PRA Health Sciences

FACT SHEET

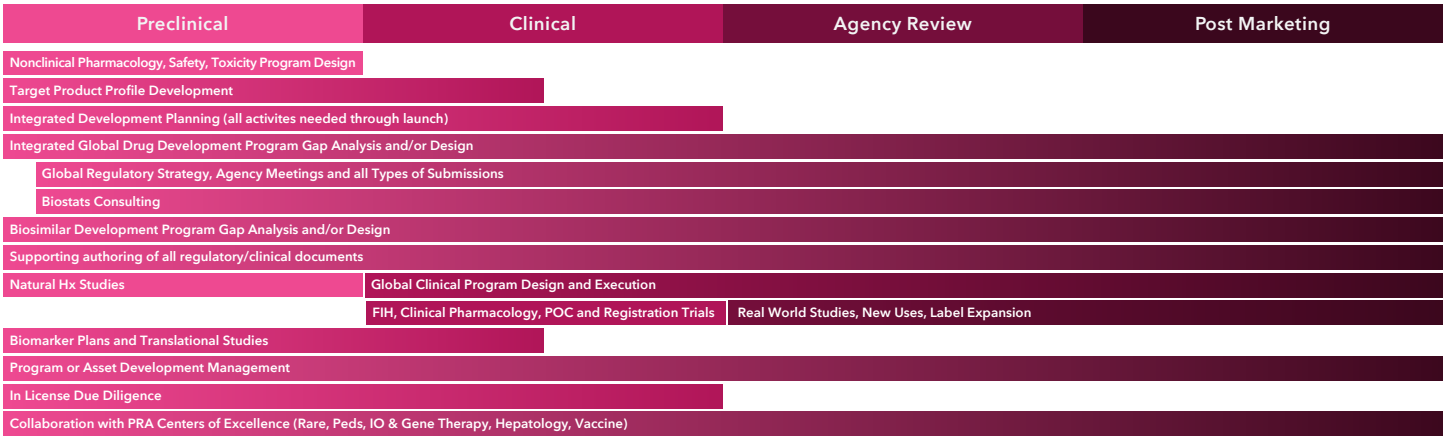
Center for Global Drug Development

PRA's Center for Global Drug Development (CGDD) knows what it takes to deliver new drugs to the market. Our leaders ensure that all services focus on the goal of achieving patient access to new drugs.

Executive Summary

The CGDD team, staffed by former pharmaceutical development leaders, has experience across the development lifecycle and a strong working knowledge of all key functions, from non-clinical to clinical to regulatory, statistics, manufacturing, and beyond. The CGDD team ensures that various development activities come together seamlessly to deliver successful outcomes.

The CGDD team works closely with subject matter experts (SMEs) across PRA and client organizations to ensure that client scientific strategy and business objectives are translated effectively into business and strategic outcomes. Using a holistic approach, CGDD helps clients meet their goals through strategic planning, support, and oversight throughout the product lifecycle continuum.



"Delivering new drugs to patients who need them is a complex undertaking. A successful strategy requires a holistic view of the landscape and a sharp focus on delivering assets to the marketplace, subject matter expertise, and an ability to see the whole playing field—ensuring that everything comes together seamlessly. The asset-focused, end-to-end view of the CGDD team helps ensure successful development of our client's assets."

MARK A. LANE
Executive Director, Center for Global Drug Development at PRA Health Sciences

Expertise & Experience

- With team members each having 25 years of global product development experience, CGDD provides developmental and strategic guidance for products from early stages through post-marketing support.
- All CGDD experts have led global cross-functional drug development teams. These experts have experience across many therapeutic areas and study phases, with a deep understanding of key functions, including manufacturing, formulation development, drug discovery, safety pharmacology, toxicology, regulatory, statistics, and more.

Commitment to Patients

The CGDD team focuses on the patient throughout the drug development process. For some clients, that may mean consulting a PRA expert in areas like rare diseases, pediatrics, or precision medicine. For others, it involves communicating early and often with patient advocacy groups. Our development experts apply their expertise to develop plans that make products and treatments accessible to patients.

Key Features

- We have a strong working knowledge of the various functional activities required for drug development.
- Through corporate experience, business acumen, and critical understanding of drug development we assist clients in the design and execution of global drug development and asset management strategies.

Contact

PRA's Center for Global Drug Development supports all stages of development, including:

- Global drug development strategy and target product profiles
- Program and asset management
- Integrated development strategies and plans
- Global regulatory strategy, agency meetings, and submissions (IND, NDA, BLA, and study specific)
- Clinical program and study design
- In-license due diligence
- Non-clinical and toxicology study planning
- Development program gap analyses

Contact the team at:
PRGDDTeam@prahs.com