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Clinical Trials: Enrollment Trends in Emerging Markets – South Korea

Healthcare

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2 Introduction

2.1 Report Scope

This whitepaper provides a review of Phase I to Phase IV clinical trials with a start date between January 1, 2001 and June 5, 2018, and which have a trial location in South Korea. The data for this review were derived from the Enrollment Database of GlobalData's Pharma Intelligence Center. This database includes company-sponsored clinical trials with Completed, Ongoing, Planned, and Terminated statuses. The aim of this paper is to provide an analysis of the overall patient enrollment trends in South Korea.

2.2 Methodology

The clinical trials data used for these analyses were extracted from the Enrollment Database of GlobalData's Pharma Intelligence Center. The data included interventional (94%) and observational (6%) clinical trials with a start date between January 1, 2001 and June 5, 2018, and which have trial locations in South Korea. These trials included multinational trials, where South Korea is one of many countries included in the study, as well as trials conducted exclusively in South Korea. The Enrollment Database of the Pharma Intelligence Center recorded 3,658 trials that satisfied the above criteria. The data were analyzed and segmented by study duration, study enrollment period, enrollment rate, number of subjects enrolled, enrollment efficiency, trial phase, single-country or multinational trial, therapy area, major indication, and number of sites. The top five Therapy Areas and Indications were obtained using the Clinical Trials Database with the Enrollment Database criteria as listed above in Section 2.1. A few outliers in the dataset were excluded from the analysis, including 22 trials from enrollment period, 20 trials from enrollment rate, 21 trials from study duration, 13 trials from number of subjects enrolled, and 10 trials from a combined analysis of enrollment period and study duration. In this report, a small number of Phase I/II, Phase II/III, and Phase III/IV trials were combined with Phase II, Phase III, and Phase IV trials, respectively.

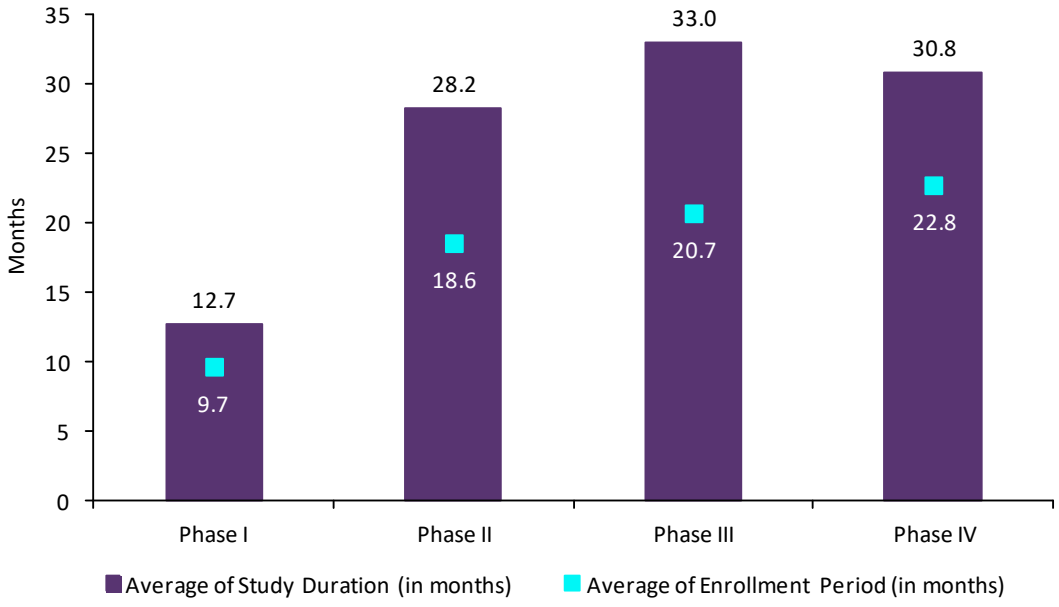
3 Enrollment Landscape in South Korea

3.1 Average Enrollment Period and Study Duration by Phase in South Korea

Of the 3,658 clinical trials in South Korea with a start date between January 1, 2001 and June 5, 2018, Phase III trials had the longest study duration versus Phase I, Phase II, and Phase IV trials, while Phase IV trials required the most time to enroll patients (Figure 1). Phase I trials had the shortest average study duration at 12.7 months, and an average enrollment period at 9.7 months. This is in keeping with expectations, as Phase I trials generally recruit smaller numbers of subjects, and subjects who are healthy. Although the average study duration was five months longer for Phase III than Phase II trials, there was little difference in enrollment period.

Phase III trials had the longest study duration while Phase IV trials required the most time to enroll patients.

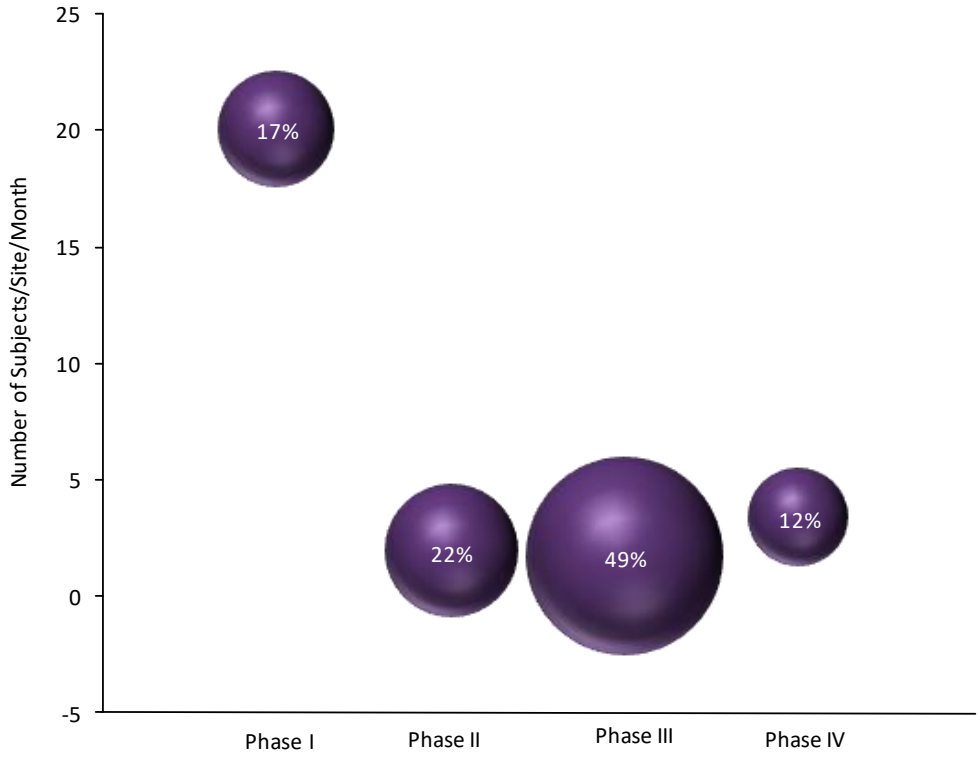
Figure 1: Average Enrollment Period and Study Duration by Phase in South Korea



Source: GlobalData

On average, enrollment rates for clinical trials in South Korea, which includes both single-country and multinational trials, decrease as products move through clinical trials (Figure 2). Phase I trials have the highest enrollment rates, enrolling 20 subjects/site/month, and the third largest number of trials, as shown by the bubble size in the figure below. Phase III trials make up 49% of the total trials being analyzed in this whitepaper, and have a low enrollment rate of 1.7 subjects/site/month. These later-stage trials often have such slow enrollment rates because they require the largest number of patients per trials.

Figure 2: Enrollment Rate by Trial Phase in South Korea



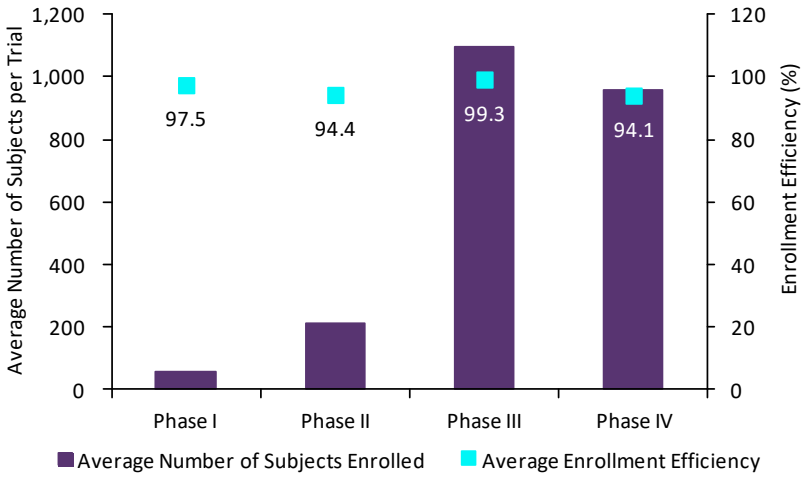
Source: GlobalData

3.2 Enrollment Efficiency and Number of Subjects by Phase in South Korea

Enrollment efficiency is high overall in South Korea, with the lowest rate at 94% in Phase II.

Overall, clinical trials in South Korea have high enrollment efficiency regardless of the developmental phase, as shown in Figure 3, with the lowest enrollment efficiency at 94.1% in Phase IV. Phase III enjoys the highest enrollment efficiency at 99.3% and, as expected, has the highest average number of subjects. The average number of subjects recruited in Phase III is 1,098, compared to 958 in Phase IV, only 211 subjects in Phase II, and 55 subjects in Phase I.

Figure 3: Average Number of Subjects and Enrollment Efficiency by Phase in South Korea

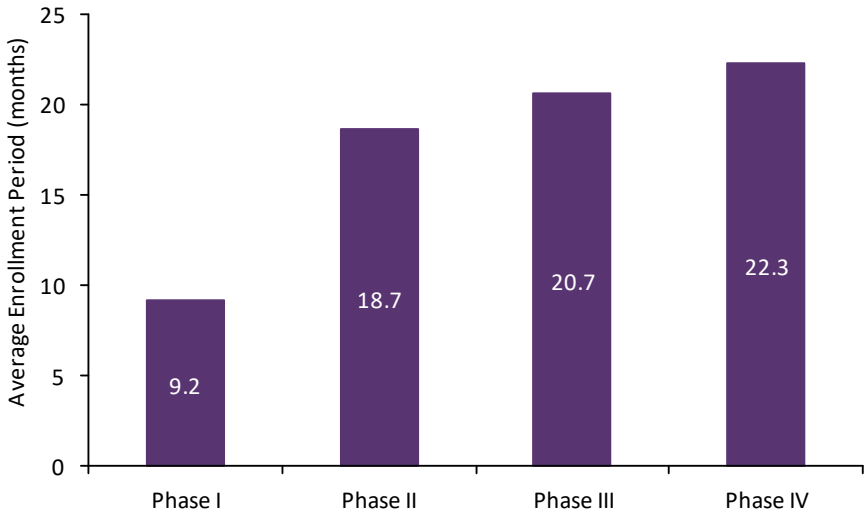


Source: GlobalData

3.3 Average Enrollment Period over the Last Decade in South Korea

Looking at the average enrollment period in South Korea over the last decade, GlobalData found it was 9.2 months for Phase I clinical trials, 18.7 months for Phase II clinical trials, 20.7 months for Phase III trials, and 22.3 months for Phase IV clinical trials (Figure 4). Spanning the entire timeframe, Phase I clinical trials consistently had the shortest enrollment periods, as expected. On average, Phase IV clinical trials have exhibited the longest enrollment periods.

Figure 4: Average Enrollment Period by Phase in South Korea, 2008–2017



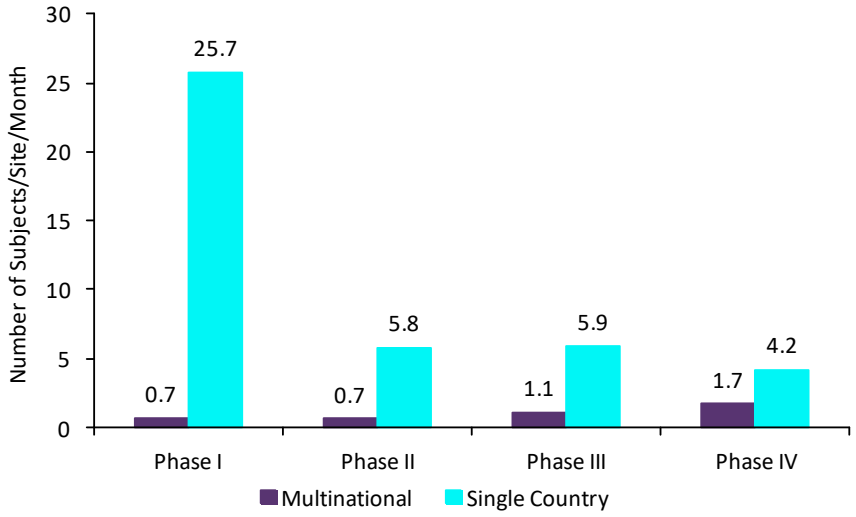
Source: GlobalData

3.4 Enrollment Rate of Single-Country and Multinational Trials by Phase in South Korea

The enrollment rate of single-country trials exceeded that of multinational trials in every phase. The rate was 37 times higher in single-country trials in Phase I, eight times higher in Phase II, five times higher in Phase III, and two times higher in Phase IV, as shown in Figure 5. A much higher enrollment rate of subjects enrolled in single-country trials can be attributed to the single regulatory and ethical authority, as well as the availability of subjects meeting the inclusion criteria for trials.

Single-country trial enrollment rate was higher in all phases than multinational trial enrollment rate.

Figure 5: Enrollment Rate by Phase in Multinational and Single-Country Trials in South Korea



Source: GlobalData

3.5 Dominant Therapy Areas in South Korea by Enrollment Rate

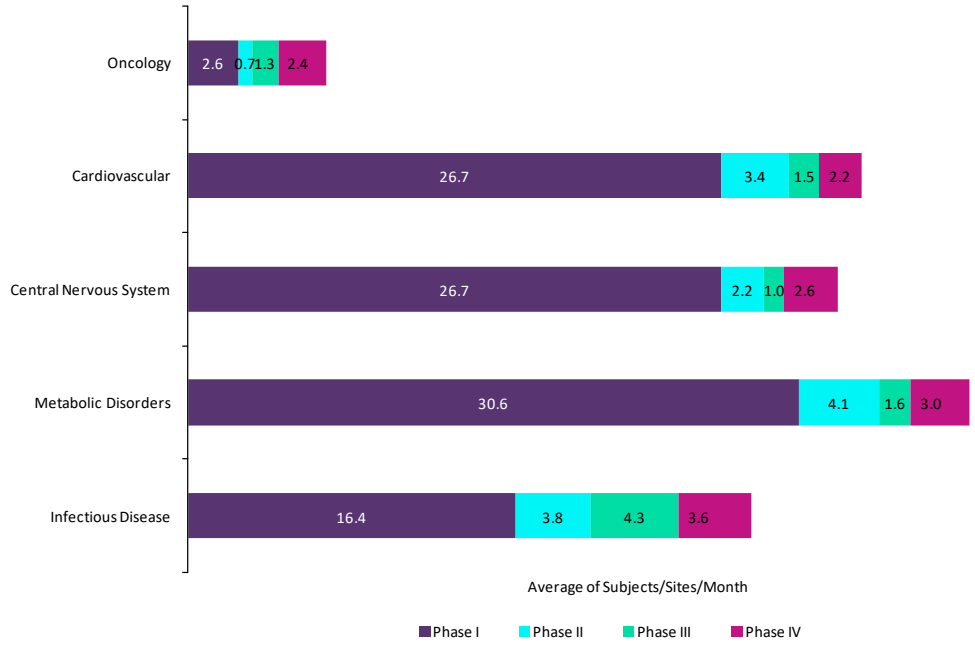
Oncology was the largest therapy area by count of clinical trials in South Korea, at 994 trials. Metabolic Disorders was the second largest therapy area, followed by Central Nervous System, Cardiovascular, and Infectious Disease. However, when comparing enrollment rates between these top five therapeutics areas, Oncology had the slowest overall rate at 1.3 subjects/site/month. Cardiovascular had the highest overall enrollment rate at 10.1 subjects/site/month, with the lowest Phase IV enrollment rate out of any of the top five therapeutic areas (Figure 6).

Oncology was the major therapy area by clinical trial count in South Korea, but had the slowest overall enrollment rate of the top five therapy areas.

One of the reasons Oncology may have the slowest enrollment rate is that it has the longest average study duration, at 40 months, and the longest enrollment period, at 23.2 months, of the top five therapeutic areas (Figure 7). The converse is true of Metabolic Disorders, which had the fastest enrollment rate as well as the shortest study duration and enrollment period.

Oncology trials also often require an invasive procedure like a biopsy in order to determine eligibility, and individuals may be reluctant to go through that process if there is no guarantee they will be included in the study. Another issue that may account for the low enrollment rate may be intense competition for patients due to the high number of Oncology trials in South Korea.

Figure 6: Enrollment Rate of the Top Five Therapy Areas in South Korea



Source: GlobalData

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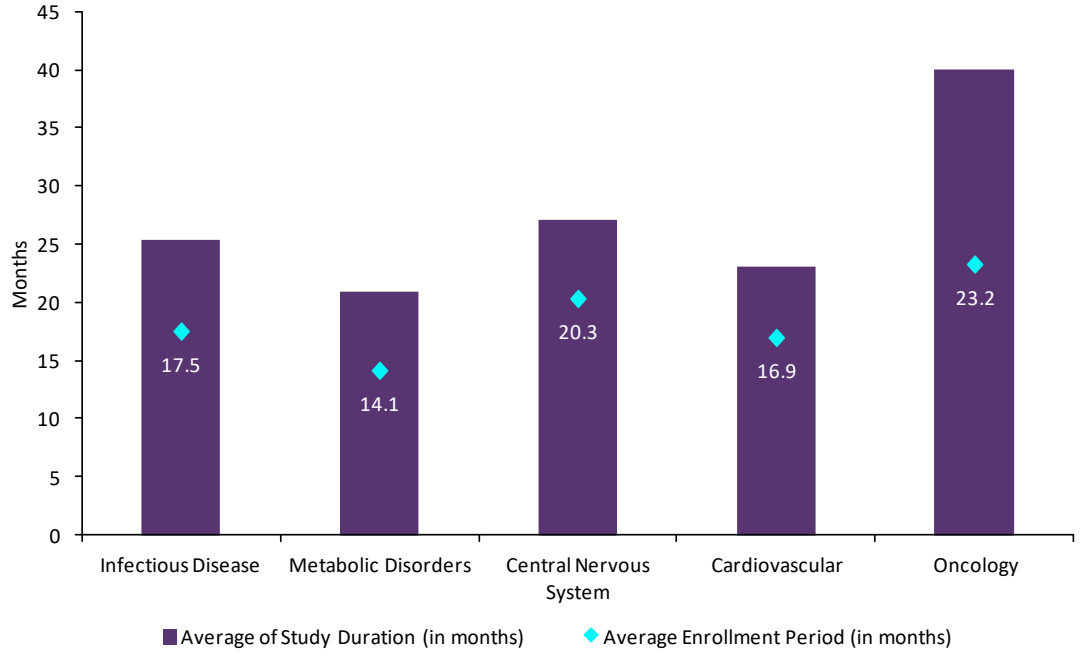
Figure 7: Study Duration and Enrollment Period of the Top Five Therapy Areas in South Korea

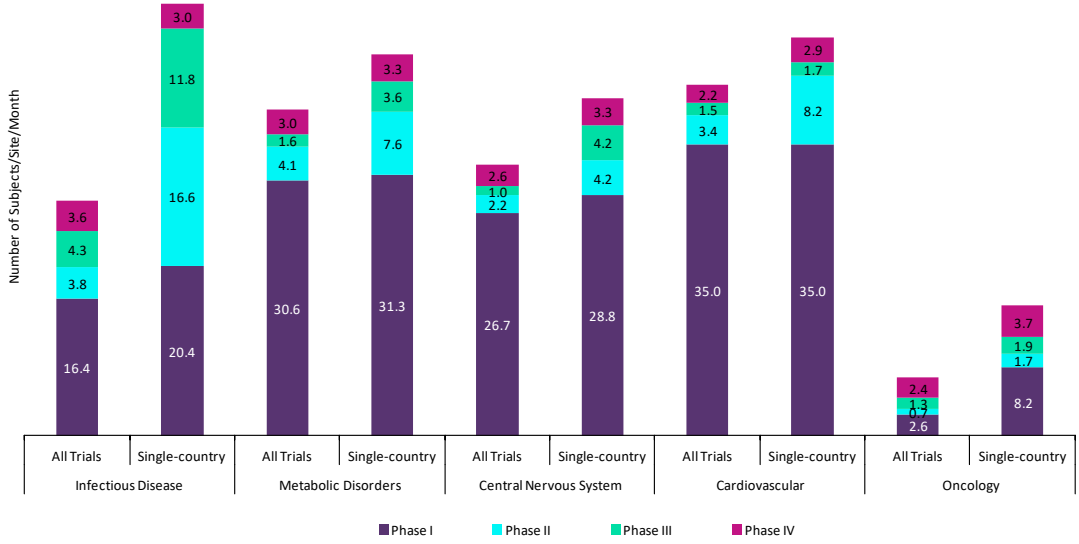


Source: GlobalData

When only single-country trials in South Korea were analyzed in these top five therapeutic areas, the overall enrollment rate increased 2–3 times in all therapy areas. This implies that one of the reasons these top five therapy areas find it easier to accrue participants is because there are more single-country trials. On further analysis, GlobalData found that 51.2% of Cardiovascular clinical trials were single-country trials, with Metabolic Disorder, Infectious Disease, and Central Nervous System over 40%. Only 12.7% of Oncology clinical trials were single-country trials. Thus, the low overall enrollment rate for Oncology trials could be attributed to the increased number of multinational trials.

Enrollment rate was also found to increase across all therapy areas as the phases progressed (Figure 8). Phase III saw the largest increase in enrollment rate when looking only at single-country trials, which was 1.6–2.3 times higher than when taking both single-country and multinational trials into account.

Figure 8: Enrollment Rate of the Top Five Therapy Areas in Single-Country Trials in South Korea



Source: GlobalData

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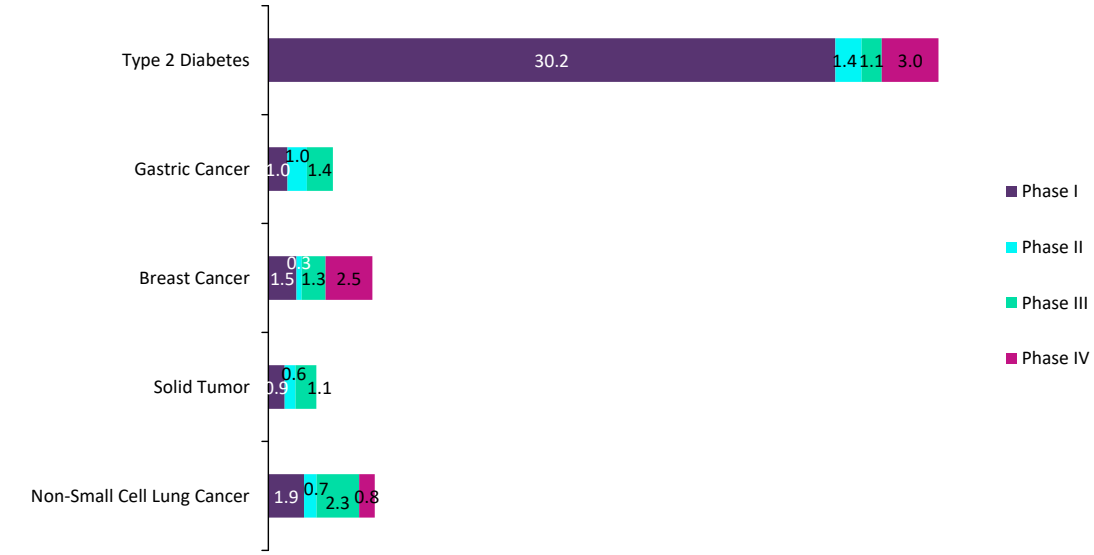
3.6 Top Indications in South Korea by Enrollment Rate

The largest number of clinical trials by indication in South Korea took place in Type 2 Diabetes with 302 trials, followed by Non-Small Cell Lung Cancer, Breast Cancer, Solid Tumor, and Gastric Cancer. Unlike with the top therapy area, the top indication did have the highest overall enrollment rate, at 6.34 subjects/site/month. The lowest enrollment rate overall was Solid Tumor at 0.79 subjects/site/month. Type 2 Diabetes had the highest enrollment rate in Phase I, Phase II, and Phase IV trials (Figure 9).

Type 2 Diabetes was the most frequently studied indication in South Korea and had the highest overall enrollment rate of the top five indications.

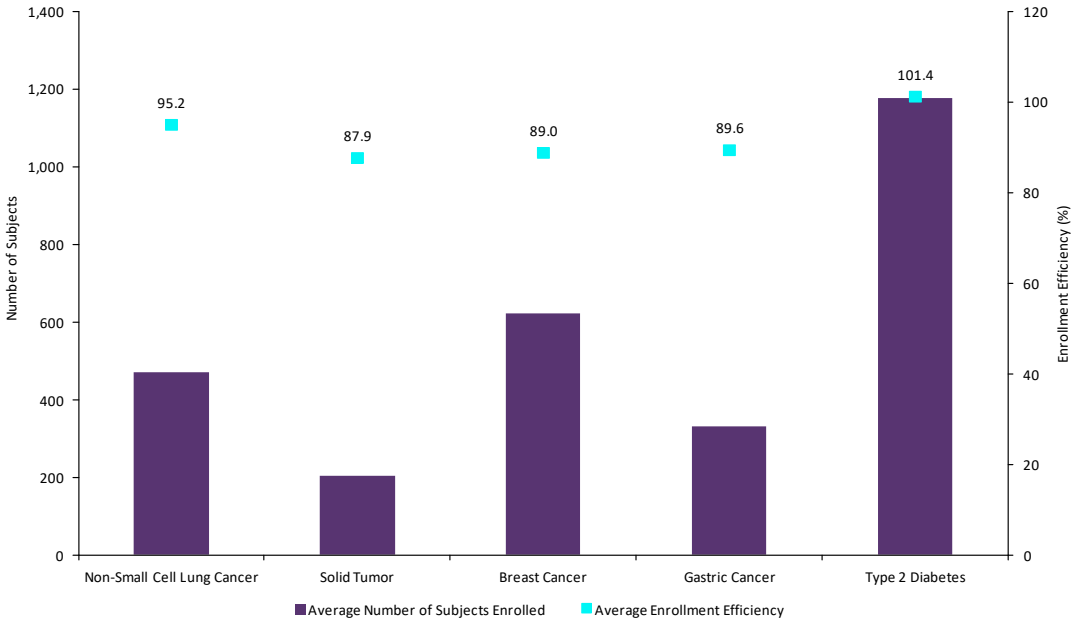
Figure 9: Enrollment Rate of the Top Five Indications in South Korea



Source: GlobalData

Type 2 Diabetes also features the highest average enrollment efficiency of the top five indications, at 101.4% (see Figure 10). As this indication had the highest clinical trial count, it is not surprising that Type 2 Diabetes also had the highest average number of subjects enrolled, at 1,179 participants. Solid Tumor had the lowest enrollment efficiency at 87.9%, as well as the lowest accrual of subjects coupled with a low enrollment rate (Figure 9).

Figure 10: Number of Subjects and Enrollment Efficiency in the Top Five Indications in South Korea



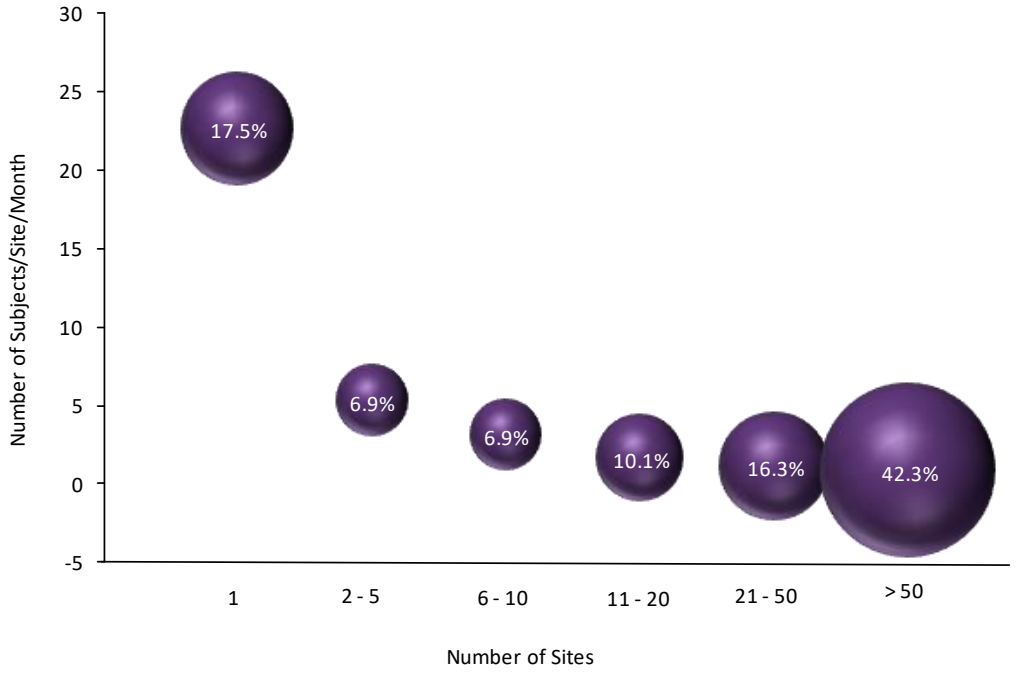
Source: GlobalData

3.7 Enrollment Rate by Number of Sites in South Korea0.

Overall, GlobalData found that in both multinational and single-country trials run in South Korea, the higher the number of sites there were in a trial, the lower the enrollment rate would be (Figure 11). The highest count of clinical trials (shown by the size of the bubble), at 42.3% of the total, was trials with a site count of above 50. The second highest count of clinical trials, at 17.5%, was clinical trials with a site count of one. The enrollment rate is 22.7 subjects/site/month for the single-site trials compared to only 2.3 subjects/site/month in trials with a site count over 50.

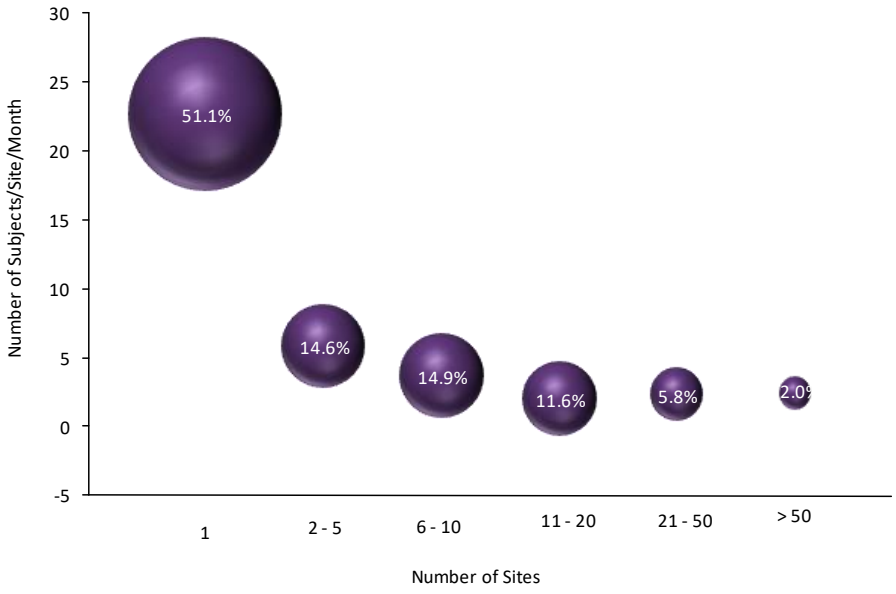
When compared to only single-country trials, the enrollment rate trend remained the same, with enrollment dropping as more sites were added to a trial (Figure 12). However, the count of clinical trials in these brackets reversed dramatically, with 51.1% at just one site. The trial size continued to drop as the number of sites increased.

Figure 11: Enrollment Rate by Number of Sites in South Korea



Source: GlobalData

Figure 12: Enrollment Rate in Single-Country Trials by Number of Sites in South Korea



Source: GlobalData

3.8 Summary

GlobalData performed multiple analyses of Phase I to Phase IV clinical trials in South Korea that met the enrollment database criteria. Later-stage trials, such as Phase III and Phase IV, were found to have a longer study duration and enrollment period. The enrollment rate, which was represented as subjects/site/month, decreased through the pipeline, with Phase IV being an exception. This was mirrored by the decrease in enrollment rate as the number of sites increased in a trial. The average number of subjects enrolled in trials in South Korea increased from Phase I through Phase III, and the enrollment efficiency was 94.4% or above. Single-country trials were found to have an at least two times higher enrollment rate than multinational trials in all phases. Enrollment rates were also found to increase predominantly for single-country Phase I trials when compared to the enrollment rates of all trials.

The top therapy area was Oncology, followed by Metabolic Disorders, Central Nervous System, Cardiovascular, and Infectious Disease. Oncology had the highest clinical trial count but the lowest overall enrollment rate. Oncology also had the longest average study duration and enrollment period. Type 2 Diabetes was the major indication in South Korea by trial count, followed by Non-Small Lung Cancer, Breast Cancer, Solid Tumor, and Gastric Cancer. Type 2 Diabetes also had the highest overall enrollment rate, average number of subjects enrolled, and enrollment efficiency.

4 About the Authors

4.1 Analyst, Clinical Trials Database

Scotty Chung-Siu, MPH, BS, is an Analyst at GlobalData in Fairfax, Virginia, where his primary responsibilities include updating database updates for major drug indications, producing analytical reports, maintaining and improving database functionality through quality assurance testing, and providing customer service through client queries. Prior to joining GlobalData, Scotty worked as the Research Analyst at PharmSource researching biotechnology, medical technology and pharmaceutical product development information. Scotty holds a Master of Public Health with a concentration in Environmental Health from Eastern Virginia Medical School and a Bachelor of Science in Biology from George Mason University.

4.2 Managing Analyst, Clinical Trials Database

Brooke Wilson, **BSc Biotech(Hons),** is the Managing Analyst of Clinical Trials at GlobalData in Washington, D.C., where she is responsible for the development and enhancement of the clinical trials and investigator database. Prior to GlobalData, Brooke was the Head, Lead Sheet at PharmSource for 12 years where she gained solid experience in every aspect of drug development, and drove the content and production of the Lead Sheet product. Brooke managed and trained analysts, and worked with software developers for product enhancements based on clients' needs. She has experience in interacting with clients and working with sales as a Lead Sheet technical expert. Brooke graduated from the University of Newcastle, Australia, with a BSc in Biotechnology, followed by an Honors degree in Biotechnology with a thesis focused on intestinal bacteria.

4.3 Global Director of Databases and Analytics

Revati Tatake, PhD, is the Global Director of Databases and Analytics at GlobalData in New York City, where she is responsible for the development and continuous enhancement of databases in the company's *Pharma Intelligence Center*. Revati has diverse experience, both in academic research and the healthcare industry, where she worked on several research, drug discovery, and competitive intelligence projects across many therapeutic areas. Before joining GlobalData, Revati worked at Citeline, where she was involved in competitive intelligence and analytics of clinical trials and products in the areas of Autoimmune/Inflammation, CNS, and Ophthalmology. Previously she worked at Boehringer Ingelheim Pharmaceuticals for over 10 years, where, as a Senior Principal Scientist, she led drug discovery projects involving traditional high-throughput screening, as well as innovative approaches for gene and cell therapies. She is a co-inventor on many issued US patents and

applications related to projects on cell and gene therapies. Revati holds a PhD in Tumor Immunology from the Tata Cancer Research Institute in Mumbai, India. She was also a postdoctoral fellow at the University of Connecticut Health Center.

4.4 Global Head and EVP of Healthcare Operations and Strategy

Bornadata (Bonnie) Bain, PhD, is the Global Head and EVP of Healthcare Operations and Strategy. Bonnie has almost 20 years' experience in the healthcare sector and a proven track record of developing innovative solutions on both the client and agency sides of the business. Bonnie was GlobalData Healthcare's first western analyst and under her leadership, the company launched a number of premium syndicated reports, analytical tools and databases in the pharmaceuticals and medical devices space. Prior to GlobalData, Bonnie was Vice President and Global Research & Analysis Director for Informa's Pharma Division, which includes Datamonitor Healthcare, Scrip Group, and Business Insight. Bonnie also worked for several years at Decision Resources as an Analyst and Project Manager. On the client side of the industry, Bonnie worked for several years as a Senior Manager in Marketing Strategy and Analytics at Boston Scientific where her work contributed to the successful commercialization of the first ever Access and Visualization Platform at the company. Bonnie has a PhD in Biochemistry and Molecular Biology from Purdue University and completed a Post-Doctoral Fellowship in Molecular Pharmacology at the University Of Miami School Of Medicine. She also has a graduate certificate in Applied Management Principles from Purdue University Krannert School of Management.

5 About the Pharmaceutical Clinical Trials Team

GlobalData's Pharmaceutical Clinical Trials Team focuses on ensuring that the company's records of clinical trials are accurate, inclusive, and comprehensive. The team works to make sure that the most up-to-date information on clinical trials is always available to clients through the Pharma Intelligence Center.

6 About GlobalData

GlobalData is a leading global provider of business intelligence in the Healthcare industry. GlobalData provides its clients with up-to-date information and analysis on the latest developments in drug research, disease analysis, and clinical research and development. Our integrated business intelligence solutions include a range of interactive online databases, analytical tools, reports and forecasts.

With an unmatched team of analysts, epidemiologists, and consultants, we provide high-quality, accurate, and transparent insight that can help you achieve growth and increase business value. Our analysis is supported by a 24/7 client support team, and our analyst teams are available to further address client-specific issues or information needs on an inquiry or proprietary consulting basis.

GlobalData has offices in New York, San Francisco, Boston, London, India, Korea, Japan, Singapore, and Australia.

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