



# CLINICAL DEVELOPMENT

*Advance your asset from first-in-man through Phase III studies*

**Plan and implement highly targeted and efficient clinical operations.**

**Optimize your trial design and strategy.**

Whether you are preparing to enter a Phase I, II or III trial, your study is unique and the stakes are high. We want to make your success our

priority. At IQVIA™ Biotech, we are using unparalleled real world data and advanced technologies to dramatically improve clinical trial performance, and therapeutic and operational expertise to bring clarity and predictability to the design and start-up processes.



## KEY CHALLENGES

- **Developing study protocols** to deliver an optimal data set, within budget, supporting target product claims
- **Applying innovative trial designs** such as adaptive pathways and bucket studies
- **Selecting optimal sites** to drive faster trial start-up and patient recruitment
- **Maintaining tight control** of trial budget through predictability and transparency of spend
- **Meeting critical milestones** on time and budget, including first-patient-in, last-patient-in, and database lock
- **Conducting interim analyses and post-study close-out** against statistical analysis plan

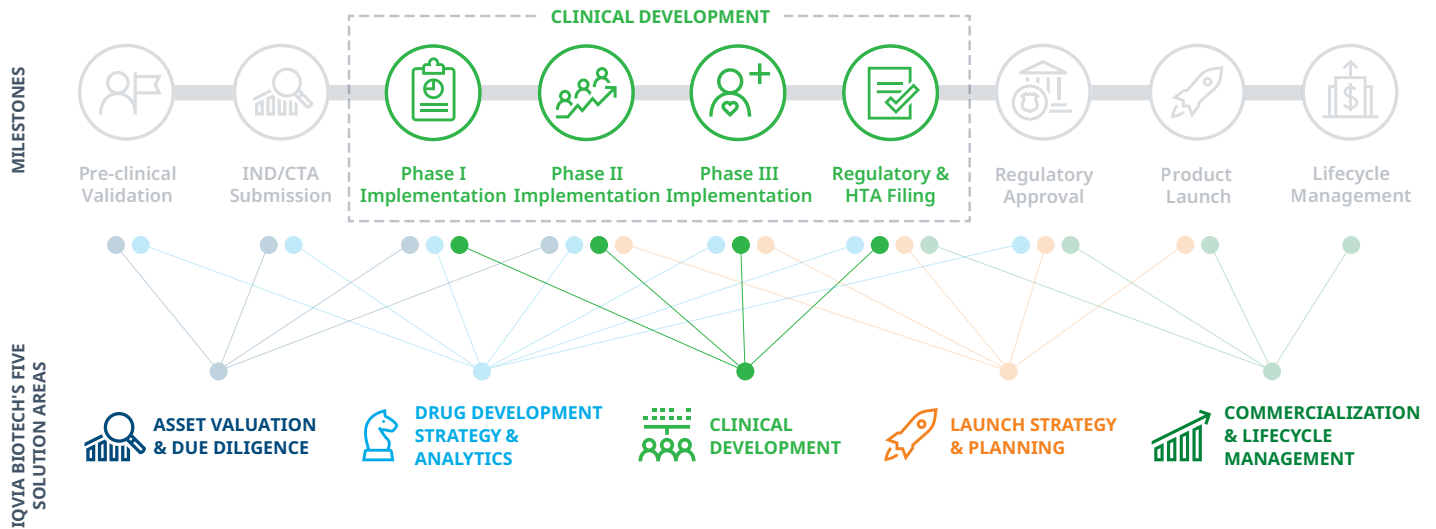
**Clinical Development** is only one of the ways IQVIA Biotech can help you advance your asset. We offer a comprehensive set of flexible solutions that can be customized to your specific needs, meeting you where you are in the development journey.

## WAYS WE CAN HELP

- ✓ Protocol validation and optimization
- ✓ Investigator and site ID
- ✓ Site recruitment and start-up
- ✓ Patient recruitment and engagement
- ✓ Clinical monitoring (CRAs)
- ✓ Project management
- ✓ Lab services
- ✓ Safety and pharmacovigilance
- ✓ Biostatistics
- ✓ Data management
- ✓ Cardiac safety/ECG

# ADVANCE ASSET VALUE ACROSS MILESTONES

Spanning strategic consulting, clinical development, product launch and commercialization



IQVIA Biotech's five key solution areas – Asset Valuation & Due Diligence, Drug Development Strategy & Analytics, Clinical Development, Launch Strategy & Planning, and Commercialization & Lifecycle Management – support you at different milestones in your journey. Our suite of flexible solutions enables you to pick and choose what's right for you. No matter where you are in your development or commercialization journey, IQVIA Biotech can help you advance your asset with confidence and credibility.

## ACTIVITIES FOR THE CLINICAL DEVELOPMENT MILESTONES

### PHASE I IMPLEMENTATION

- TPP/Clinical development planning
- Assess safety profile
- Early proof of concept

### PHASE II IMPLEMENTATION

- Proof of concept confirmed
- Adaptive approaches for Phase III
- End of Phase II agency meeting

### PHASE III IMPLEMENTATION

- First patients enrolled
- Interim analysis and data results
- Commercial planning and Phase IIIb/IV activities

### REGULATORY & HTA FILING

- Application review, writing, publishing, submission
- Pre-NDA/MAA meeting

*IQVIA Biotech can help you strengthen your position with investors and partners, and advance the value of your asset.*