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REINVENTING THE UNSUSTAINABLE PHARMACEUTICAL R&D MODEL

POTENTIAL FOR A HEALTHIER HUMANITY

The race to create a vaccine to combat the COVID-19 virus and the resulting pandemic exposed the world to something the scientific and pharmaceutical community knew for more than three decades prior; the promise of advancements in biotechnology can enable synthesis of certain biological molecules in microorganisms and other living cells using recombinant DNA technology. Commonly known as large molecules or biologics, it includes a wide range of products: nucleic acid-based therapies (e.g., RNAi, gene therapy, gene editing), blood components, cellular and tissue therapies (e.g., CAR T cell therapy, allogeneic transplants) and others. Potential uses of these innovative therapies create new options for treating a multitude of rare diseases, cancer, Alzheimer's, Huntington's, and immune deficiency, thus explaining how seven of the ten top selling drugs are already biologics.

While biologics and specifically cell gene therapy have been receiving much glamour, attention, and venture funding, small molecule therapies are by no means taking a backseat. They accounted for 75 percent of all new medicines approved in the US in 2020 and will continue to make up the lion's share of prescriptions. This is especially true as they are useful in non-genetic, prevalent, and multifactorial diseases which affect a broad spectrum of patients. Further, the ability to design small molecules capable of interacting with and modulating RNA can open new avenues to target challenging disease pathways that have previously been considered undruggable. The future is very exciting for the health of humanity, but there is a problem. If the existing unsustainable Pharmaceutical R&D model is not dramatically reinvented, many viable treatments may never make it market.

CHALLENGES TO OVERCOME IN THE EXISTING PHARMA R&D MODEL

Exponentially rising cost

Over the past eight years, global research and development expenditures in the pharmaceutical industry grew by over 45%. It went from 137 billion in 2012 to a total of nearly 200 billion U.S. dollars globally. This increase in expenditures is permeating throughout the R&D process including the initial research of disease, the compound testing over pre-clinical, and all clinical trial stages. With the CAGR for the industry at one-fifth lower than R&D expenditures at 36%, there is less return on capital thus destroying shareholder value.

Long cycle times

The overall complexities of drug development are increasing. For one, biologics have opened more options that need to be evaluated faster. Another concern is that the growing number of oncology trials as well as the number of therapies targeted at unmet needs and smaller patient subgroups have made it difficult to enroll and retain clinical trial participants. Overall, these issues have created delays and contributes to year-on-year growth in cycle times.

Productivity & Approval

The number of drug candidates that make it from Phase I trials to market remains low at approximately 10% despite the significant increase in R&D investment. Even with various 'fast-track' efforts from regulatory agencies like the US FDA, the number of approved drugs peaked in 2018 at 53 with data as recent as 2021 taken into consideration.

Addressing Payors in the R&D Process

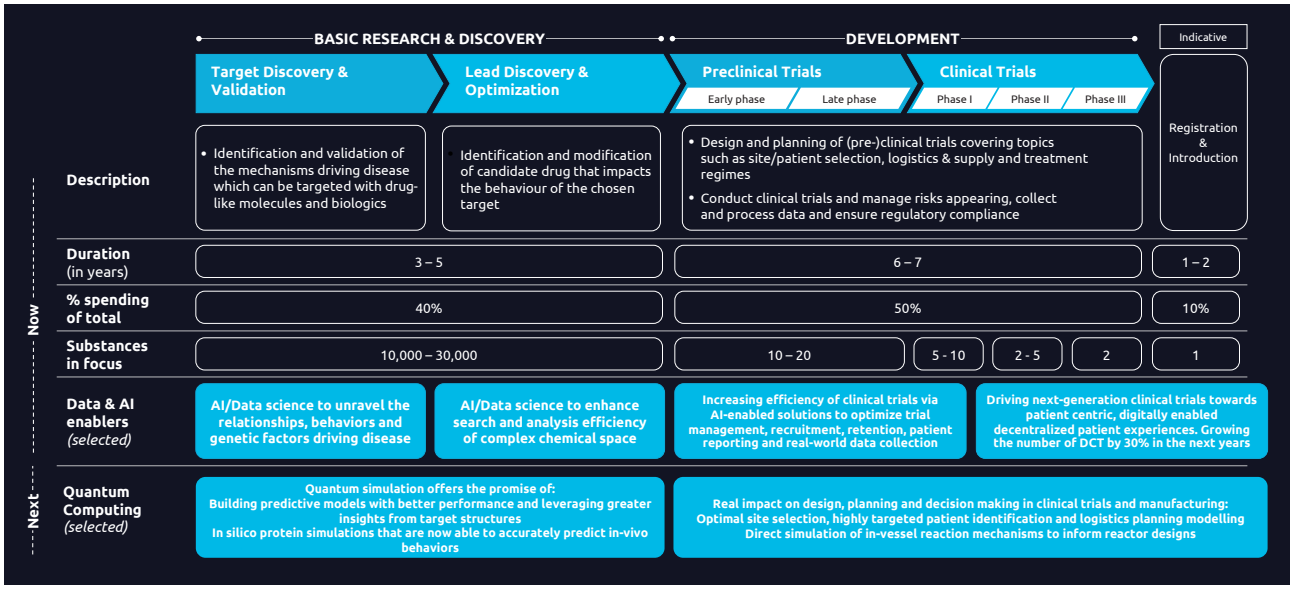
While addressing payors could be considered a commercial activity, it has implication all the way back to the R&D process. Payers are increasingly requesting more health economic and real-world evidence (RWE) to substantiate reimbursement and formulary positioning. Companies that fail to build this into the R&D process risk formulary exclusions, significantly reducing the return on a costly R&D investment.

SOLUTIONS FOR REINVENTING THE MODEL

Data Driven R&D

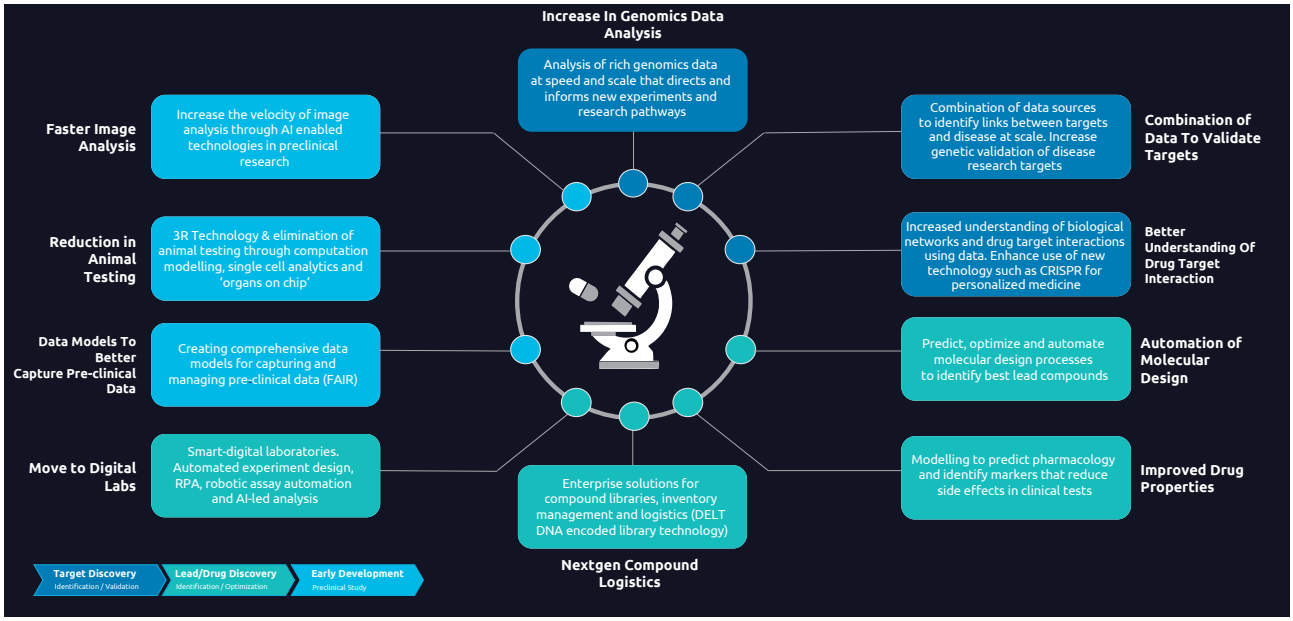
While Pharma has embraced the concept of data & artificial intelligence (AI), many are too narrowly focused on one portion of the R&D value chain or is single solution oriented. To accelerate value, there will need to be multiple solutions, applied across the value chain needs to be executed at pace and scale.

THE IMPACT OF DATA & AI ON DRUG DISCOVERY AND CLINICAL TRIALS IS SIGNIFICANT



In addition, to data and analytics, digital technologies can enable discovery in new ways.

THE POTENTIAL FOR DATA DRIVEN ENTERPRISES TO USE DATA AND NEW TECHNOLOGIES TO ADDRESS BUSINESS REQUIREMENTS IN DISCOVERY IS INCREASING.



Applying the right solutions in every facet of the R&D process shorten cycle times and accelerates value.

Virtualizing & Augmenting Clinical Trials

The challenges associated with recruiting for clinical trials along with the cost associated with non-virtual trials are major contributors to the expenditure and unsustainability of Pharma R&D. Virtual decentralized clinical trials (DCT) can help alleviate that burden. Pharma companies will need to adopt the approach and scale to maximize the benefits. In conjunction with DCT, prior to human trials animal testing can also be transformed through 3R technology, computation modelling, single cell analytics and 'organs on chip'. This both reduces the need for animal testing and accelerates the process. In addition, RWE can be leveraged to augment clinical trial data to shorten the cycle on the back end.

People Transformation: Organizational Embedding & Culture Change

Behind new digital capabilities and expanding analytics, there are still people. In early phase research, an expedited 'realization and release' culture needs to be adopted. Often, researchers and their corresponding team 'realize' the unlikely success of a molecule but are unwilling to terminate a project which they are endeared to given the time, effort and hope invested. To minimize the resulting long-term consequences, embedding artificial intelligence and appropriate incentives can help ensure these low probability options are 'released' from process, meaning the project ended and resources reallocated. Doing this more rapidly in early stages, can increase the probability of success in later stages where the cost of failure is much higher. More broadly, the research and investigator community will need adapt to a new paradigm of work where both humans and machines (AI, IA and Connected Device) need to work together in smart laboratories and virtual clinical trials.

IN SUMMARY

The field of therapeutic options is expanding, creating new opportunities for treatments only previously imaged. In like manner, the complexity and expenditures associated with R&D has also continued to expand. Accordingly, pharmaceutical companies will need to continue to reinvent their model, accommodating new partnerships, technologies, and processes in a streamlined approach that is systematic and grounded in digital and analytics. The stakes are high for making this transition – with shareholder value and patient treatments on the line.

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