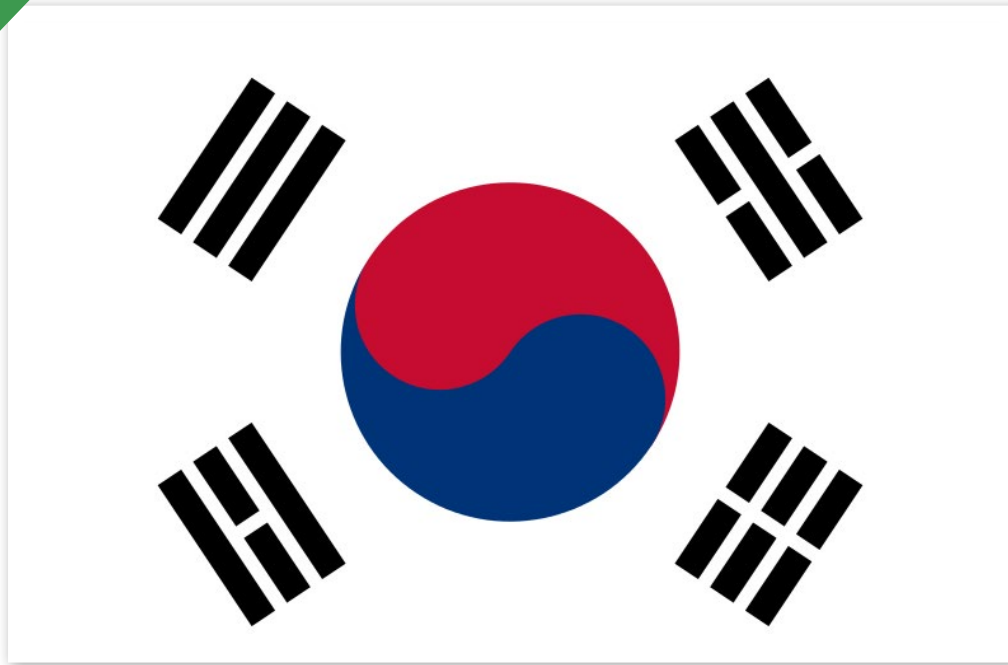


PREVIEW



South Korea: Clinical Development Country Profile



Report Overview

In this report, ISR provides insight into the clinical development environment, sponsor and service provider activities, and population "health status" for South Korea.

109
Pages

76
Charts and
Graphs

Q2,
2013
Publication Date

Valuable for:

- **Clinical Operations**
- **Medical Directors**
- **C-Suite**
- **Portfolio Management**

Major Sections:

1. **Introduction**
2. **Industry Interviews**
3. **Korea Health Statistics**
4. **Healthcare Technology and Medication Use**
5. **Service Provider Capabilities**
6. **Domestic Clinical Service Providers**
7. **Domestic Non-Clinical Service Providers**

How you can use this report:

- Understand how sponsors and CROs view South Korea as a site for clinical trials
- Uncover logistical details for conducting South Korean trials
- Illustrate the benefits and drawbacks of conducting trials in South Korea
- Learn how South Korea compares to other countries on a variety of scales so the reader can best consider the areas in which South Korea may be beneficial as a trial site for their particular company

What you will learn in this report:

- How population characteristics, qualified investigators, and government policies and incentives make South Korea the 8th most active and most valuable country for clinical trial activity
- On-the-ground insights from numerous high-level R&D employees in sponsor organizations and country heads from multinational CROs
- Health statistics in Korea, including disease incidence and prevalence, use of imaging technologies, and use of medicines in major therapy areas
- Contact details for pharma companies and principal investigators in South Korea

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 - Background / History
 - Master Agreement & Preferred Vendor
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- DreamCIS Inc.
 - Background / History

- Master Agreement & Preferred Vendor
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GDFI Co., Ltd.

- Background / History
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Orient Bio

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Biototech

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Chemon Inc.

- Background / History
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- Background / History
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- Services Offered

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International Pharma Company List and Locations

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About ISR

Sample Page

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Introduction

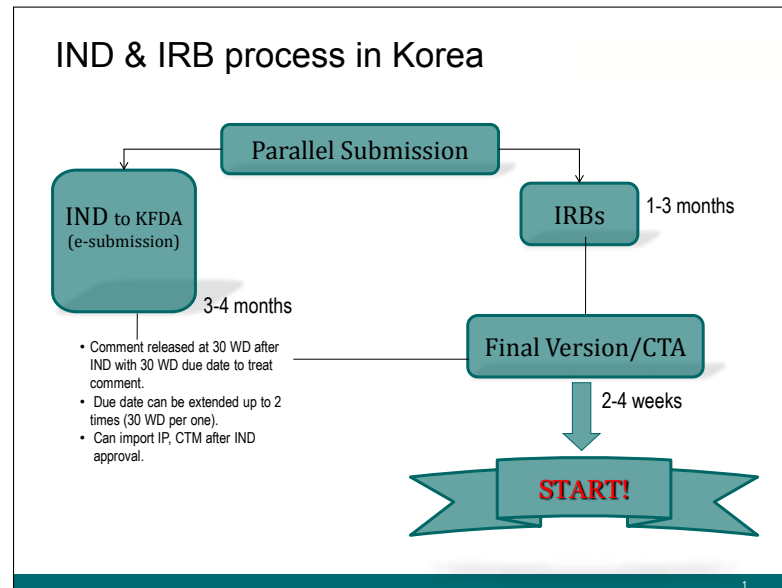
Finding patients for clinical trials is hard. Finding patients willing to participate is one thing, keeping them enrolled is another. Finding them with the requisite medication history (or lack thereof) is challenging. Competing with other sponsor or CRO companies adds additional hurdles to overcome. Overcoming all of these obstacles in a reasonable timeframe adds additional pressure. So it is no wonder sponsor and CRO organizations are expanding globally to not only find patients for clinical trials, but also to commercialize their products.

This is where South Korea comes into play.

The South Korean government has put in place several initiatives to encourage innovation in the healthcare industry. Combine this with a highly educated population, a western-style medical practice, a highly wired (or wireless) communications infrastructure, and a population concentrated in a few urban areas, and South Korea starts to look like a pretty good place for clinical development activities.

Sample Page

The regulatory requirements in Korea are similar to ICH countries. The Korean Food and Drug Administration (KFDA), which is reportedly soon to become the Ministry of Drug and Food Safety (MDFS), will have greater powers to initiate legislation and deal with food and drug safety issues. Reviews by the MDFS and Institutional Review Board (IRB) can be done in parallel which helps to expedite the process.



Sample Page

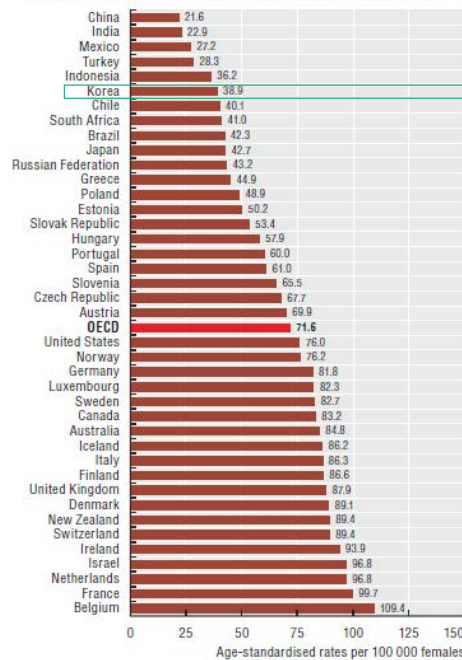
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Female breast cancer incidence

Age-standardized female breast cancer incidence rates of South Korea are well below the OECD average. South Korea reports a rate of 38.9 per 100,000 females while the OECD reports a rate of 71.6 per 100,000 females.

1.11.2 Female breast cancer incidence rates, 2008



Source: Ferlay et al. (2010).

StatLink <http://dx.doi.org/10.1787/888932523804>

Sample Page

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Service Provider Capabilities

	Applied Biopharm Inc.	C&R Research	DreamCIS Inc.	GDFI Co., Ltd.	LSK Global PS	Medical Excellence Inc.	Orient Bio	PharmaCRO	Bio-Core Co., Ltd.	Biototech	Chemon Inc.	Korea Institute of Toxicology
Clinical Trial												
Preclinical				●								
Phase I				●								
Phase II-III				●								
Phase IV				●								
Post Marketing				●								
Lab Services												
Bioanalysis												
Bioavailability												
Bioequivalence												
Pharmacokinetic												
Toxicology				●								
Services												
Biostatistics				●								
Clinical Monitoring				●								
Data Management				●								
Drug Safety				●								
Feasibility Studies				●								
Medical Writing				●								
PMS & Pharmacovigilance				●								
Project Management				●								
Protocol Development				●								
Protocol/ CRF Review				●								
Site & Investigator Selection												
Study Design				●								
Regulatory Affairs												
IRB				●								
Global Studies												
				●								
Quality Assurance												
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Consulting												
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Training												
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