Unmet Need in ABDD Project

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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

- Change
- Build consensus
- Gather evidence
- Formulate recommendations
- Identify solutions
- Target problem areas in clinical trials

Unmet Need Project
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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