CATALYST ONCOLOGY

Catalyst Oncology Consulting

Catalyst Oncology Consulting is focused solely on the development of new treatments in Oncology. Catalyst Oncology Consulting provides a unified expert platform to support biotech companies through all phases of development from lead optimization through NDA. We partner with clients to effectively develop their assets by utilizing the best emerging science and regulatory support to improve cancer diagnosis and treatment.

Services We Offer

- **Drug Development Strategy Workshops** provide a unified framework to assess risk, identify gaps and lay out an optimum development pathway for FIH or Investor targets
- **Flexible Access** to highly experienced Regulatory, Preclinical, Toxicology, Pharmaceutical Development partners and Oncology SMEs.
- **Bespoke Consulting Project Teams** offer an integrated collaboration to support clients' key milestones and provide flexible, complementary knowledge and resources.

Industry Leading Experts

Offering the opportunity to assemble experts and partners, with an average of 20 years expereince, to advise clients on minimum & optimal development pathways, including:

- Pharmaceutical Development
- Biomarker Development
- CMC
- Medical Writing
- Pharmaceutical Physicians
- Biostatisticians
- Medical Scientists
- Translational Scientists
- Regulatory Experts
- PD/PK Experts
- Toxicologists
- Clinical Operations/Oncologists

"Catalyst clearly demonstrated they have the expertise and connections to evaluate this scenario thoroughly. They were very easy to work with and the quality of the output we received, together with its speed, was impressive"
Clinical Pharmacology Leader
US Biopharmaceutical

"A fabulous job – many thanks all. A clear basis around which to plan our transition from discovery to development."
CEO
UK Biopharmaceutical

CATALYST ONCOLOGY

We are your partners in product development, serving as an extension of your study team

Exploratory

- Preclinical Development Strategy and Planning
- Portfolio Assessment and Prioritization
- In-licensing due diligence
- Vendor identification and Oversight
- Program Management

Non Clinical

- Regulatory pathway assessment
- Toxicology assessment
- PK/PD analysis
- Preclinical study modeling
- Preclinical study design and protocol development
- Bioequivalence strategy

CMC

- IND/CTIS/MHRA/TGA preparedness review
- Process development scoping
- Product development plan
- Manufacturing Compliance assessment
- QMS planning and implementation
- GMP review

Pre-IND

- Agency liaison
- Clinical development strategy
- Clinical study design and protocols
- Pre-IND meeting plan, preparation & attendance
- Special designation requests
- IND/BLA/CTIS/MHRA/TGA preparation and submissions

IND/CTA

- IND/BLA/CTIS/MHRA/TGA preparation and submissions
- Protocol amendments
- Labeling review

EOP2A

- Review and assess clinical trial results
- Clinical hold review and response
- Pediatric study plan
- Meeting plan, preparation, attendance and follow-up

Pre-NDA/BLA

- Phase III study review
- Meta analysis
- Meeting plan, preparation, attendance and follow-up

Regulatory

- Global agencies
- Preparation and submission
- Regulatory compliance

We can help

- Develop and deliver optimized Drug Development Plans to deliver the best asset to patients & investors
- Deliver a gap analysis report to frame an asset's technical, clinical and commercial risks and likelihood of success
- Assess the challenges and unique questions through a unified SME platform.