

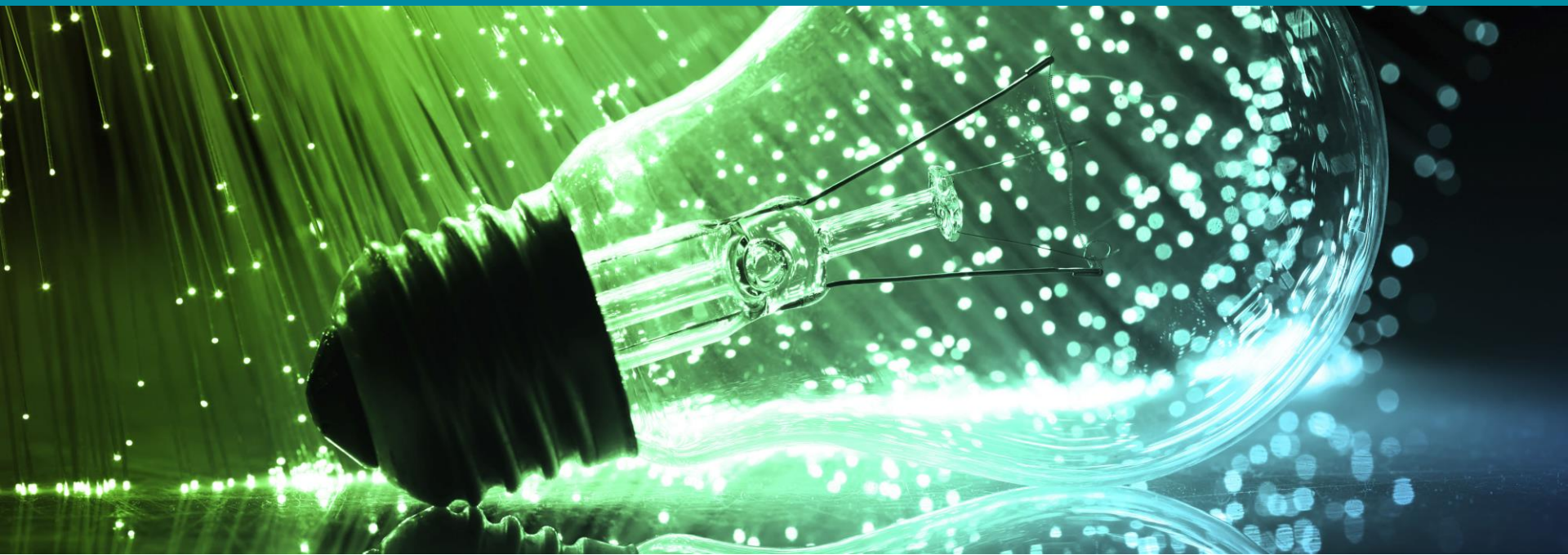
# Unmet Need in ABDD Project

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## Disclaimer

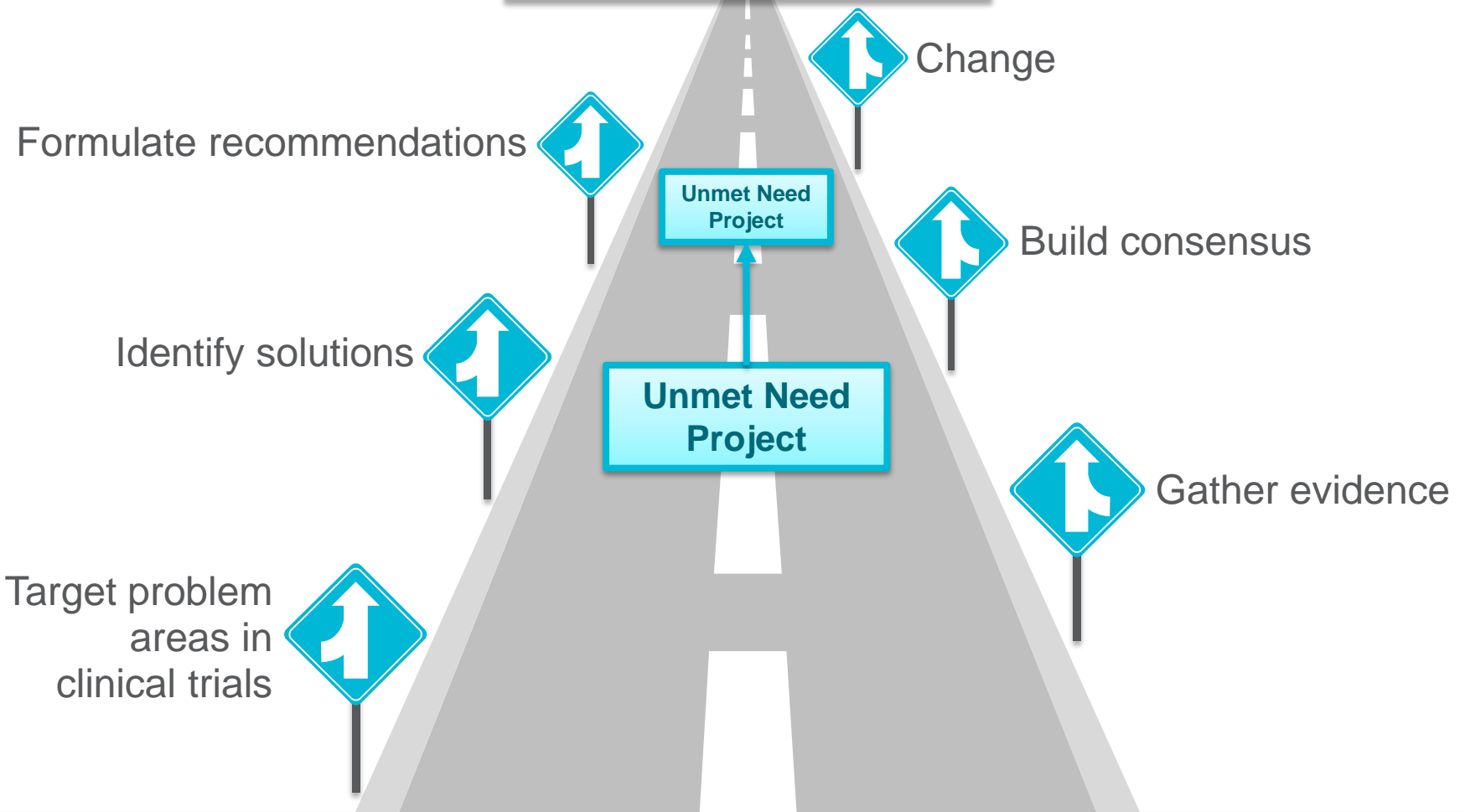
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# Meeting Objectives

- **Present perspectives from patients, caregivers and physicians on antibacterial drugs developed using streamlined approaches**
- **Identify focus group themes and discuss topics which should be further explored or where draft recommendations could be made**
- **Obtain feedback to improve labeling, risk communication, public understanding and stewardship**

**Better, Streamlined,  
Fit for Purpose  
Clinical Trials**



# The Issue

- ▶ Many economic and regulatory disincentives to the development of new antibacterials exist
  - Process is long and costly
  - Trials are difficult to enroll, complete & analyze
  - ROI is low (not blockbusters, low & infrequent use)

***Yet the need to develop more treatment options for patients with unmet need is urgent***

# What We Need to Know

- ▶ The perspective of patients and providers regarding the use of newly approved drugs for which there might be
  - *greater uncertainty and*
  - *lower levels of precision*
- ▶ E.G., when developed using streamlined approaches

# Objectives & Methods

## Objectives:

- Characterize patient and provider opinions regarding the tradeoffs between precision and uncertainty in the context of non-traditional pathways to antibiotic development
- Identify the specific needs for patient and provider education and clarifications to improve patient understanding of the need to expedite the availability of antibiotics to a limited patient population without full knowledge of the risk (safety information).

## Methods:

- Conduct focus groups to solicit patient views
- Conduct SSIs and FGs to solicit provider views
- Identify specific need for education/clarifications

# Anticipated Impact

- Increased tolerance among patients and providers of the tradeoffs between precision and uncertainty in the use of antibacterials developed using streamlined approaches
- Increased awareness among patients and providers of the need for expedited development processes
- Improved uptake and appropriate use of antibacterials developed using streamlined approaches

# Terms

## ➤ Streamlined development approaches

- Refers to approaches to antibacterial drug development for serious bacterial infections that a sponsor ***may consider*** using

## ➤ Unmet medical need

- A condition for which treatment or diagnosis ***is not adequately addressed*** by available therapies

## ➤ Serious conditions

- A disease or condition associated with morbidity that has ***substantial impact on day to day functioning***

## ➤ Antimicrobial Stewardship

- Programs that promote the appropriate use of antimicrobials, improve patient outcomes, reduce microbial resistance, and decrease the spread of infections caused by multidrug-resistant organisms

# Thank you.



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