

Introduction

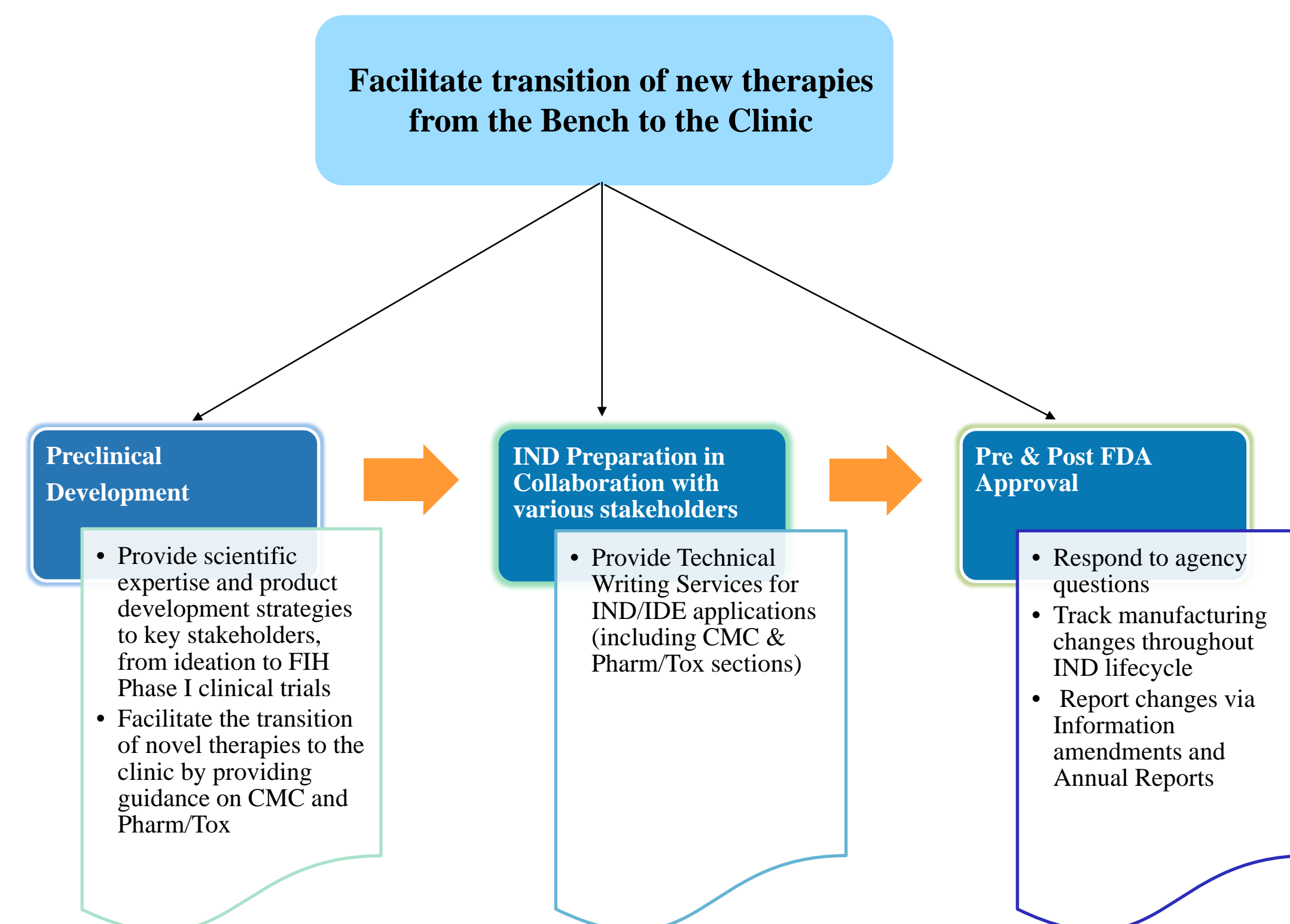
- The world around cancer research and treatment is evolving rapidly. While unmet medical need will continue to drive future cancer research and development, the core values of any cancer treatment will remain the same – Safety, Efficacy, and ultimately Cure
- The exponential advancement of science and technology, alongside fast-paced regulatory changes and requirements impacts development of new cancer therapies
- Regulatory compliance and product development are key enabling factors that facilitates the movement of innovative therapies through investigative and regulatory processes
- At MSKCC, the Investigational New Drug & Device office (INDO) and Product Development (PD) Units review regulatory trends, utilizing technology and scientific expertise which guide the decision making process for novel agents

Regulatory Oversight

- It is important to understand the regulatory standards and guidelines at an early stage of drug development for any cancer therapy
- Regulatory surveillance will ensure balancing change in regulatory trends with advancing technological and scientific breakthroughs
- The INDO's comprehensive regulatory strategy helps to eliminate all potential hurdles that could impact successful IND applications from pre-clinical to IND approval

Product Development

- The product development team (PDT) at MSKCC facilitate translation of therapeutic discoveries to clinic by providing scientific expertise and strategy to meet the required clinical, non-clinical, and critical quality attributes of the clinical product for FIH clinical trials



Roles of MSK product development team at pre and post IND approval stages

- The PDT collaborates with our core facilities, investigators, and regulatory team to achieve all the preclinical requirements for MSK's IND/IDE studies in the pipeline including the preparation of IND applications/technical documents for regulatory submissions

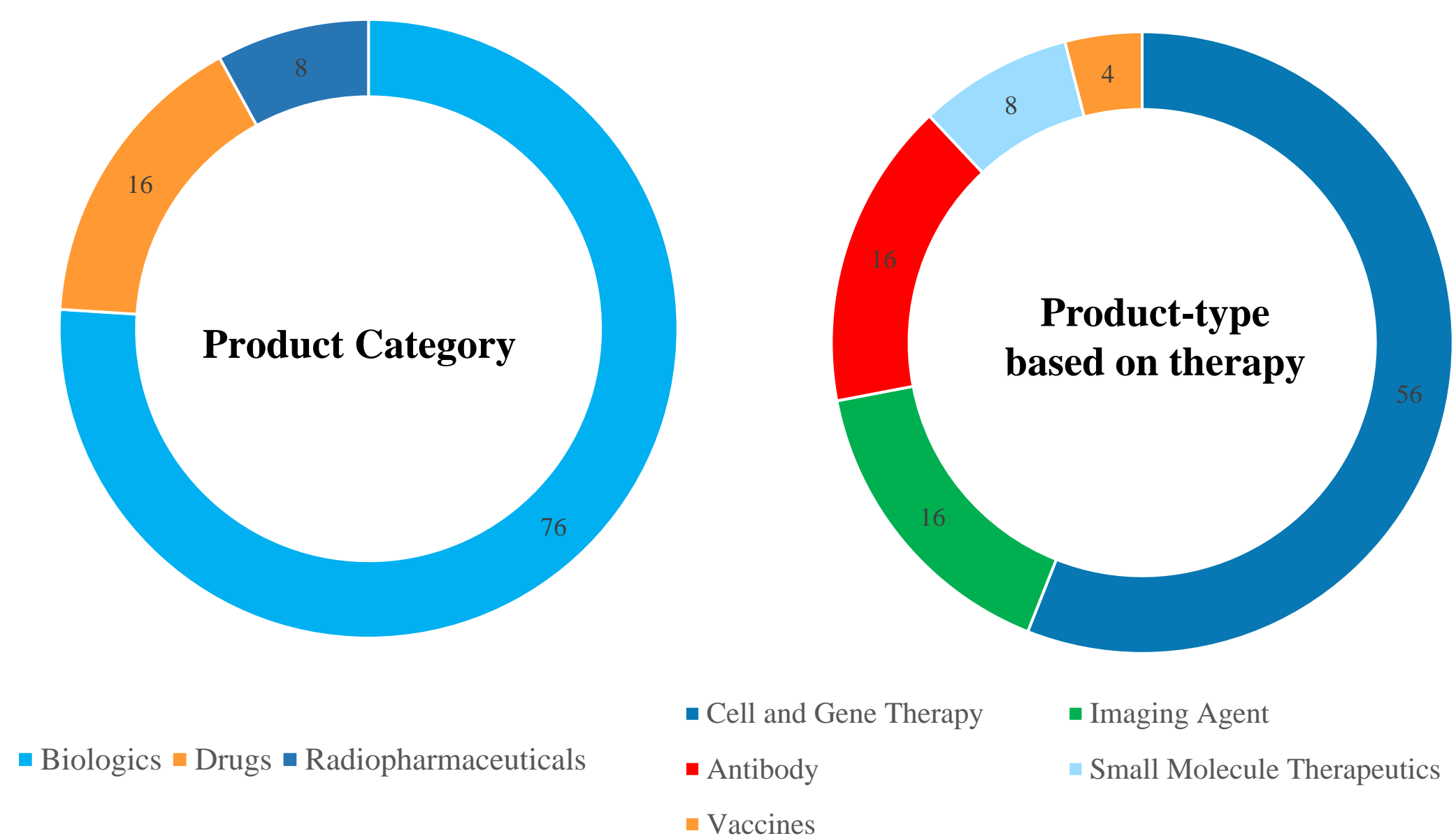
Key Resources

INDO & PD team continues to utilize the following internal resources and FDA's drug development programs to develop new therapies:

- FDA's expedited drug development programs such as breakthrough therapy drug designation, orphan drug designation, and rare pediatric disease designation to accelerate development of therapies for unmet medical needs
- Internal review committees – The Investigational New Drug and Device committee reviews and addresses both the clinical and regulatory component of the new IND application before FDA submission
- External collaborations with biotechnology partners
- Internal SOP's and regulatory resources for investigators

Outcomes

- Improved regulatory compliance and decision-making process - We continue to learn from FDA's feedback during IND review process and have successfully managed to improve our IND submission process for both clinical and regulatory components of IND applications
- Return on Innovation (ROI) - MSKCC continues to utilize FDA's expedited drug development programs for unmet medical needs to contribute towards ROI
- Enhanced pace of product development – Effective regulatory strategy and cross-functional collaborations have helped us reduce the time-lag between “aha” moment of ideation for a therapy to its clinical development



Current project pipeline of MSK manufactured products

Future Directions

- Enhancing the current protocol management system to streamline regulatory operations
- Develop commercialization pathways transitioning MSK manufactured products to biotech collaborators
- Continue to improve record of regulatory successes and drug approvals
- Regulatory Intelligence
 - Continue to develop creative regulatory pathways and solutions
 - Optimize digital solutions
 - Use data to create actionable regulatory information

