Capgemini invent

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 had known for over three decades: there is great potential in recombinant DNA technology. The promise of advancements in biotechnology can enable the synthesis of certain biological molecules in microorganisms and other living cells. 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, such as cancers, Alzheimer's, Huntington's, and immune deficiencies. This explains why 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. Furthermore, 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 to 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 Compound Annual Growth Rate (CAGR) for the industry at one fifth lower than R&D expenditures at 36%, there is less return on capital, thus destroying shareholder value.

Productivity & Approval

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

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 and the number of therapies targeting unmet needs. Additionally, smaller patient subgroups have made it difficult to enroll and retain clinical trial participants. Overall, these issues have created delays and contribute to year-on-year growth in cycle times.

Addressing Payors in the R&D Process

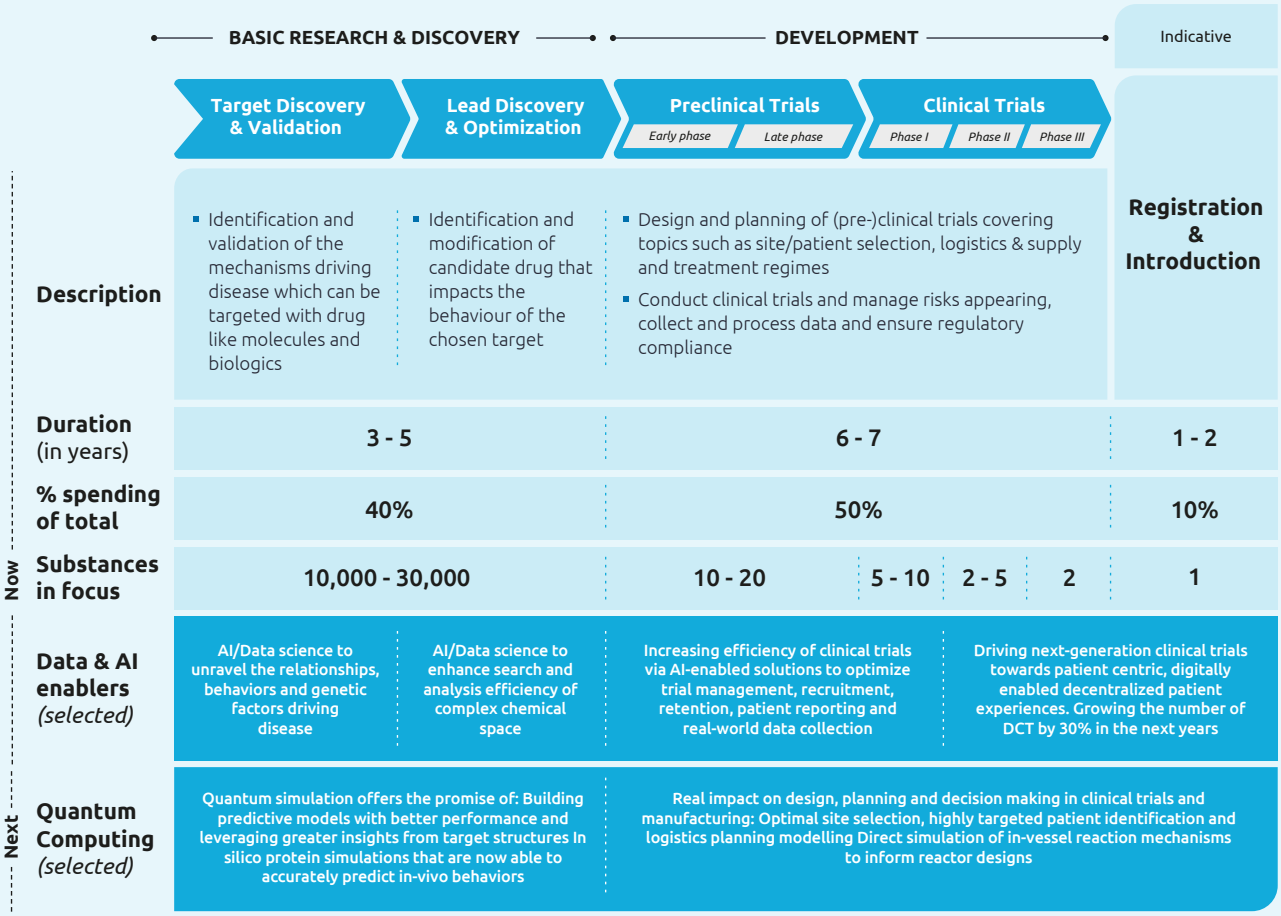
While addressing payors could be considered a commercial activity, it has implication all the way back to the R&D process. Payers are increasingly requesting more health related economic and real-world evidence (RWE) to substantiate reimbursement and formulary positioning. Companies that fail to build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

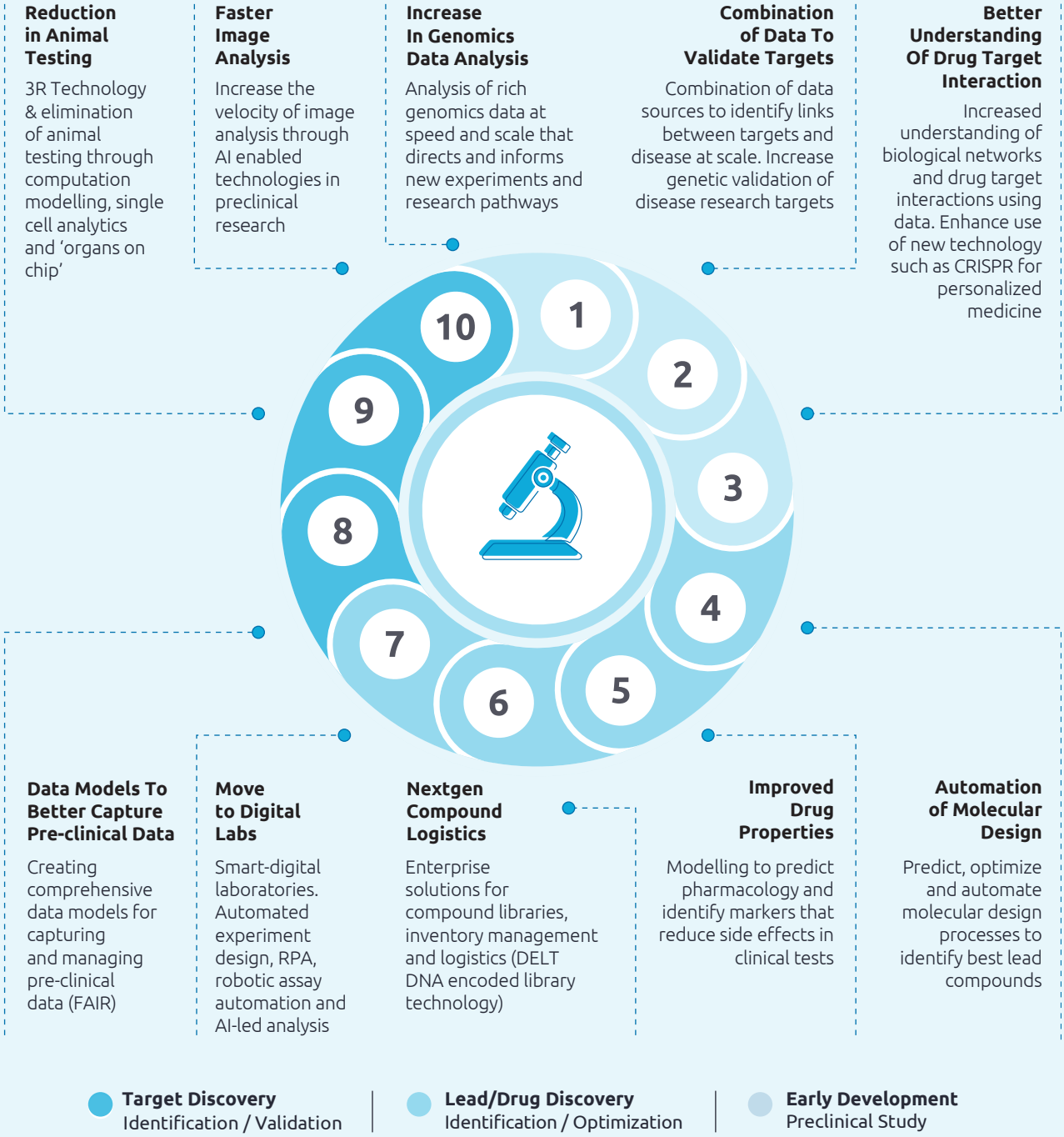
While Pharma has embraced the concept of data and artificial intelligence (AI), many are too narrowly focused on one portion of the R&D value chain or are single solution oriented. To accelerate value, there will need to be multiple solutions, applied across the value chain needs to be executed at pace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

The impact of Data and 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 shortens cycle times and accelerates value.

Virtualizing and Augmenting Clinical Trials

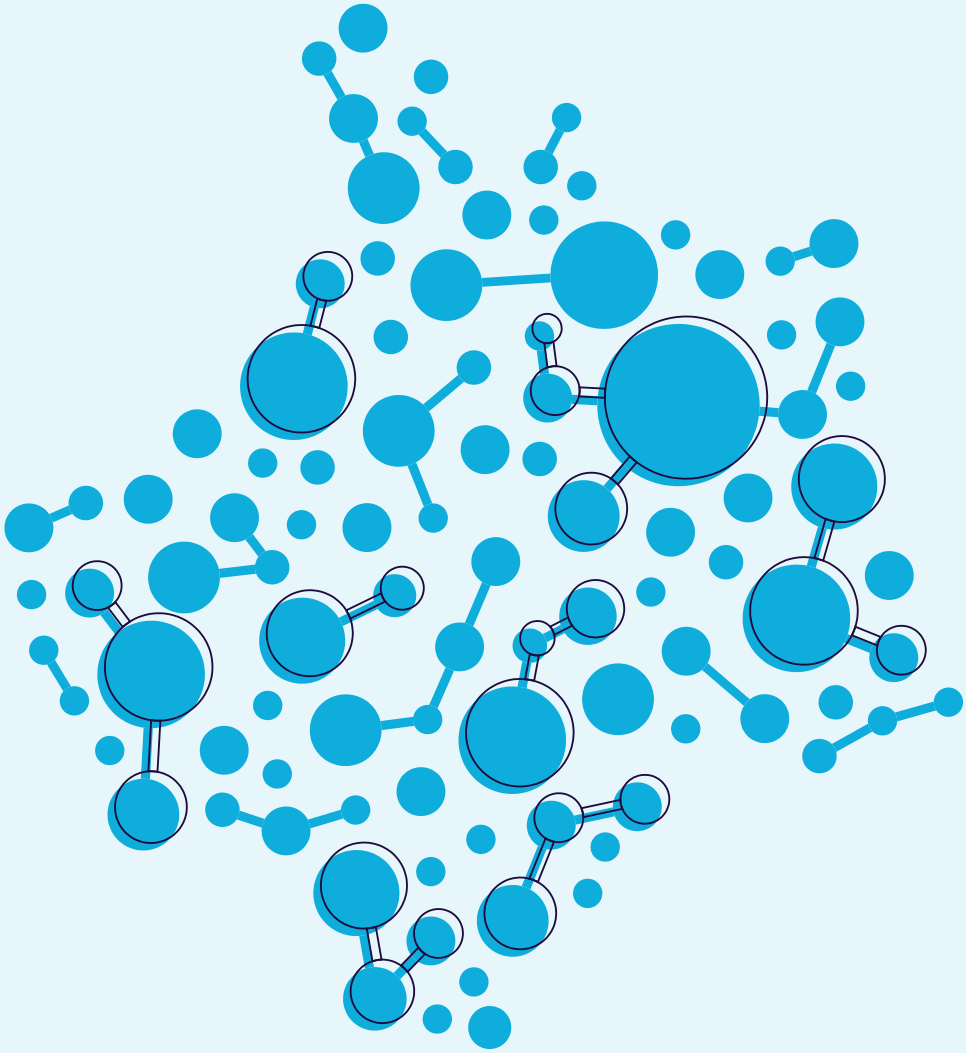
The challenges associated with recruiting for clinical trials along with the cost associated with non-virtual trials are major contributors to the expenditure and unsustainability of Pharma R&D. Virtual Decentralized Clinical Trials (DCT) can help alleviate that burden. Pharma companies will need to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

People Transformation: Organizational Embedding and 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 in which they have invested time, effort, and hope. To minimize the resulting long-term consequences, embedding artificial intelligence and appropriate incentives can help ensure these low probability options are released from the process, meaning the project ended and resources reallocated. Doing this more rapidly in the early stages can increase the probability of success in later stages, when 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 the same way, the complexity and expenditures associated with R&D have 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.



ABOUT THE AUTHORS

Alexandre de Germay

is the Chief Executive Officer at Laboratoires Majorelle. He has more than 30 years of experience in the pharmaceutical industry leading world class organizations like Pfizer and Sanofi globally. He is well versed in leveraging the full potential of advanced analytics, Real-World Evidence, and digital to transform business models and the interactions of healthcare professionals.

Broderick Jones

is the Global Head of Life Science for Capgemini Invent. He is a senior executive with more than 20 years of experience working with premier global companies across Healthcare and Life Sciences. He has led business and digital transformation to drive unparalleled customer experience and internal operational excellence globally.

Connie Wu

is a Customer First Consultant for Capgemini Invent. She is focused on applying creativity, strategy, design, and data to re-invent businesses, drive change, and orchestrate customer centric transformation.

If any queries, do reach out to our Life Sciences Country Leads.

Pesanello, Michele
michele.pesanello@capgemini.com

Balachandran, Arry
arry.balachandran@capgemini.com

Sinner, Axel
axel.sinner@capgemini.com

Stich, Christoph
christoph.stich@capgemini.com

Dobles, Ivania
ivania.dobles@frog.co

Roudil, Guillaume
guillaume.roudil@capgemini.com

Vossion, Damien
damien.vossion@capgemini.com

Madelon, Camille
camille.madelon@capgemini.com

Diana, Chiara
chiara.diana@frog.co

Karkera, Suday
suday.karkera@capgemini.com

Shirke, Poonam Prakash
poonam-prakash.shirke@capgemini.com

Jones, Broderick
broderick.jones@capgemini.com

Capgemini invent

About Capgemini Invent

As the digital innovation, design and transformation brand of the Capgemini Group, Capgemini Invent enables CxOs to envision and shape the future of their businesses. Located in more than 36 offices and 37 creative studios around the world, it comprises a 10,000+ strong team of strategists, data scientists, product and experience designers, brand experts and technologists who develop new digital services, products, experiences and business models for sustainable growth.

Capgemini Invent is an integral part of Capgemini, a global leader in partnering with companies to transform and manage their business by harnessing the power of technology. The Group is guided everyday by its purpose of unleashing human energy through technology for an inclusive and sustainable future. It is a responsible and diverse organization of over 340,000 team members in more than 50 countries. With its strong 55-year heritage and deep industry expertise, Capgemini is trusted by its clients to address the entire breadth of their business needs, from strategy and design to operations, fueled by the fast evolving and innovative world of cloud, data, AI, connectivity, software, digital engineering and platforms. The Group reported in 2021 global revenues of €18 billion.

Visit us at

www.capgemini.com/invent

GET THE FUTURE YOU WANT