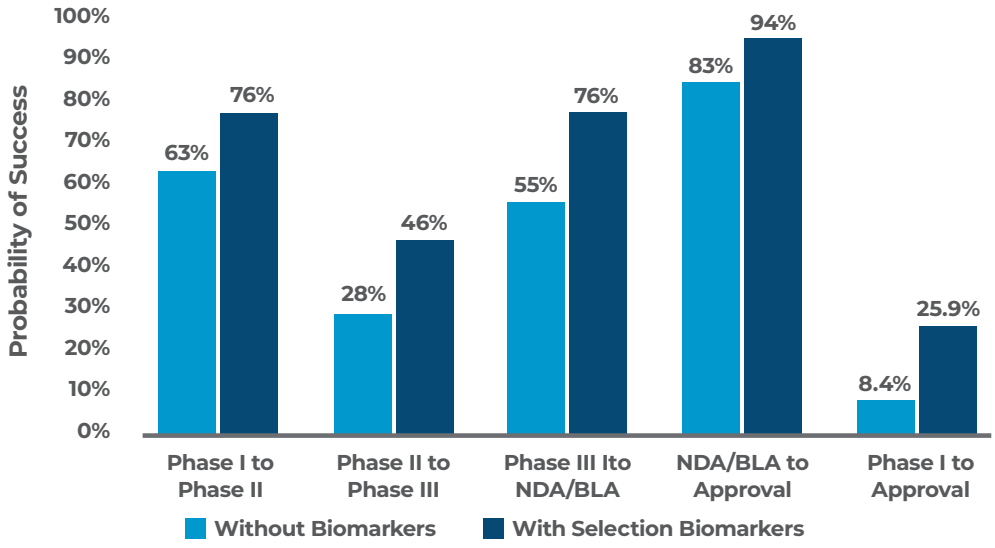
Flagship BIOSCIENCES

PHASE 1 THROUGH COMPANION DIAGNOSTICS (CDX) SUPPORT

Flagship Biosciences, Inc. provides contextual biomarker data services, powered by our proprietary image analysis technology, allowing our pharmaceutical partners to make confident, more informed decisions about their development programs.

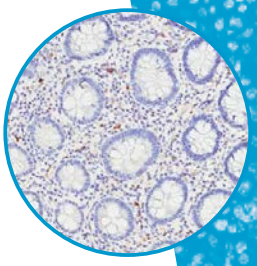
Our integrated team of scientists, pathologists, tissue analysts, data scientists and assay development experts has supported over 350 clinical trial studies in the last 6 years in our CAP/CLIA laboratory.

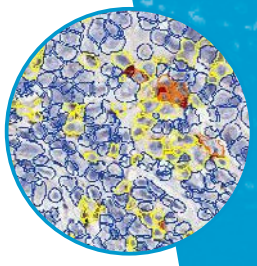
Probability of Success
With or Without Selection Biomarkers



The probability of drug development success is consistently higher with the co-development of an appropriate biomarker beginning at the early stages of development. Co-development results in increased drug efficacy, better safety profiles, and more personalized treatment.

These improved results are amplified with the use of Flagship's proprietary image analysis platform, which provides the industry's most accurate large tissue data sets which cannot be obtained with any other method.





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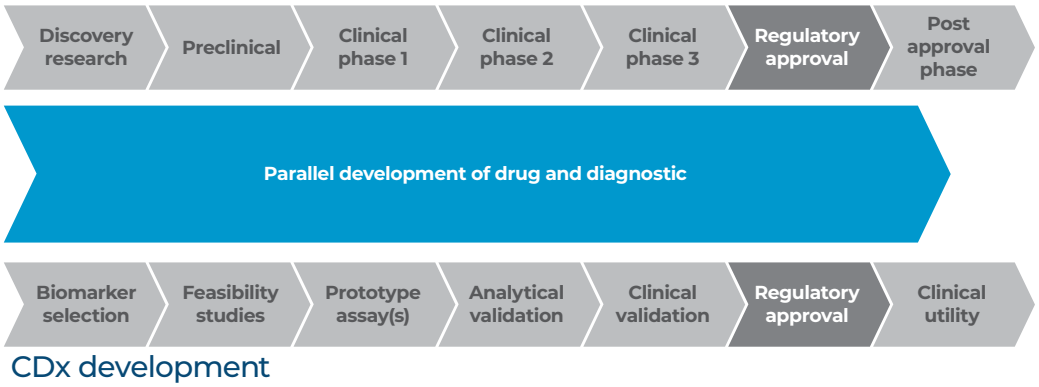
Expert insights for your tissue data.

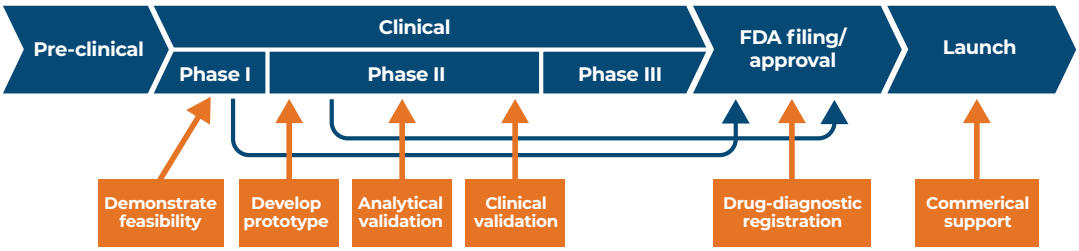
At each step in the process, our team will provide contextual data, including tumor, stoma, and immune characterization, to ensure the right patients as well as the most informative endpoints are obtained. Due to the objective nature of image analysis and the large volume of data that is generated, pathology interpretations are unbiased and cut-point evaluation can be adapted at any stage to mitigate risk.

Drug development



CDx development

Pharmaceutical development stages



A companion diagnostic assay provides information that is required for the safe use of a therapeutic drug. A complementary diagnostic identifies patients that respond well to a drug. It also mitigates risk by enabling the assessment of patient benefits.

PHASE I: ***Demonstrate feasibility:*** Flagship can use existing CDx, RUO, or novel IHC/ISH assays along with our proprietary image analysis to develop solutions that accurately and consistently identify the biomarker(s) that are most critical to your therapeutic.

PHASE II: ***Develop prototype:*** Flagship will validate the appropriate tissue biomarker solution as a Lab Developed Test (LDT) in our CAP/CLIA accredited lab for use in patient selection.

Analytical validation: While delivering the biomarker solution as an LDT, Flagship and our partner will collect the analytical data to ensure that it is accurately selecting the appropriate data to understand the performance of the biomarker.

Clinical validation: While delivering the biomarker solution as an LDT, Flagship and our partner will collect the performance data to ensure that it is accurately selecting the appropriate patients for therapy.

PHASE III / FDA FILING: ***Drug-diagnostic registration:*** Flagship will work with our partners to ensure that the analytical and clinical data collected during the clinical trial shows that the performance of the LDT is sufficient to support a CDx.

LAUNCH: ***Commercial support:*** Flagship's CAP/CLIA lab can support any tissue-based CDx test within the U.S. Our global partners, or any lab capable of running the validated IHC/ISH assay, can support the wet assay portion of the test while Flagship can perform image analysis on images obtained from any of these labs.

TO LEARN MORE ABOUT FLAGSHIP

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