DRUG DEVELOPMENT STRATEGY & ANALYTICS

Align your development strategy to critical market drivers

Create a compelling target product profile and clinical development strategy.

Align to critical market drivers, including regulatory, payer, and commercial requirements.

When you understand the specific landscape and market for your product, you can develop a strategy that will effectively translate into trial execution – avoiding costly amendments down the road. A comprehensive clinical development plan will provide a roadmap for key activities – including cost and timeline factors – for investors and key stakeholders.

KEY CHALLENGES

- **Understanding market dynamics and stakeholder** requirements spanning payers, prescribers, regulators, and patients
- **Mapping the market opportunity** for your asset in targeted therapeutic area and indications
- **Identifying targeted claims and endpoints** needed for desired product usage and reimbursement goals
- **Articulating and anchoring your clinical and commercial product goals** in a target product profile
- **Mapping clinical and/or regulatory plans** required for approval and value demonstration to drive funding

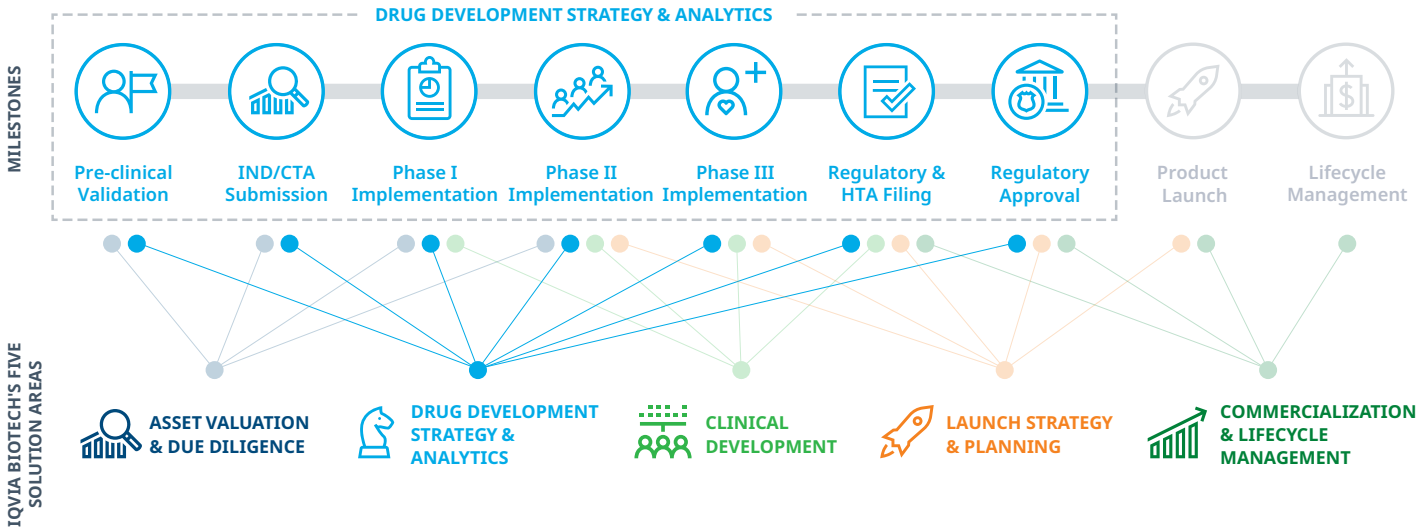
Drug Development Strategy & Analytics is only one of the ways IQVIA™ Biotech can help you advance your asset. We offer a comprehensive set of flexible solutions that can be customized to your specific needs, meeting you where you are in the development journey.

WAYS WE CAN HELP

- **Therapeutic area strategy**
- **Indication sequencing**
- **Asset prioritization**
- **Payer and commercial endpoints**
- **Value proposition**
- **Target product profile**
- **Regulatory strategy and plan**
- **Clinical development strategy/plan**
- **Translational medicine and biomarker strategy**
- **Real world evidence strategy**

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 DRUG DEVELOPMENT STRATEGY & ANALYTICS MILESTONES

PRE-CLINICAL VALIDATION

- Asset valuation
- Technical evaluation
- IND/CTA gap analysis

IND/CTA SUBMISSION

- Pre-IND/Scientific advice meeting
- Protocol writing
- Planning for accelerated designations

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.

IQVIA™ BIOTECH

CONTACT US

iqviabiotech.com