Flagship Biosciences
Empowering Oncology with Computational Tissue Analysis

Contextually, analysis is more than just mere 'measurement.' Unfortunately and counter-intuitively, in the oncology space, results of tissue analysis are perceived as units on a single digit scale. The varied levels of insights that pathologists can glean from tissue samples cannot be entirely shoehorned into single numbers. For assays can tell more than just Yes/No of whether a patient should be inducted for a clinical trial in question. An assay scorecard derived from novel technologies such as machine learning, can tell the who, why, why not, and how about a given patient population.

Immuno-oncology (I-O) has proven to be an anchor point for the archers of oncology in their mission to develop (and shoot) therapeutic arrows against cancer. Owing to its promising potential, the novel approach—wherein the body's immune system is made to fight cancer—has picked up full traction in the pharmaceuticals and diagnostics space. However, for I-O, when it comes to clinical trials, the uncertainty factors associated with traditional assays reduce clarity deriving enough information to support treatment and decision-making. When the very gist of immuno-therapy revolves around developing treatment strategies that are personalized to patients, it is essential to equip pharma developers with better predictive diagnostic tools. In other words, the information or content required to select patients who are better suited to a particular immunotherapeutic drug, needs to be contextual. The generic bio-marker based diagnostics assays that are also applied for supporting I-O drugs falls short of providing a holistic view on factors that contribute to tumorigenesis, different features of the disease in question, and even on patient response profiles. In effect, regardless of the similarities between therapy and tumor type, there is a need for clinically proven, patient specific selection strategy using a unique testing and scoring approach. Besides, for technology-aided next-gen sequencing to truly marvel at I-O, in-depth visibility is imperative into any kind of cell interaction and reaction. This is where Flagship Biosciences brings in their Computational Tissue Analysis (cTA™) platform that delivers a detailed tissue-based portrait of tumor and tumor microenvironments.

THE FLAGSHIP SCORECARD

"We make existing tissue-based assays more powerful as predictive diagnostics by adding significantly more data from our cTA™ platform. We deliver this data in a scorecard spanning several different areas where the sample will show the biological context of the tissue. How tumor and non-tumor cells interact with biomarker-positive versus biomarker-negative cells, and how all that leads to a potential patient being identified a responder or non-responder to a given therapeutic, essentially ensuring that the right drug gets to the right patient," says Trevor D Johnson, CEO of the company.

Flagship's IO Scorecard represents a patient's specific set of 'biofeatures' visually. In addition to providing patient response predictions and helping distinguish patient populations, scorecards can establish a baseline to help identify changes in
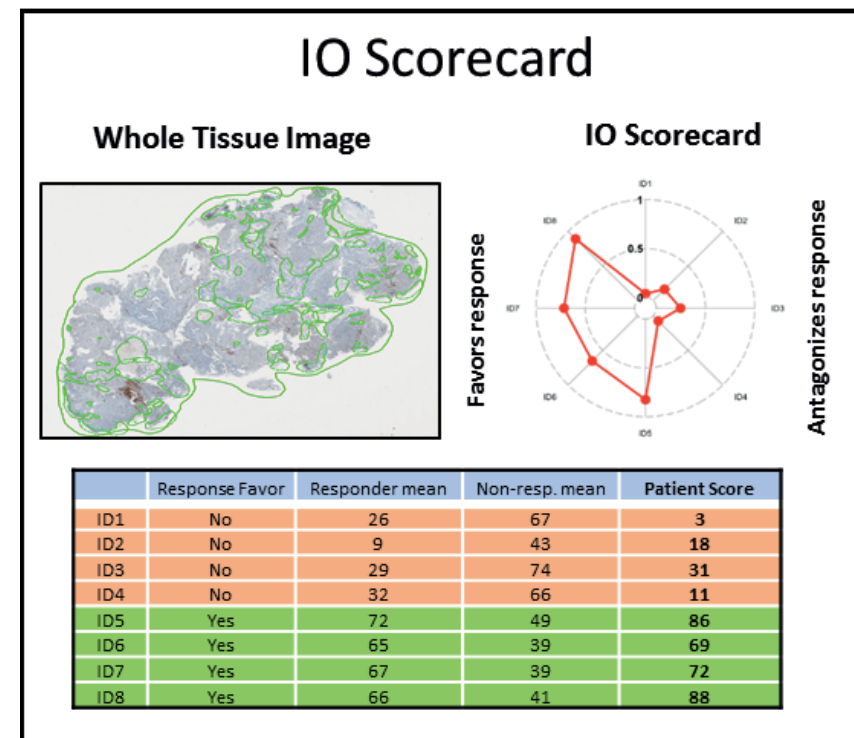
Trevor D Johnson

biofeature profiles over time such as immune response to a therapy regimen. cTA™'s powerful machine learning determines which Biofeatures are the most important for distinguishing responders and non-responders. Once its algorithm is trained in tune to the trial in question, the biofeature can be used to select future patients for treatment. Crucial features

	Response Favor	Responder mean	Non-resp. mean	Patient Score
ID1	No	26	67	3
ID2	No	9	43	18
ID3	No	29	74	31
ID4	No	32	66	11
ID5	Yes	72	49	86
ID6	Yes	65	39	69
ID7	Yes	67	39	72
ID8	Yes	66	41	88

for response are ranked and selected to build a high power model for predicting patient response. Moreover, Information conveyed through Flagship's scorecard report can be easily comprehended by patients as well.

EASE OF ONBOARDING

The ease of leveraging Flagship's powerful solution is yet another massive differentiator of the company. Clients need not have to change their existing workflows, investments in technology, or even the assays that they use. "Clients simply send us an image, or a copy of the image, that is already part of their

traditional pathology workflow. From there on we apply our cTA™ analysis on those images and return to them diagnostic information that is far beyond what they can achieve in the traditional sense," mentions Johnson.

Unlike most image analysis software in the market, cTA™ emphasizes identifying the cells first instead of rendering them as pixels. In addition to their robust technology platform, Flagship Biosciences brings in entire operational workflows that pertain to histo-technology, image, and analytics, pathologists and scientists. This ensures that each sample that goes through the operation is being correctly identified, characterized, and their data is promptly reported back to the company's clients. The company thus positions itself as a one-stop shop for their clients by helping them streamline the various functional elements of I-O trials.

Johnson recalls the recent collaboration of a client, a major pharma company in the country, who was able to successfully revive trials on a promising oncology compound, which they almost discarded off as a futile throwaway drug. During their last-shot phase 1 trial, the company was not able to figure out why patients were not responding to the medication. Flagship Biosciences' image analysis solution identified the biological setting and context of tissues that defined responders and non-responders. Convinced of their value proposition, the pharma company hired Flagship Biosciences to run all of their inclusion criteria for this assay moving forward down the clinical trial pathway, through to phase 2 of the trial.

> " Our goal is to empower physicians with a scorecard that ensures the right drug gets to the right patient "

With the rate of advancements in I-O, the diagnostics landscape will turn all the more complicated and harder to tackle for clinical players who refrain from modernizing their traditional assay means. With an entity like Flagship Biosciences at their trial's disposal, it will be harder not to. Having established their worth in the I-O clinical trials arena, Flagship Biosciences envisions to further sharpen their edge within clinical diagnostics. "We are planning to have our data as part of a patient report which will go back to the oncologist to decide which therapeutic pathway is best for a patient. That is the level of involvement we are looking to achieve," concludes Johnson. CR