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How to Develop Your Impact-Maximizing Strategy in Early Development

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Indication prioritization is the process to identify, evaluate, and compare/contrast different potential development paths for a platform or drug to enable a company to strategically select the indication(s) that have the greatest potential for inflecting value and fulfilling corporate development objectives.

A thorough indication prioritization project can add value across multiple scenarios including identification of indications that: (1) provide the most rapid path to generating meaningful preclinical and clinical validation / proof-of-concept (PoC) of an asset and/or a platform; (2) have the greatest clinical and commercial potential; and (3) are of greatest interest and value to internal and external stakeholders including investors, potential partners, and ultimately payers, physicians and patients. Employing a robust, strategic analytical process to prioritize therapeutic indications not only benefits the company by providing a risk-mitigated, valuable, and defensible path to market, but also benefits patients in accessing differentiated medical innovations.

Recommended Approach

Indication prioritization is a multiple-step process that should involve (1) developing an understanding of the company's unique scientific value proposition and its corporate development goals, (2) compiling a starting list of indications relevant to the company's platform / mechanism of action and goals, (3) triaging the starting list, and (4) diving deep into the scientific and commercial rationales and risks and benefits resulting in a shorter list of thoughtfully-curated, prioritized indications.

While some companies have a clear vision for where a product or platform may be *scientifically* relevant, we have found that many companies when selecting initial indications do not sufficiently analyze *development and commercial risk and opportunity* and the resulting (positive or negative) impact on value and optionality. Even developing a meaningful starting list of potential indications is not a trivial undertaking as there are often more relevant indications than one might think. For example, in our Autoimmune and Inflammatory Disease practice we have carefully curated a list of over 150 possible indications, as no definitive list of autoimmune and inflammatory conditions exists. We continually vet and update this list based on evolving understanding of the diseases combined with learnings from research with experts in the space.

With a relevant starting list in place, we engage in a triage step to evaluate each indication at a high level. Executing on an initial triage results in a smaller set of potentially attractive indications, enabling more time and resources to be spent carefully vetting and prioritizing among only those most likely to be relevant for a particular company/product/platform.

With a smaller and more manageable list in place, the final step is to evaluate each indication using a set of scientific, clinical, and commercial criteria. We develop comprehensive rating matrices based on key technical and strategic factors unique to the company. We incorporate up to 16 different factors such as mechanistic rationale, predictive preclinical models, competitive landscape, market size, regulatory path, clinical trial feasibility, biomarker strategy, and trial

design requirements (length, size, risk). We also recommend including physician, payer, and business development key opinion leader (KOL) interviews to then extract insights on expert rationale and direction for innovators.

After completion of this indication prioritization process, companies have a clearly defined and robustly supported path to pursue those therapeutic indications that have the highest probability of scientific, clinical, and commercial success and thus are of greatest interest to investors and potential partners.

Positive Impact for Companies

There has been a major shift for biotech and pharma investments during the first half of 2022, forcing many companies to adapt. Companies need to show their value quickly and clearly, position themselves in ways that prepare them for higher-value financing and partnerships, and/or extend their cash runway and narrow their focus. Prioritizing indications, along with having a clear and well-researched and -supported rationale for your choices, **informs and justifies the overall strategy** of the company and positions companies for success in this new market environment.

While the result of an indication prioritization is immediate clarity on which development path(s) to pursue, there are long lasting benefits as well. The final data repository after an indication prioritization provides an operational tool that can be referenced while navigating future indication selection decisions. A company can refer to this when talking with potential partners or investors as proof that all options were considered and that decisions were made based on a thoughtful, thorough, and strategically minded process. When a program is advancing through the clinic, this data repository can also be reviewed to determine the best follow-on or expanded development pathways.

Positive Impact for Patients

We need to **make the drug development process more efficient and effective** for patients to receive access to life-changing and -saving medical advances. When companies more thoughtfully and strategically prioritize indications based on scientific relevance AND a high probability of development and commercial success, they more strategically **deploy resources and capital and are better able to demonstrate their value to investors, physicians, patients, and payers.** This results in more useful and differentiated **medical advances getting to the market quickly and successfully** to help patients, including patients in currently underserved indications.

Summary

Medical innovation is advancing at a historic rate but often companies are pursuing the same targets in the same indications, introducing commercial risk and potentially thwarting investment and partnerships until meaningful differentiation is clinically or even commercially differentiated. Executing a robust indication prioritization process enables companies to identify and pursue a risk- and opportunity-balanced portfolio and favorably position their programs with key stakeholders.

About

For over 30 years, Lumanity (https://lumanity.com/) has advised hundreds of biotech companies with diverse platforms and targets across therapeutic areas and stages of development and often conduct indication prioritizations that provide an expert, objective analysis, and recommendations to support decision making and investor- and partner-relations.

Danielle Marra, MS, MBA
Principal, Autoimmune and Inflammatory Disease Co-Lead, BioConsulting at Lumanity (https://lumanity.com/)

As Principal, Autoimmune and Inflammatory Disease Co-Lead, BioConsulting, Danielle co-leads the rapidly growing autoimmune and inflammatory disease practice. Within this space, she is responsible for helping early-stage companies more quickly or efficiently achieve value inflection via a range of projects, including indication or target prioritization and sequencing, therapeutic area growth strategy, identification and evaluation of partnering opportunities, and commercial market assessments.

Prior to joining the firm in 2011, Danielle spent 5 years as a scientist at an emerging biotech company focused on the oral delivery of peptide therapeutics for metabolic and autoimmune bone diseases.

Danielle holds a Master's Degree in Molecular Biology and an MBA from Rutgers University. She holds a BS in Biology from the College of New Jersey.

David Lomb, PhD
Vice President, Director of Consulting Services, Autoimmune and Inflammatory Disease Co-Lead, BioConsulting at Lumanity (https://lumanity.com/)

As a Vice President, Autoimmune and Inflammatory Disease Co-Lead, BioConsulting, David leads opportunity assessment, indication prioritization, search, and strategy projects. David co-leads the autoimmune and inflammatory disease practice, leads the fibrosis and ophthalmology practices, and regularly contributes to projects in several other therapeutic areas including dermatology, neurology, and oncology.

Prior to joining Defined Health (now part of Lumanity) in 2010, David was a postdoctoral fellow at Harvard Medical School working in the Paul F. Glenn Laboratories for the Biological Mechanisms of Aging as well as the Early Technology Assessment Program sponsored by the Office of Technology Development.

David earned a PhD in Pharmacology from the University of Rochester and Bachelor of Science degrees in both Biochemical Pharmacology and Psychology from the University at Buffalo.

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