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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