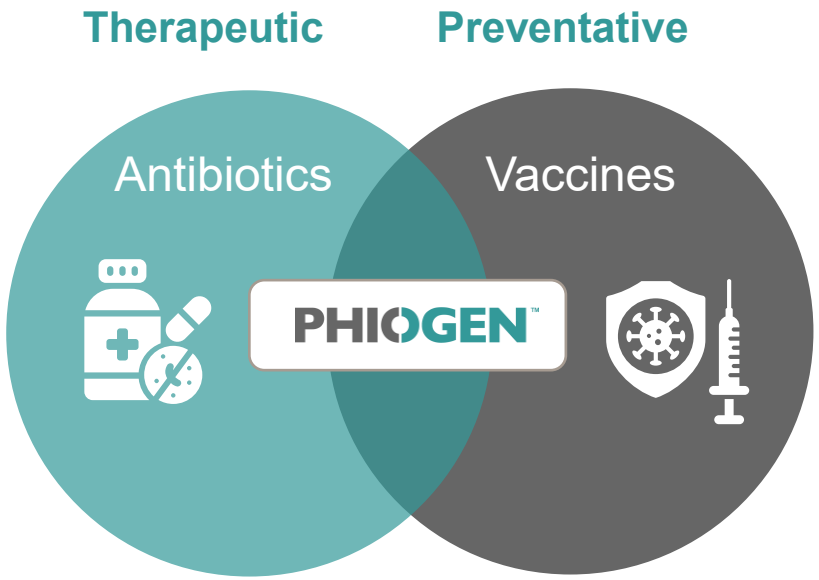
PHIOGEN™ candidates represent a world-first in infectious disease management

DUAL-ACTION THERAPEUTICS

Immediate effect.
Long lasting prevention.

**For illustrative purposes*

Current standard of care for rUTI relies on binary interventions with limited performance



- Antibiotic resistance
- Short-term solution
- Reactive therapy

- Limited vaccine options
- Low performance
- No activity on active infection

Our novel product eliminates invasive *E. coli* infections while driving an immune response

Our technology evolves phage with desired traits…

- **Antimicrobial** to clear active infections
- **Anti-resistant** to sustain performance
- **Immunogenic** to deliver long-term protection

…generating fixed formulation phage that can be scaled for **widespread commercial use.**

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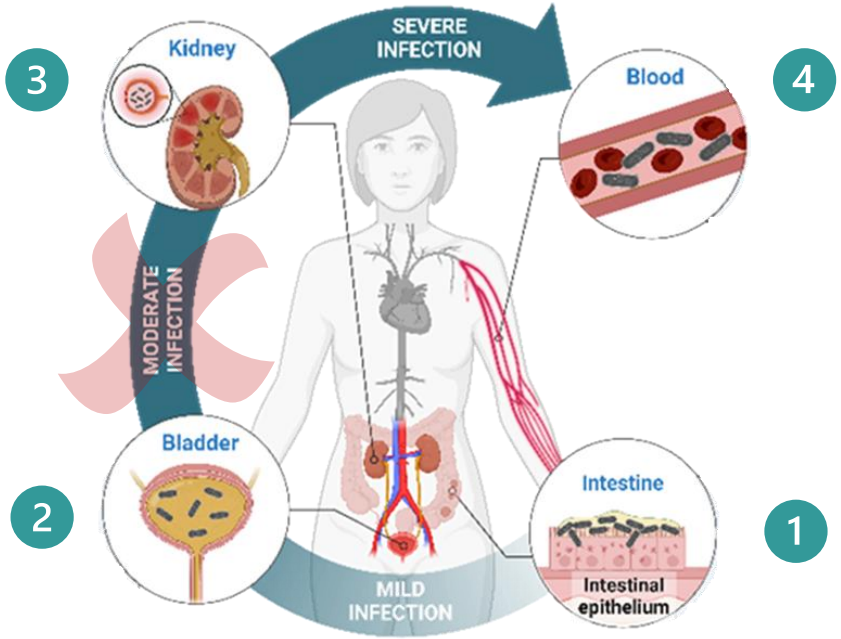
PHI-UI-01: Novel dual-action preventative solution

Preventing recurrent *E. coli* infections through phage-induced killing and immunization

New fixed drug product that stimulates the immune system against the infecting strain of Extraintestinal pathogen *Escherichia coli* (ExPEC)…



… preventing progression of invasive ExPEC that results in **a quarter of all blood stream infections**.

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What is a Target Product Profile (TPP)?

ATPP is the 'North Star' for drug development

- Strategic document outlining desired drug/therapeutic profile at launch
- Guides R&D, regulatory, and commercial decisions
- Aligns stakeholders on development goals
- Framework for FDA/EMA discussions

- **Key Elements:**
  - Indication & patient population
  - Efficacy & safety targets
  - Dosing & administration
  - Differentiation vs. standard of care
  - Commercial & access considerations

- **Bottom Line: "*Your Patient and Product on a Piece of Paper*"**

Standard TPP outline that translates from R&D to clinical development

Key characteristic	Minimal Requirement	Ideal Requirement
Indication	Adults with history of recurrent urinary tract infections (rUTI) with *Escherichia coli*	Adults at risk of rUTI with *E. coli* extended to kidney transplant, neutropenic fever, CAUTI, kidney stones and prostatic hypertrophy.
Target demographic	>18 years old women and men	All ages women and men including pregnant women*
Presentation	Single-dose vial	Multi-dose vial
Dosing regimen	Intravenous (bolus) for 3 days	Intravenous (bolus) once daily for 1 day.
Human dose	TBD	TBD
Safety profile	Local or systemic side effects are equivalent to, or less than those for other treatment	Local or systemic side effects are equivalent to, or less than those for other treatments
Efficacy	>60% reduction of infection	>80% reduction of infection
Duration of protection	One year	Five years; three months after birth*
Coverage	>90% of globally clinically relevant *E. coli* isolates including >90% drug-resistant strains	>95% of globally clinically relevant *E. coli* isolates including >99% of drug-resistant strains
Stability	18 months at 2-8°C, 6 months at room temperature	Three years at 2-8°C, 12 months at room temperature
Contra-indications	Some limitation of use associated with recent receipt of other vaccines	No prohibition of use in patients that have recently received other vaccines
Marketing attributes	COGs acceptable in LMIC	Compatible with Essential Program on Immunization, COGs acceptable in LMIC

**The TPP evolves with each phase of clinical development; in our case, we developed one as soon as the target pathogen and indication was decided.*

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Building a TPP with the end in mind starting with the patient and desired outcome

"Customer Archetype" or "Patient Profile"

- **"Lisa", Female, 46, Bank teller** – otherwise healthy, mild hypertension
- **History:** > 3 UTIs/year for 5+ years, post-menopause onset
- **Symptoms:** Dysuria, frequency, pain, odor with urine
- **Prior treatments**: Multiple antibiotics (resistance emerging), vaginal estrogen, probiotics, cranberry supplements (minimal effects)
- **Impact**: Hospitalized once for urosepsis, missing work, anxiety, intimacy concerns
- **Goal:** Durable prevention strategy beyond antibiotics

Patients | Clinicians | Researchers | Patient Advocacy

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PHIOGEN partners with Live UTI Free for patient insight and pre-enrollment

Topic	Description
Pre-Screening and insight from target patient population	▪ **PHIOGEN has parted with Live UTI Free to** gain patient insight in phage products, experiences with UTIs, and pre-enrollment with our target patient population in our clinical trial. ▪ Deployed a 70-question survey – 420 respondents from over 31 countries across the world *"For over 20 years I have suffered with recurrent/chronic urinary tract infections. I am either suffering the symptoms, or taking an antibiotic and suffering with its side effects, or waiting for one or the other to start again. To be cured of all this, even for just 6 months at a time, would be life-changing for me." – female, 73, California, USA* *"If it works, it would literally change my life. I'm 37 and have experienced UTIs since age 4. I do not remember what peeing without pain feels like, even when I don't have an active UTI there's burning. It has destroyed many of my relationships due to fear of intimacy because of the following pain from new infections being triggered." – female, 37, United Kingdom* *"It would mean the world to me to get solution. I can say years and years of this is pure misery. I have lost almost all to this, even my willing to live." – female, 25, Finland* *"After a urologist told me this year that he doesn't know what to do to help me; this would be so amazing & gives me hope again." – female, 61, South Africa*

LIVE UTI FREE

Live UTI Free is a global patient research, recruitment and advocacy organization.

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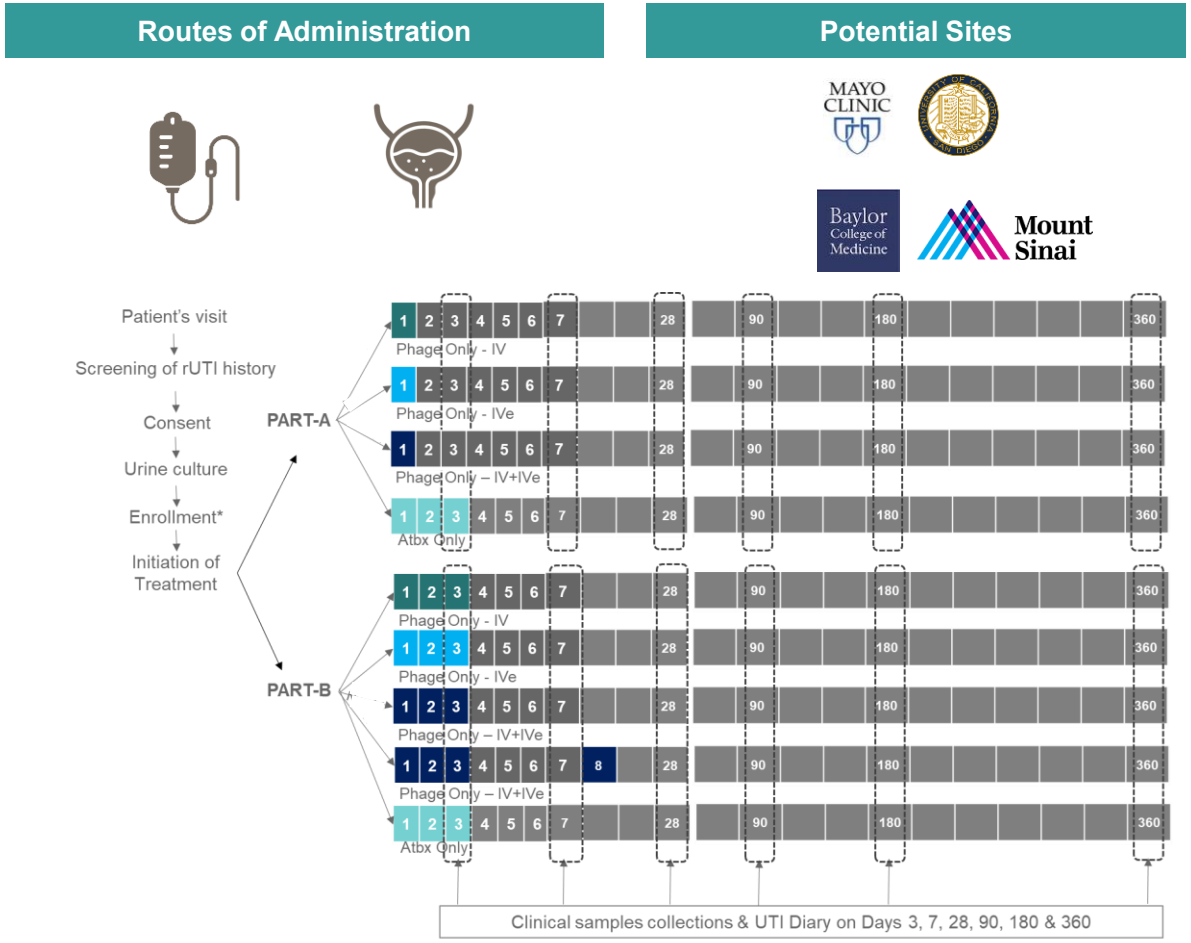
Defining features that shape your TPP across clinical, preclinical, regulatory, commercial, and patient dimensions

TPP should be informed by key insights

- Clinical trial design
- Route of administration
- Dosing frequency
- Shifts in standard of care or clinical guidelines
- Pre-clinical safety read out (trial read outs)
- Need of diagnostics or pre-screening (biomarkers)
- Endpoints and FDA/EMEA guidance
- Health economics and patient preferences
- Manufacturing and delivery challenges

- **Bottom Line:** Your TPP should be a living document that evolves and changes as new information is obtained

Draft example of a clinical trial design based on TPP



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PHIOGEN™ represents the future for controlling infectious diseases

Only company focused on building a clinical pipeline based on **evolved phage that generate immunity**

Highly **experienced team** spanning phage biology, commercialization and clinical development

Uniquely **de-risked candidates** that have undergone authorized **use in human subjects** prior to starting clinical trials

Access to **world-leading science** and infrastructure at Baylor College of Medicine and the Texas Medical Center

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