Flagship BIOSCIENCES

Expert insights for your tissue data.

ACCELERATING DRUG DEVELOPMENT THROUGH INNOVATIVE TISSUE ANALYSIS

YOUR PARTNER FOR FASTER DRUG DEVELOPMENT

YOUR LAB DOWN THE HALL

A guide for key scientists and managers in immuno-oncology drug development.

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INSIDE THIS GUIDE

INTRODUCTION: THE CHALLENGE FOR DRUG DEVELOPERS

Successfully bringing a drug to market is an extraordinarily complex process that involves significant challenges, including:

- Identifying how a drug works in a clinical setting.
- High research and development costs.
- Increasing failure rates of drug candidates.
- Multi-year timelines required for each phase.
- Complex regulatory requirements and processes.

With intense competition, speed to market is key. Drug developers need innovative ways to help minimize the impact of these challenges in order to accelerate drug development.

$1.3 BILLION

AVERAGE COST TO GET A NEW DRUG TO MARKET*

*Estimated Research and Development Investment Needed to Bring a New Medicine to Market 2009-2018 March 3, 2020 *JAMA*

WHAT DOES IT TAKE TO ACCELERATE DRUG DEVELOPMENT?

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Technology reduces research time.

- Artificial intelligence and advanced data analysis deliver higher-quality data.
- Automation in data management and delivery creates faster turnaround.

People speed up decision-making.

- Expert interpretation puts data in context for actionable intelligence.
- Science team collaboration gives insights for more informed problem-solving.
- Project manager coordination facilitates faster decision-making.

Process drives efficiency.

- Combining data with scientific analysis identifies best path forward, quicker.
- Regulatory guidance during development saves time and costs.

Why accelerate?

- Reduce delays in delivering critical drug therapies.
- Determine failed drug candidates faster.
- Get to market before the competition.
- Save significantly on costs.

ACCELERATION THROUGH INNOVATIVE TECHNOLOGY

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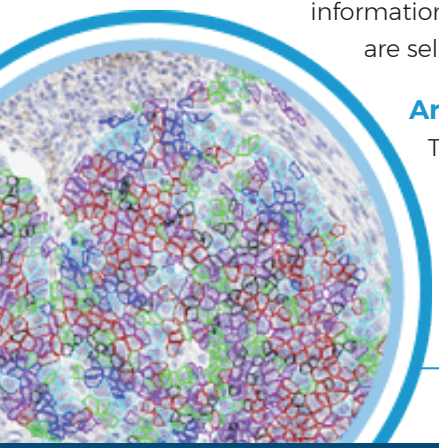
Technology gives researchers a distinct advantage in improving drug development success.

Using technology can discover issues earlier in development that might cause a drug to fail. Researchers can then make critical decisions about modifying or abandoning the molecule before getting into more expensive phases later on.

Technology can also provide more complete contextual information that improves how patients are selected for clinical trials.



Artificial intelligence.

The use of artificial intelligence is rapidly ushering in a new era in drug development.

Machine learning, through pattern recognition, can dramatically shorten timelines especially in identifying drug candidates and optimizing clinical trials.

Data mining.

Drug developers need to understand how the large amounts of data — whether from their own research or published resources — affect their programs. Deep text mining, using machine learning and other sophisticated analysis techniques saves time, money and unnecessary experimentation.

Innovation in tissue analysis.

Human tissue analysis is vital in uncovering whether a drug in development will achieve its intended goals. New, proprietary technologies are simplifying this complex approach, and accelerating drug development by bridging therapeutic development with real-world results.

COMPUTER VISION COUNTS EVERY CELL. TISSUE IMAGE ANALYSIS BRINGS BIOMARKERS TOGETHER.

TECHNOLOGY IS ONLY PART OF THE PICTURE

Technology gives researchers a powerful way to gather incredibly comprehensive data faster, and often more accurately, than human-driven methods. But it's the human insight that accelerates drug development through faster decision-making.

Drug developers need access to scientists, pathologists and other experts to manage, interpret and apply data learnings to help them identify the best path forward, quicker.

CASE STUDY

Determining predictive markers of response in patient cohorts.

Background: Drug developer needed to determine efficacy of immune-oncology drug in clinical trial patients. The approach is to look for the presence of tumor-killing T Cells via CD8 expression to see if the immune system is being activated. Manual pathology work by the client had not produced reliable CD8 counts or information about the tumor microenvironment.

Flagship's analysis: Using image analysis and AI machine learning, we were able to understand:

- If there was an immune response in the tumor microenvironment.
- If the CD8 T cells interacted with the tumor.
- If the CD8 T cells infiltrated the tumor.

Advantage to client: With this highly accurate analysis, not available anywhere else, our client could quickly understand how CD8 T cells were interacting and infiltrating the tumor nests.

For details on this case study and others, contact Flagship Biosciences.

COMBINING TECHNOLOGY AND SERVICE

With the need to manage costs and accelerate timelines, contract services are playing a more significant role for small- and medium-sized drug developers. Flagship Biosciences uses a combination of technology and service to support drug developers — in effect, a "lab down the hall" to improve your chances of success.

Sophisticated tissue image analysis.

Flagship uses a proprietary process, incorporating machine learning using patented digital tissue imaging technology, statistical analysis and pathologist oversight to produce accurate, large tissue-data sets.

This process uses object-based image analysis rather than pixel-based. By working on objects produced by image segmentation, more elements can be used to improve classification accuracy.

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Flagship's proprietary process:

- Maximizes use of scarce tissue resources.
- Provides increased sensitivity, precision and reproducibility.
- Captures thousands of data points per cell.
- Delivers contextual data, including tumor, stoma and immune characterization.
- Can be applied to existing tissue samples.

Flagship provides end-to-end support.

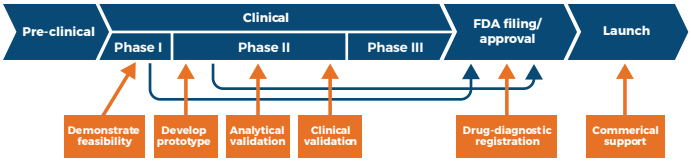
Oversight — Board-certified pathologists have final say on tissue analysis.

Analysis — Data scientists interpret how the data impacts drug development and create custom reporting procedures to give you actionable insights.

Consultation — Scientists and pathologists collaborate with you on taking next steps, improving patient selection strategies and more.

ACCELERATING YOUR DRUG DEVELOPMENT PROGRAM

1. Investigate tissue image analysis and other technologies that can save time and improve outcomes.
2. Review where your drug is in the timeline and how the tissue data can address challenges in biomarker co-development, patient selection and regulatory approval.
3. Begin collaboration with partners.



FLAGSHIP AND YOUR DRUG DEVELOPMENT TIMELINE.
AT EACH STEP, OUR TEAM PROVIDES CONTEXTUAL TUMOR AND IMMUNE DATA TO INFORM DECISIONS.

PHASE I: Demonstrate feasibility: Accurately and consistently identify the biomarker(s) that are most critical to your therapeutic.

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

PHASE III/FDA FILING: Drug-diagnostic registration: 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 can support the wet assay portion of the test while Flagship can perform image analysis on images obtained from any of these labs.

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ABOUT FLAGSHIP BIOSCIENCES

Our goal is to be as accessible as "your own lab down the hall" and give you a distinct advantage in drug development with our proprietary tissue-analysis technology and end-to-end support.

WINNER:

2020 Frost & Sullivan Enabling Technology Leadership Award —
AI-enabled Digital Pathology Solutions in Immuno-oncology

Discover how Flagship Biosciences can dramatically shorten your drug development timeline and improve patient outcomes. Contact us for more information and a free consultation.

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OUR LAB

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