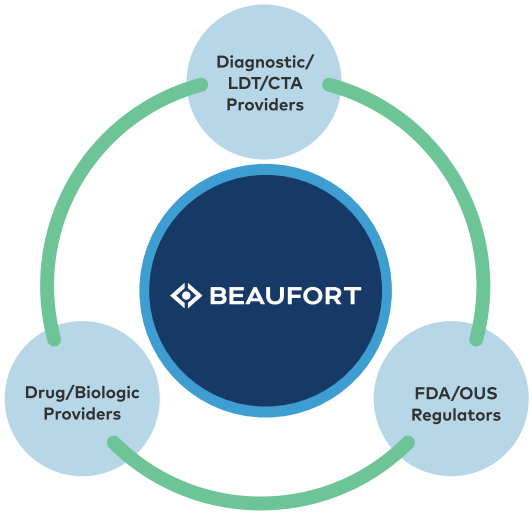
CDx expertise to accelerate co-development

Beaufort understands the evolving and complex global landscape of companion diagnostic development. Our team's clinical and regulatory experience, combined with our ongoing interactions with worldwide regulators, is what sets us apart from other CROs. From concept to market, we partner with you to develop a highly tailored and adaptable companion diagnostic co-development program that drives towards contemporaneous drug/biologic and diagnostic approvals.



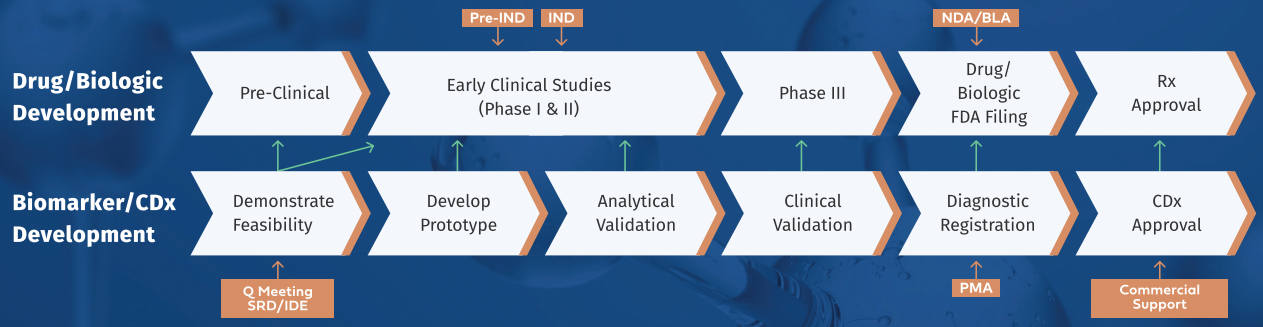
SEAMLESS COORDINATION TO INTEGRATE ALL ASPECTS OF CDX DEVELOPMENT

At Beaufort, we prioritize seamless integration with your team and other key stakeholders. Dedicated project managers oversee communication and coordination, ensuring transparency and alignment throughout the co-development process. This integrated approach optimizes decision-making and ultimately accelerates the successful market launch of your companion diagnostic.

> **Beaufort has been critical in filling gaps in knowledge and bringing a CDx to market. They have been helpful in providing insights and guidance on the best regulatory approach.**
>
> Emily Brooks, Director, Biomarkers and CDx Development, SDP Oncology

BEAUFORT

END-TO-END CDX SOLUTIONS



COMPREHENSIVE SUPPORT FROM FEASIBILITY THROUGH APPROVAL AND BEYOND

Support Feasibility

- CDx partner selection, single-site vs. distributable model considerations and platform selection
- Novel vs. follow on CDx
- Co-development process, milestones, and timelines
- Assay feasibility and analytical validation strategies
- QMS considerations

Facilitate Clinical Studies

- HUD/ HDE and breakthrough designation support
- Early FDA (CDRH) engagement – pre-submission and pre-IDE planning
- Significant risk determinations (SRDs)
- IDE submission preparation – originals, supplements, amendments, and annual reports
- Abbreviated IDE requirements for use of NSR devices in therapeutic trials
- CDx analytical testing requirements, protocol development and review
- CDx clinical validation strategies – bridging studies and transfer of efficacy analyses

Enable Clearance/Approval

- Submission support (510(k), De Novo, PMA)
- BIMO and manufacturing gap analyses and mock inspection support
- Labeling claims expansion and "group" labels
- Post-market considerations
- Product Changes and Supplementary Filings

GLOBAL CDX MARKET EXPERTISE

Our regulatory and quality assurance solutions span:

- IVDD to IVDR Transitional Planning and Implementation Strategies
- Performance Evaluation Support – Requirements for CDx Performance Studies
- Technical Documentation Preparation and Review

FIND MORE INFORMATION AT beaufortcro.com

GET IN TOUCH WITH US AT info@beaufortcro.com

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