OVERCOMING UNMET NEEDS IN INFECTIOUS DISEASE

Optimize Your Antibiotic Trials with an Experienced and Trusted Partner

Each year approximately two million people in the U.S. alone become infected with multi-drug-resistant bacteria and at least 23,000 of these die as a direct result of these infections. There is an urgent need to bring new antibiotics to the market, yet the pipeline for new antibiotics has dwindled.

The limited number of new antibiotic approvals in recent years has promoted incentivization of antibiotic development and discovery of novel MoA pathways:

► Infectious Disease Society of America (IDSA) launched a 10 by 20 initiative (a global commitment to develop 10 new antibacterial drugs by 2020)

► U.S. Government Gain Act

► 21st Century Cures Act

Many biopharmaceutical companies have recently begun novel antibiotic development, but with little experience face many challenges along the way.

INFECTION DISEASE DRUG DEVELOPMENT PAIN POINTS

► The lack of interest in antibiotic trials means there are limited experienced trial sites

► Confounding factors, such as current use of antibiotics, significantly increase the difficulty of enrolling otherwise eligible patients

► Intravenous administration of antibiotics often threatens the integrity of the study blind

► Lack of incentive for patients to return for follow-up assessments reduces likelihood of meeting endpoints

► A slow and difficult regulatory process requires expert advice and navigation
INFECTIONOUS DISEASE DRUG DEVELOPMENT SOLUTIONS

Manage Your Clinical Trial Pain Points by Partnering with an Industry Leader in Antibiotic Development

Currently, there are approximately 136 antibiotics in development (pre-registration to Phase III). Covance has deep operational expertise and scientific knowledge in infectious disease clinical development, and has experience with the top 15 antibiotic indications, including: acute bacterial skin and skin structure infections, community-acquired, hospital-acquired and ventilator-associated bacterial pneumonia, complicated intra-abdominal and urinary tract infections, bone and joint infections and bacteremia.

**LOCATING THE OPTIMAL TRIAL SITES**
- Xcellerate® Trial Design leverages data in the Covance clinical trial knowledgebase, which houses >40% global trial data at any one time – this real-world data can be used to match areas of highest patient density with the location of high-performing investigators
- We have successfully conducted 143 trials including >3,500 sites and >69,000 patients since 2012

**IDENTIFYING AND RECRUITING PATIENTS EARLY**
- Covance leverages established partnerships with key sites to identify target patients faster
- Between 20-30% of antibiotic trials experience low/non-recruitment, yet this figure was only 10% in recently completed Covance antibiotic studies

**MEETING STUDY ENDPOINTS**
- Our physicians work closely with the operations team, resulting in evaluability rates 10% greater (on average) than the study target
- Site personnel are trained to encourage patients to return for the follow-up visits, while proactively managing and following patient compliance trends

**MAINTAINING STUDY BLIND**
- Covance provides study-specific site training and planning to align staff with protocol requirements
- We use interactive technology to support maintenance of the study blind

**NAVIGATING THE REGULATORY PATHWAY**
- Between 2000-2014, Covance conducted the studies for three out of the four antibiotics that were FDA-approved, and delivered all laboratory testing for the fourth
- Our dedicated regulatory team has extensive experience with local and global regulatory bodies
- We employ effective patient compliance strategies to aid in meeting FDA and EMA requirements

Learn more about our drug development solutions at [www.covance.com](http://www.covance.com)