APU INSIGHTS
Product of APU Commercial Information Services LLC

Global Clinical Trials

Business Review & Growth Opportunities

C-SUITE

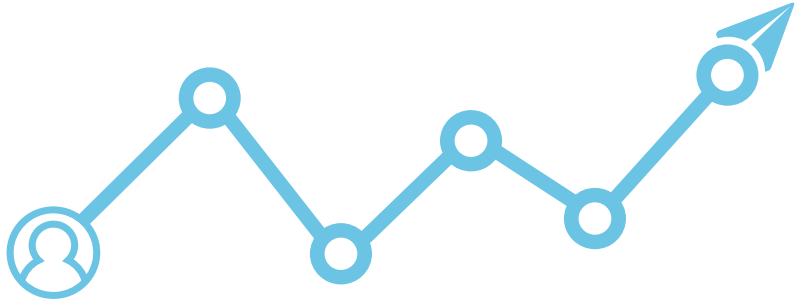
SHAPING THE FUTURE

Global Growth Opportunities Reviews

REVIEW & GROWTH OPPORTUNITIES

Since 2018, the healthcare industry has seen exciting developments in the clinical trials industry. This C-Suite study gives guidance to investors, researchers, companies regarding R&D clinical trials by explaining whereas new technological advances in medicine offer great challenges and solutions. Furthermore, giving the concept of patient connectivity and data information exchange. Many companies have diversified, such as Antidote (US and UK), by using AI-enabled technologies allowing patients to find the most suitable clinical trials, helps researchers stream their latest study information to millions of patients, and even connects them with members of the medical community directly. It's basically a very efficient online platform for enhancing access to clinical trials. Digital health and AI concepts are implemented in many different forms and analyzed. Alternatively, the well-established field of quality, risk management, and vendor oversight dabbles cautiously into analytics and innovation is discussed. CROs possess dedicated resourcing and staffing in emerging markets are better able to use strategic planning to address various global trial challenges, particularly those related to regulatory and oversight requirements. The capabilities of investigators and sites must be carefully reviewed and detailed monitoring plans established. Also critical is the ability of clinical research associates (CRAs) and clinical monitoring associates (CMAs) to cultivate strong relationships with the less-seasoned sites, including the development of innovative strategies in communication, training and education.

With heightened regulatory guidelines now in place in many global markets, the complexity of clinical trial protocol designs based on clinical trials has increased considerably. As a result, factors such as stricter patient inclusionary/exclusionary criteria can often dictate the need to expand trials globally. In these cases, Biopharma and CROs must ensure that the medical standards in the newly-targeted countries comply with the protocol complexities. In



addition, Mergers and Acquisitions offers new challenges to companies such issues are analyzed and benefits are discussed. Roche and Spark Therapeutics, Inc. entered into a definitive merger agreement last month for Roche to fully acquire Spark Therapeutics at a price of USD 114.50 per share in an all-cash transaction. Spark's additional clinical assets include SPK-9001, an investigational gene therapy for the potential treatment of hemophilia B in Phase III; and SPK-7001 for choroideremia in Phase I/II. The company is also developing SPK-3006 for Pompe disease and SPK-1001 for CLN2 disease (a form of Batten disease), which are expected to be ready for clinical development this year, as well as additional preclinical programs for Huntington's disease and Stargardt disease. The overall clinical development landscape is transforming despite the varying dynamics from region to region. Clinical trials involve multiple regulatory frameworks and research cultures, but are required to apply the same clinical data. To that end, it is critical that biopharms leverage CRO partners to have global capability support, strong localized presence and expertise in the targeted regions. Such keys strategies analyzed in such a study and top companies portfolio drugs are presented along with AI technology.

TABLE OF CONTENTS

- REVIEW & GROWTH OPPORTUNITIES

- SUMMURY

1 PHARMA DRUG DEVELOPMENT OF CLINICAL TRIALS

SECTION 1
1.1 Global Strategy of Clinical Trials
1.2 Clinical Trials R& D
1.2.1 Success rate of clinical development stages
1.2.2 Complex trials by therapeutic area and its impact
1.2.3 Oncology and neurology trials

2 THE ONCOLOGY MARKET

SECTION 2
2.1 Forecast Oncology
2.2 Global Market Number of Oncology Medicine
2.2.1 Cancer treatment landscape

3 FORECAST & CLINICAL DEVELOPMENT BY THERAPEUTIC AREA

SECTION 3
3.1 Forecast of different therapeutic area
3.1.1 Therapeutic areas and Clinical development spend per approval
3.1.2 Most Valuable R&D Projects
3.1.3 Phases of Clinical Trials

4 DIGITAL MEASURES IN CLINICAL TRIALS

SECTION 4
4.1 Examples of Digital Measures in Clinical Care
4.1.1 Examples of Digital Measures in Clinical Research
4.1.2 The utility of measurements in Clinical Trials
4.1.3 Types of measurements in clinical trials

5 NEW MOLECULES & VIRTUAL TRIALS

SECTION 5
5.1 New Molecules approved by FDA (companies and brands)
5.1.1 Digital biomarker products
5.1.2 Role of Digital biomarkers in cancer research
5.1.3 Applications of Wearable technologies
5.1.4 Landscape of Registered Clinical Trials Incorporating Digital Health in Cancer Care
5.1.5 EHR platforms

5.1.6 RWE and RWD
5.1.7 European Hematology Association 2019
5.1.8 The sickle cell landscape
5.1.9 Real world evidence (RWE) a disruptive innovation - The RWE journey
5.1.10 How today's technologies are disrupting and improving clinical trials
5.1.11 The role of new technologies and their outcomes in clinical & Virtual Trials
5.1.12 Role of AI platform in Clinical trials
5.1.13 How AI-driven protocol designs make clinical trials more intelligent
5.1.14 Technologies and the proportion of Workforce affected
5.1.15 Digital Clinical Trials "Disruptive Change is Happening Now"
5.1.16 AI for Clinical Design
5.1.17 Improved outcomes for Artificial Intelligence

SECTION 6
6.1 Natural Language Processing (NLP)
technology for analysis of database
6.1.1 Data base analysis Impact on sample size by using continuous monitoring
6.1.2 Artificial Intelligence (AI) & Machine Learning (ML)
6.1.3 The 6R model to keep in mind for AI projects in the biomedical and clinical health care domain
6.1.4 Data Complexity vs AI Complexity
6.1.5 Data Driven Clinical Research Needs Data Science
6.1.6 Tech support Artificial-intelligence technology
6.1.7 Company's Platforms in Research Protocols
6.1.8 AI is applied by most of the companies
6.1.9 Food and Drug Administration (FDA) approved drugs grew from 46 in 2017 to 59 in 2018
6.1.10 Making Real-World Data Widely Available
6.1.11 Expanding the indications for approved therapies
6.1.12 Designing more effective and successful clinical trial

SECTION 7

7.1 Privacy in Healthcare

7.7.1 Healthy Data Protection

SECTION 8

8.1 Main elements in big data lifecycle in healthcare

8.1.1 Clinical Trial Optimization

8.1.2 Worldwide Prescription Drug Sales (+ 6.9 %CAGR*2019-24)

8.1.3 Merck & Co expected to remain largest oncology player in 2024 with Keytruda

8.1.4 Keytruda knocks Humira off the top spot, Revlimid falls out of top 3

SECTION 9

9.1 The Changing Landscape for Clinical Trial Sites

9.1.1 Most challenging technologies

9.1.2 Evolution of trends

9.1.3 Health and Research Informatics (HRI) platform

9.1.4 Clinical document and safety data

9.1.5 Transaction Overview

9.1.6 Promising areas of growth

9.1.7 AI technology

9.1.8 The NLP demand for real-world evidence

9.1.9 Deep learning

9.1.10 Phase 1–3 clinical study design.

9.1.11 Time to run these trials also impacts on the potential profitability of indication expansion.

9.1.12 RWD: What are RWD and where do they come from?

10

ROLE OF REGULATORY & THE CRO IN DEVELOPMENT OF CLINICAL TRIALS

SECTION 10

10.1 Regulatory changes regarding clinical trials landscape

- 10.1.1 Challenges of implementing an integrated research model
- 10.1.2 Veradigm and Microsoft committed to integrated research
- 10.1.3 Digital Healthcare Journey & EMR-based Clinical Trials System
- 10.1.4 More Regulatory Clarity Expected
- 10.1.5 Government strategies alongside with clinical trials
- 10.1.6 Artificial intelligence (AI)
- 10.1.7 Digital therapeutics (DTx)
- 10.1.8 Pharma and biotech manufacturers opportunities
- 10.1.9 Future Perspectives of Clinical Trials
- 10.1.10 Mobile Clinical Trials Tools for Alzheimer's Disease
- 10.1.11 Roles Responsibilities and Approaches for Patient Advocacy Personnel
- 10.1.12 Pharma Outlook :12 Trends to Watch in 2019
- 10.1.13 Global Contract Research Organization Services Market, 2015-2026 (USD Million)
- 10.1.14 Global CRO market and rates of penetration
- 10.1.15 The CRO market
- 10.1.16 The CRO (M&A activity) market
- 10.1.17 Roche to Acquire Spark Therapeutics

11

TRIAL RECRUITMENT AND THE NEW THERAPIES (TRENDS IN ONCOLOGY)

SECTION 11

11.1 Innovative drugs in 2018 bringing 59 new treatment options to patients

- 11.1 .1 Precision targeting to better detect a treatment effect
- 11.1 .2 Digital Health Applications Transforming Clinical Development
- 11.1 .3 Over 40 assets are in clinical development for NASH
- 11.1 .4 Development of patient pools that will accelerate trial recruitment and biomarkers across therapeutic areas
- 11.1 .5 Predicted Percent Change in Productivity by Therapy Area and Trend from 2018 to 2023
- 11.1 .6 Alzheimer's therapies were discontinued in 2018
- 11.1.7 Trends Driving Change in Oncology Clinical Development
- 11.1.8 -||- (continued)

SECTION 12

12.1 Top AI Investors for Drug Discovery
12.1.1 Regional Comparison of AI for R& D and Drug Discovery
12.1.2 AI for Drug Discovery, Biomarker Development & Advanced R&D
12.1.3 Mergers and Acquisitions
12.1.4 AI for Drug Discovery Biomarker Development &Advanced R&D
12.1. 5 Reasons for Declining efficiency of R&D
12.1.6 Top AI Experts in Drug Discovery Distribution by countries
12.1.7 Key Investors in AI for Clinical Trials
12.1.8 Key Companies Applying AI for Drug Discovery and Advanced R&D
12.1.9 Top AI Drug Discovery Conferences in 2019
12.1.10 Top AI - Drug Discovery Conferences in 2019
12.1.11 Industry Developments Q1 2019
12.1.12 Industry Developments Q1 2019
12.1.13 AI for Drug Discovery Biomarker Development & Advanced R&D
12.1.14 Annual Revenue of Global Pharma
12.1.15 Top 30 Women AI Experts in Drug Discovery
12.1.16 Location of the top women AI in pharma and healthcare
12.1.17 Pipeline by development phase, 2019 versus 2018
12.1.18 Drivers of change in clinical development

EXECUTIVE SUMMARY
PHARMA DRUG DEVELOPMENT OF CLINICAL TRIALS 1
THE ONCOLOGY MARKET 2
FORECAST AND CLINICAL DEVELOPMENT BY THERAPEUTIC AREA 3
DIGITAL MEASURES IN CLINICAL TRIALS 4
NEW MOLECULES AND VIRTUAL TRIALS 5
THE ROLE OF NEW TECHNOLOGIES IN CLINICAL TRIALS 6
THE ROLE OF PRIVACY IN HEALTHCARE 7
R&D (CLINICAL TRIALS & WORLDWIDE PRESCRIPTION DRUGS) 8
GROWTH OPPORTUNITIES 9
ROLE OF REGULATORY AND THE CRO IN DEVELOPMENT OF CLINICAL TRIALS 10
TRIAL RECRUITMENT AND THE NEW THERAPIES (TRENDS IN ONCOLOGY) 11
INDUSTRY DEVELOPMENT OF GLOBAL PHARMA 12

EXECUTIVE SUMMARY

Digital health and mobile technologies will enable the capture of drug efficacy and safety data remotely within the bounds of clinical trials, and are therefore expected to improve patient safety, enable virtual trial formats and ease site work burden. This C-Suite study analyses the trends, the challenges and growth opportunities in global clinical trials. The emergence of new data sources and analytic tools are also c hanging clinical development. Curated real-world data (RWD) sources will be used to optimize trial design, speed trials by aiding selection of investigators and sites, and enable new trial designs, for example by acting as virtual/synthetic control arms and supporting pragmatic, adaptive and real-world evidence (RWE) registry trial designs.

In oncology, pools of pre-screened patients will accelerate trial recruitment and biomarkers will improve success rates, leading to productivity improvements as high as 104 percent and 71 percent, respectively. Biomarkers will also yield consistently high improvements in productivity of over 45 percent across four other therapy areas: GI/NASH, rare disease, neurology and cardiovascular. In addition, oncology and neurology trials will see approximately 30 percent or greater improvements in productivity over the next five years the largest increases in productivity across therapy areas while respiratory will see the largest decrease in productivity. Over the last several years, the pharmaceutical and healthcare organizations have developed a strong interest in applying artificial intelligence (AI) in various areas. The demand for the ML/AI technologies, as well as for ML/AI talent, is growing in pharmaceutical and healthcare industries and driving the formation of a new interdisciplinary field data-driven drug discovery/healthcare. The overall success of all the companies in the industry depends strongly on the presence of highly skilled interdisciplinary leaders, able to innovate, organize and guide in this direction. It will be crucial to hire top AI experts, especially for Big Pharma companies that are fighting to survive. The number of companies working on disruptive innovation has increased substantially over the past few years and investment in this sector is massive. Direct to-patient

EXECUTIVE SUMMARY
PHARMA DRUG DEVELOPMENT OF CLINICAL TRIALS 1
THE ONCOLOGY MARKET 2
FORECAST AND CLINICAL DEVELOPMENT BY THERAPEUTIC AREA 3
DIGITAL MEASURES IN CLINICAL TRIALS 4
NEW MOLECULES AND VIRTUAL TRIALS 5
THE ROLE OF NEW TECHNOLOGIES IN CLINICAL TRIALS 6
THE ROLE OF PRIVACY IN HEALTHCARE 7
R&D (CLINICAL TRIALS & WORLDWIDE PRESCRIPTION DRUGS) 8
GROWTH OPPORTUNITIES 9
ROLE OF REGULATORY AND THE CRO IN DEVELOPMENT OF CLINICAL TRIALS 10
TRIAL RECRUITMENT AND THE NEW THERAPIES (TRENDS IN ONCOLOGY) 11
INDUSTRY DEVELOPMENT OF GLOBAL PHARMA 12

strategies are introducing new players to the industry and this may also support clinical trials by making those more accessible to more patients. As these strategies evolve, patient privacy and data protection will continue to be something that stakeholders need to consider and we are already seeing technologies that may address these issues. Although pharma companies and CROs are certainly here to stay, they need to change how they look at everything they do across the entire spectrum of drug development. Innovation should be part of their DNA and how they are going to adapt to change. Companies need to become more agile so that they are open to learning. Failure needs to be tolerated because failure if dealt with in the correct way is what leads to success. These concepts are embedded in technology companies so pharma companies and CROs may need to start thinking and acting more like these organizations.

The US and Great Britain remain home for the largest number of top experts. Investment in future medical innovation continued to grow in 2018 reflecting confidence in scientific innovation to tackle unmet health needs. Venture capital firms invested over USD 23 billion in 2018, with a record number of deals recorded, and the 15 largest pharmaceutical companies recorded more than USD 100 billion in R&D expenditure for the first time, up 32 percent over the past five years. The composite progression time from the initiation of Phase I clinical development for a drug until a registration decision is reached was 12.5 years in 2018, up six months from 2017, and resuming the gradual lengthening of progression time for all drugs in development. The composite success rate of clinical development from Phase I trials to regulatory submission based on the percent of drugs successfully progressing to each next stage of development fell to 11.4 percent in 2018, down from 14.4 percent in 2017, and was below the average of 14 percent in the prior ten years. All stages of clinical development saw declines in success rates in 2018, with Phase I and Phase III trial success both falling by 7–8 percent. Success rates by development stage have all generally been consistent over the past decade, with 2015 an exceptional year, when the composite success rate exceeded 22 percent. While therapy classes

EXECUTIVE SUMMARY
PHARMA DRUG DEVELOPMENT OF CLINICAL TRIALS 1
THE ONCOLOGY MARKET 2
FORECAST AND CLINICAL DEVELOPMENT BY THERAPEUTIC AREA 3
DIGITAL MEASURES IN CLINICAL TRIALS 4
NEW MOLECULES AND VIRTUAL TRIALS 5
THE ROLE OF NEW TECHNOLOGIES IN CLINICAL TRIALS 6
THE ROLE OF PRIVACY IN HEALTHCARE 7
R&D (CLINICAL TRIALS & WORLDWIDE PRESCRIPTION DRUGS) 8
GROWTH OPPORTUNITIES 9
ROLE OF REGULATORY AND THE CRO IN DEVELOPMENT OF CLINICAL TRIALS 10
TRIAL RECRUITMENT AND THE NEW THERAPIES (TRENDS IN ONCOLOGY) 11
INDUSTRY DEVELOPMENT OF GLOBAL PHARMA 12

and drug types under development have changed during the past decade, oncology has had slightly lower composite success rates (12 percent) than non-oncology (14.1 percent). To examine the productivity of the clinical development process, a Clinical Development Productivity Index was developed measuring trial success in relation to the effort invested in trials. Applying this new metric across trials in nine of the largest therapy areas showed that productivity has declined overall from 2013 to 2018 falling 27 percent from 2013 to 2018, heavily influenced by a decrease in productivity in Phase I of 55 percent over that period and declines in Phase III since 2016. Phase II and Phase III trial productivity remained relatively stable since 2010. Declining productivity in Phase I was driven by declines in success rates of 7 percent and increases in trial complexity (which includes numbers of trial participants, eligibility criteria, research sites countries, and endpoints) of 6 percent. In 2018, complexity rose due to increases in all complexity elements excepting the number of trial sites and countries. For instance, the number of patients expected to participate in clinical trials across the nine key therapy areas increased 10 percent over 2017 with growth influenced by an increase of the number of patients in Phase III oncology and neurology trials. Section 1: Pharma Drug Development of Clinical Trials

EXECUTIVE SUMMARY
PHARMA DRUG DEVELOPMENT OF CLINICAL TRIALS 1
THE ONCOLOGY MARKET 2
FORECAST AND CLINICAL DEVELOPMENT BY THERAPEUTIC AREA 3
DIGITAL MEASURES IN CLINICAL TRIALS 4
NEW MOLECULES AND VIRTUAL TRIALS 5
THE ROLE OF NEW TECHNOLOGIES IN CLINICAL TRIALS 6
THE ROLE OF PRIVACY IN HEALTHCARE 7
R&D (CLINICAL TRIALS & WORLDWIDE PRESCRIPTION DRUGS) 8
GROWTH OPPORTUNITIES 9
ROLE OF REGULATORY AND THE CRO IN DEVELOPMENT OF CLINICAL TRIALS 10
TRIAL RECRUITMENT AND THE NEW THERAPIES (TRENDS IN ONCOLOGY) 11
INDUSTRY DEVELOPMENT OF GLOBAL PHARMA 12

SECTION 1:
PHARMA DRUG DEVELOPMENT OF CLINICAL TRIALS

1.1 Global Strategy of Clinical Trials

The clinical trial is a foundational pillar of the pharmaceutical drug discovery process. The potential impact of advanced analytics in clinical operations is significant and wide-ranging: from faster, lower-cost trials to higher data quality.

The clinical environment is changing rapidly and simultaneously becoming more complex: the rise of personalized medicine has led to increasingly complex protocols; trials today are more often targeted at smaller patient populations that are also harder to find, while competition for sites and patients is becoming ever more fierce; meanwhile, continuing globalization of clinical operations requires a coordinated effort across countries, meanwhile, clinical operations continue to globalize, requiring a coordinated effort across countries. (1), (2)

Pharma drug development cycle and success rates in clinical trials

It takes up to 15 years and an average total R&D expenditure of 1.5–2 billion USD to bring a single new drug to the market. About half of this investment is spent on clinical trials, with Phase III trials being the most complex and most expensive. Phase III trials compare a new drug to the standard-of-care drug. Every patient in a phase III study is watched closely. The study will be stopped early if the side effects of the new drug are too severe or if one group has much better results. Phase III clinical trials are often needed before the FDA will approve the use of a new drug for the general public.

Probabilities of success for compounds to proceed through the clinical trial stages vary from phase to phase, and lead to a situation where only one of 10 compounds entering clinical trials advances to FDA approval.

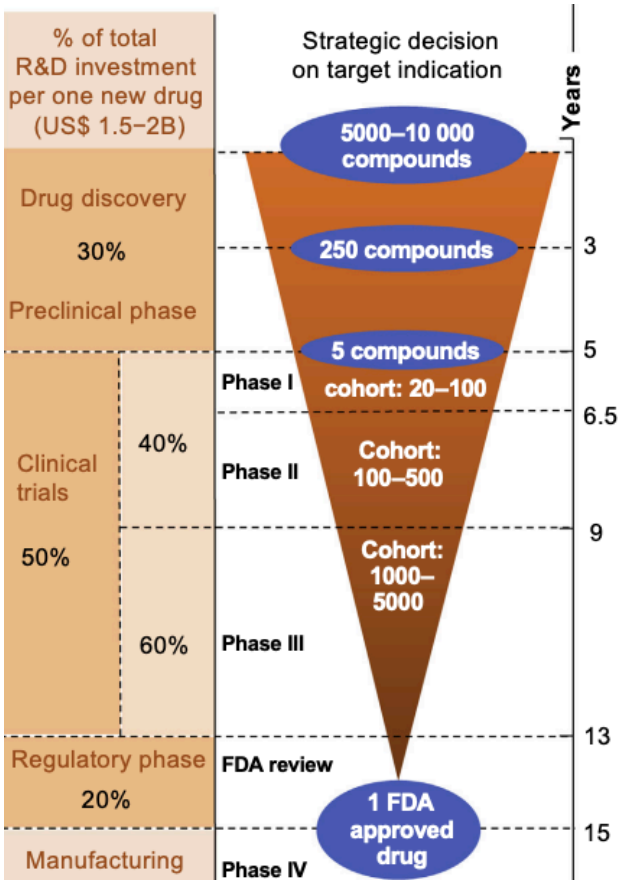
High clinical trial failure rates are one major cause for the prevailing inefficiency of the drug development cycle. Against this backdrop, then, it is no surprise that the execution of clinical trials has become increasingly challenging.

1. Stefan Harrer, Pratik Shah, Bhavna Antony, Jianying Hu Trends in Pharmacological Sciences (2019) Artificial Intelligence for Clinical Trial Design.

2. Cell Press. (2019). Review evaluates how AI could boost the success of clinical trials. ScienceDaily.

EXECUTIVE SUMMARY
PHARMA DRUG DEVELOPMENT OF CLINICAL TRIALS 1
THE ONCOLOGY MARKET 2
FORECAST AND CLINICAL DEVELOPMENT BY THERAPEUTIC AREA 3
DIGITAL MEASURES IN CLINICAL TRIALS 4
NEW MOLECULES AND VIRTUAL TRIALS 5
THE ROLE OF NEW TECHNOLOGIES IN CLINICAL TRIALS 6
THE ROLE OF PRIVACY IN HEALTHCARE 7
R&D (CLINICAL TRIALS & WORLDWIDE PRESCRIPTION DRUGS) 8
GROWTH OPPORTUNITIES 9
ROLE OF REGULATORY AND THE CRO IN DEVELOPMENT OF CLINICAL TRIALS 10
TRIAL RECRUITMENT AND THE NEW THERAPIES (TRENDS IN ONCOLOGY) 11
INDUSTRY DEVELOPMENT OF GLOBAL PHARMA 12

PHARMA DRUG DEVELOPMENT CYCLE



COMPOUND SUCCESS RATES FOR CLINICAL TRIALS

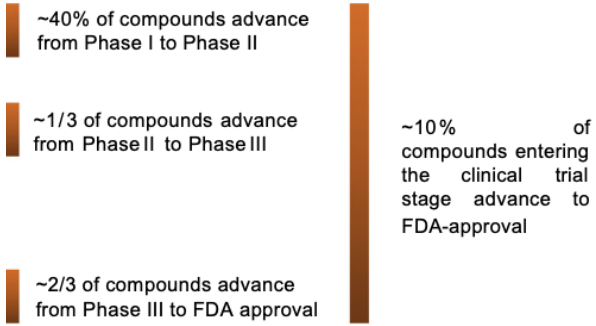


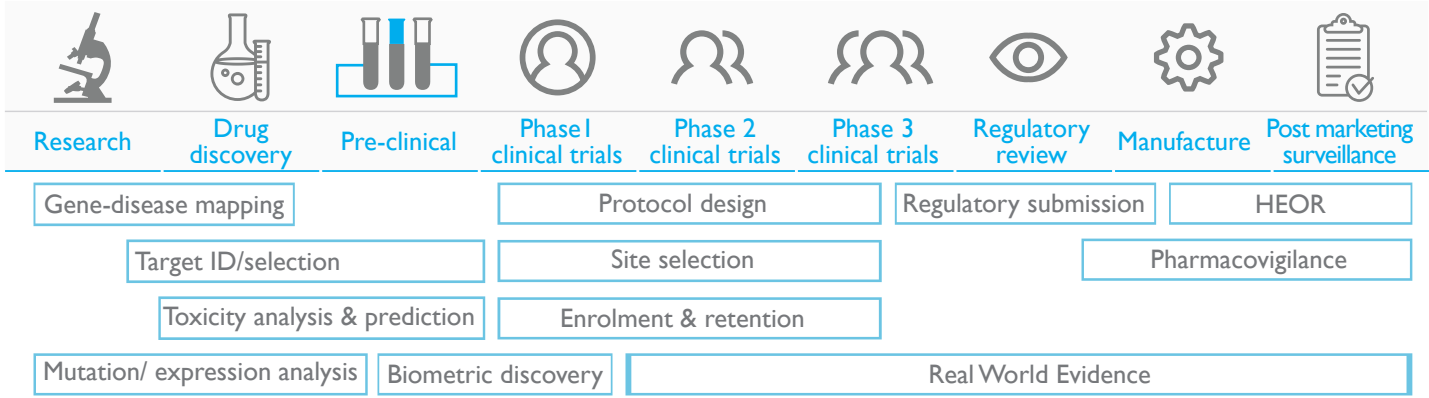
Figure 1 | The Pharma Drug Development Cycle

EXECUTIVE SUMMARY
PHARMA DRUG DEVELOPMENT OF CLINICAL TRIALS 1
THE ONCOLOGY MARKET 2
FORECAST AND CLINICAL DEVELOPMENT BY THERAPEUTIC AREA 3
DIGITAL MEASURES IN CLINICAL TRIALS 4
NEW MOLECULES AND VIRTUAL TRIALS 5
THE ROLE OF NEW TECHNOLOGIES IN CLINICAL TRIALS 6
THE ROLE OF PRIVACY IN HEALTHCARE 7
R&D (CLINICAL TRIALS & WORLDWIDE PRESCRIPTION DRUGS) 8
GROWTH OPPORTUNITIES 9
ROLE OF REGULATORY AND THE CRO IN DEVELOPMENT OF CLINICAL TRIALS 10
TRIAL RECRUITMENT AND THE NEW THERAPIES (TRENDS IN ONCOLOGY) 11
INDUSTRY DEVELOPMENT OF GLOBAL PHARMA 12

1.2 Clinical Trials R&D

Artificial Intelligence (AI) and machine learning, when combined with big data, has the potential to greatly improve the clinical trial process. Hidden signals within vast pools of Real-World Data may only be found when processed by advanced AI algorithms. There are many areas within clinical trials where these insights may drive change. With the ability to process and analyse large pools of data, AI has the potential to identify potential risks in the clinical development process and highlight them early.

Figure 2 | AI assistance in the drug development process



AI also has applications for recruiting clinical trial patients. This processing can be difficult and time-consuming for investigating companies such as CRO and the patient. According to a White House briefing only 3 percent of cancer patients in the US are enrolled in clinical trials. A Cognizant report on recruitment forecasts estimated that 80 percent of clinical trials fail to meet enrolment timelines and one third of Phase III study terminations are due to recruitment issues. The disruptive potential of digital technology could drive the most value in the pharmaceutical industry in the future. Pharma companies are planning to start or have already started experimenting with Artificial Intelligence (AI), mobile health (mHealth), Big Data, wearable health-tracking technologies, internet of things and remote wireless monitoring. An overview of clinical guidelines reforms is been provided to

EXECUTIVE SUMMARY
PHARMA DRUG DEVELOPMENT OF CLINICAL TRIALS 1
THE ONCOLOGY MARKET 2
FORECAST AND CLINICAL DEVELOPMENT BY THERAPEUTIC AREA 3
DIGITAL MEASURES IN CLINICAL TRIALS 4
NEW MOLECULES AND VIRTUAL TRIALS 5
THE ROLE OF NEW TECHNOLOGIES IN CLINICAL TRIALS 6
THE ROLE OF PRIVACY IN HEALTHCARE 7
R&D (CLINICAL TRIALS & WORLDWIDE PRESCRIPTION DRUGS) 8
GROWTH OPPORTUNITIES 9
ROLE OF REGULATORY AND THE CRO IN DEVELOPMENT OF CLINICAL TRIALS 10
TRIAL RECRUITMENT AND THE NEW THERAPIES (TRENDS IN ONCOLOGY) 11
INDUSTRY DEVELOPMENT OF GLOBAL PHARMA 12

show how regulatory affect the clinical trials cost and duration. How innovative clinical trials has solved those problems. This time is which relationship management is crucial. In the annual Views from the C-Suite survey, company leaders, investors are asked to assess what they see as the leading opportunities and challenges in the global business operating environment of clinical trials over the next 12 months. Essentially, clinical trials are research studies which seek to determine if a medical treatment or device is safe and effective for humans. While the pharmaceutical drug industry has experienced some fluctuations, it remains a profitable market. Global prescription drug expenditures are estimated to reach nearly 1.5 trillion dollars by 2021 according to Quintiles IMS Holding. (3)

1.2.1 Success rate of clinical development stages

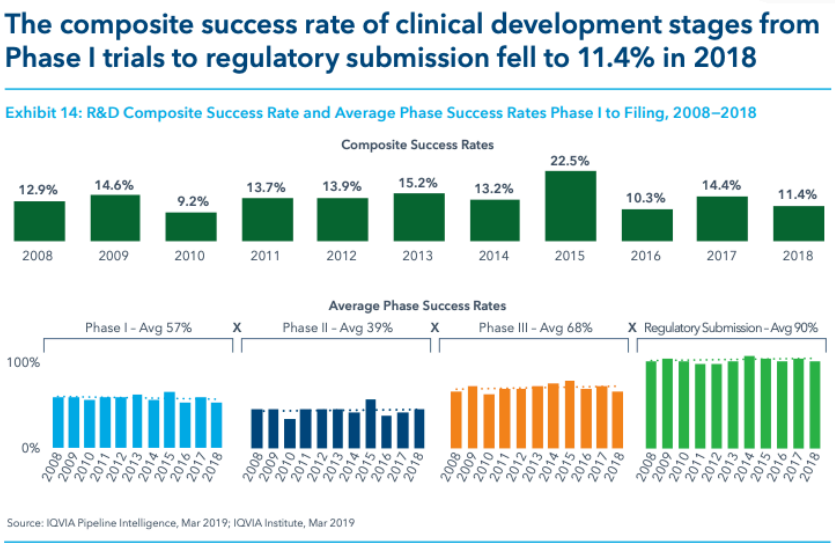


Figure 3. R&D Composite Success Rate and Average Phase Success Rates Phase I to Filing, 2008–2018.

3. Results healthcare. (2019) CRO Sector M & A drivers and market trends.

EXECUTIVE SUMMARY
PHARMA DRUG DEVELOPMENT OF CLINICAL TRIALS 1
THE ONCOLOGY MARKET 2
FORECAST AND CLINICAL DEVELOPMENT BY THERAPEUTIC AREA 3
DIGITAL MEASURES IN CLINICAL TRIALS 4
NEW MOLECULES AND VIRTUAL TRIALS 5
THE ROLE OF NEW TECHNOLOGIES IN CLINICAL TRIALS 6
THE ROLE OF PRIVACY IN HEALTHCARE 7
R&D (CLINICAL TRIALS & WORLDWIDE PRESCRIPTION DRUGS) 8
GROWTH OPPORTUNITIES 9
ROLE OF REGULATORY AND THE CRO IN DEVELOPMENT OF CLINICAL TRIALS 10
TRIAL RECRUITMENT AND THE NEW THERAPIES (TRENDS IN ONCOLOGY) 11
INDUSTRY DEVELOPMENT OF GLOBAL PHARMA 12

The composite success rate of clinical development stages from Phase I trials to regulatory submission fell to 11.4 percent in 2018, down from 14.4 percent in 2017. The success rates for Phase I and Phase III trials both fell by about 7.5 percent while Phase II improved by less than 1 percent. Composite success rates fluctuated over the past decade, with 2015 an exceptional year where the rate exceeded 22 percent. The composite success rate for 2018 was also well below the average of 14 percent for the prior ten years (2008–2017) in part due to drops in success of Phase III and Phase I trials. The mix of drug types under development and the number of drugs per therapy area changed during the past decade shifting toward oncology, biologic and specialty drugs, in which the success rates for oncology is slightly lower than for research overall. (4)

1.2.2 Complex trials by therapeutic area and its impact (5)

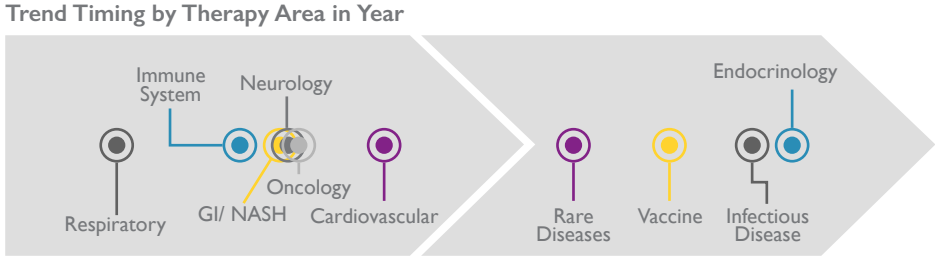


Figure 4. Infectious disease and endocrinology trials will be impacted more slowly by trends.

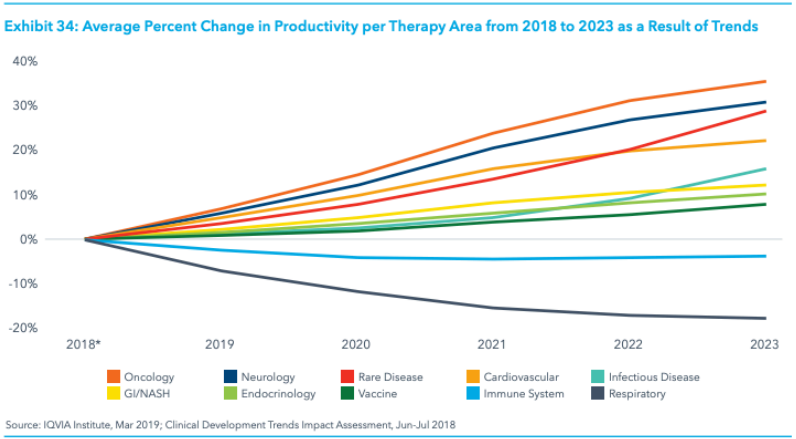
4. 5. IQVIA. The Changing Landscape of Research and Development. Innovation, Drivers of Change, and Evolution of Clinical Trial Productivity. (2019).

EXECUTIVE SUMMARY
PHARMA DRUG DEVELOPMENT OF CLINICAL TRIALS 1
THE ONCOLOGY MARKET 2
FORECAST AND CLINICAL DEVELOPMENT BY THERAPEUTIC AREA 3
DIGITAL MEASURES IN CLINICAL TRIALS 4
NEW MOLECULES AND VIRTUAL TRIALS 5
THE ROLE OF NEW TECHNOLOGIES IN CLINICAL TRIALS 6
THE ROLE OF PRIVACY IN HEALTHCARE 7
R&D (CLINICAL TRIALS & WORLDWIDE PRESCRIPTION DRUGS) 8
GROWTH OPPORTUNITIES 9
ROLE OF REGULATORY AND THE CRO IN DEVELOPMENT OF CLINICAL TRIALS 10
TRIAL RECRUITMENT AND THE NEW THERAPIES (TRENDS IN ONCOLOGY) 11
INDUSTRY DEVELOPMENT OF GLOBAL PHARMA 12

1.2.3 Oncology and neurology trials (6)

Oncology will see the largest percentage increase in productivity of any therapy area, while both respiratory and immune system trials will see decreases in productivity. Infectious disease and endocrinology are also predicted to be among the top five in terms of absolute impact to productivity, however, their starting productivity values are higher. Oncology, neurology, rare disease and cardiovascular trials will see the most significant increases in productivity on a percent basis over the next five years. Oncology will be transformed by the development of patient pools that will accelerate trial recruitment and biomarkers, which will improve success rates. Neurology trials will see the most significant impact from digital health, followed by biomarkers and regulatory changes. Respiratory will only see positive effects from RWD and predictive analytics both derived from the growth in the use of big data and its analysis but is otherwise seeing declines. (7)

Figure 5. Oncology and neurology trials will see approximately 30 percent or greater improvements in productivity over the next five years.



Average Percent Change in Productivity per Therapy Area from 2018 to 2023 as a Result of Trends

6. 7. Ibid 5

APU INSIGHTS
Product of APU Commercial Information Services LLC

HPD-CS-CLINICAL-TR-KB291119

Designed and produced by APU Insights Creative Studio

C-SUITE