



**CLINICAL TRIALS POLICY ANNEX: IMPROVING
COLOMBIA'S CLINICAL RESEARCH ENVIRONMENT**
Learning From International Best Practices and Country Case Studies

INTRODUCTION

Within the context of Colombia seeking to improve its attractiveness to clinical research this *Clinical Trials Policy Annex* is a briefing document on the clinical research policy environment. While it accompanies the main report *Challenges and Opportunities – Developing the Biotechnology Sector in Colombia* and is meant to be read in conjunction with that document, this Annex can also be used on a stand-alone basis for informing discussion on public policies aimed to increase flows of clinical research.

Clinical trials are fundamental components of the biopharmaceutical research and development process. They enable companies and drug regulators to ensure that new drugs will be safe and effective for use. They also often uncover novel applications of medicines and medical devices or facilitate tailoring drugs to different populations.

Beyond this, clinical trials have crucial wider public health, social and economic benefits that align with many strategic policy objectives of governments today. These include enabling development and local access to needed cutting edge treatments, building domestic capacity in biopharmaceutical and clinical research and containing health care and pharmaceutical costs.¹

Yet some countries manage to attract more clinical trials than others. These include not only developed but also developing and emerging markets. Critically, most of the global leaders in terms of clinical trials intensity also attract a larger share of the riskier, early-phase trials which represent the cutting edge research in therapeutic areas such as oncology or of biologic drugs.²

In this respect, it is relevant to ask how these countries have succeeded in making themselves more attractive. A sizeable body of literature discusses which factors are most important for stimulating growth of investment in clinical trials in a given country.

In this context, this Annex does the following:

- Provides a detailed overview of the socio-economic benefits of conducting clinical trials to a host country – why are clinical trials important and what are some of the benefits they have to local patients and the wider economy in a given host country?
- Looks at some of the best practices and policy measures aimed at enhancing domestic attractiveness for clinical research as adopted by four countries which are now considered leaders in the global clinical research arena.

The four countries examined in this Annex are:

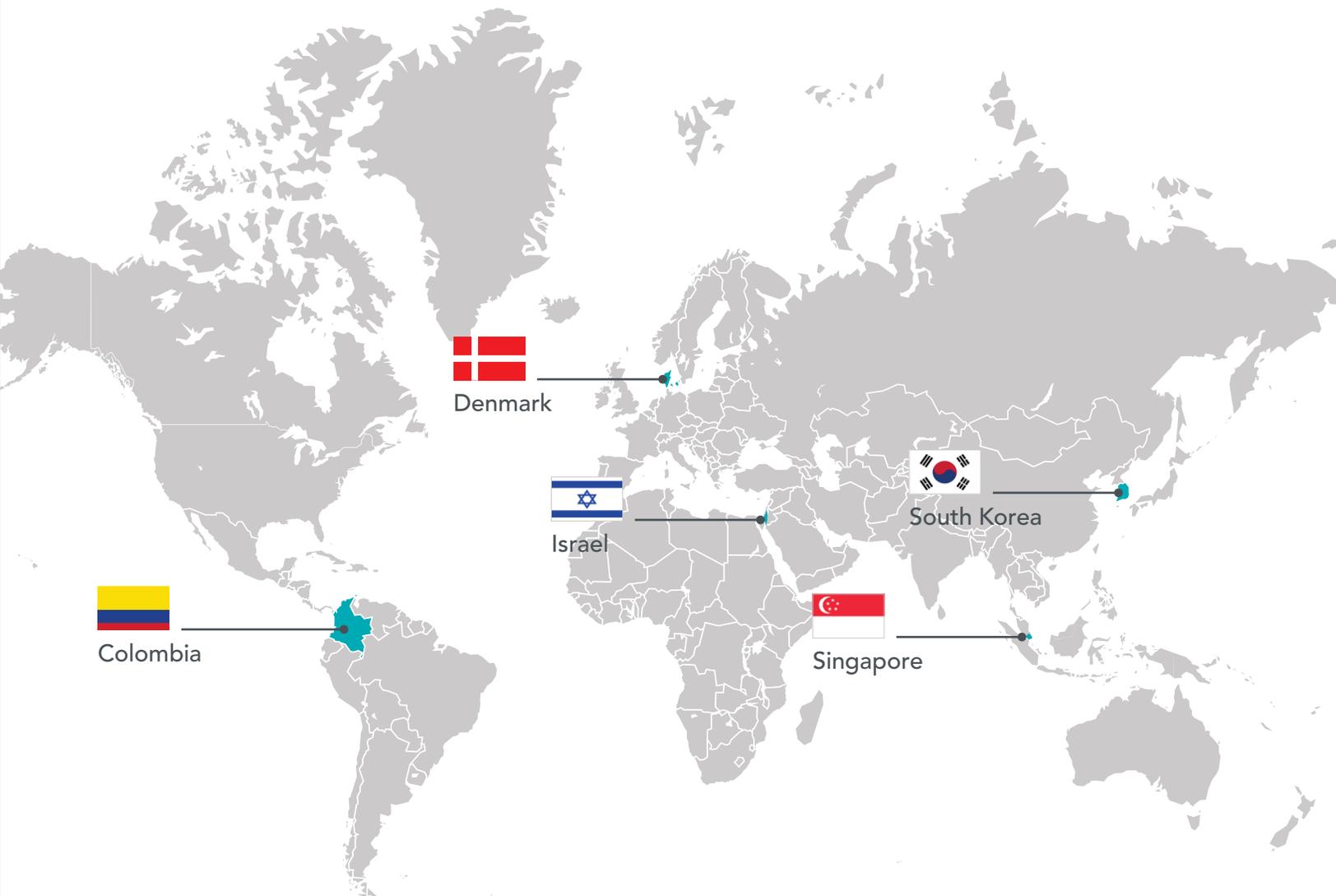
1. Denmark
2. Singapore
3. South Korea
4. Israel

These country case studies are followed by an analysis of the current state of the clinical research environment in Colombia, with the intention to identify the barriers and challenges in place and what can be done to overcome them and enhance Colombia's attractiveness in the field of clinical research.



BEST IN CLASS: COUNTRY CASE STUDIES OF A SAMPLE OF THE WORLD'S TOP CLINICAL RESEARCH DESTINATIONS

Clinical trials represent one of the most important activities carried out by biopharmaceutical companies in different countries. Clinical research is a cornerstone of the drug development process. Conducting clinical trials is part of an extensive process for determining which compounds out of hundreds under investigation may be further developed and eventually brought to market, and in what manner.



What are clinical trials and where do they figure in the drug development process?

The main purpose of clinical trials is to test and provide proof of the safety, quality and efficacy of new drugs or new uses, forms or dosages of existing drugs. Clinical trials are conducted within a highly controlled and studied environment where all aspects of a drug candidate are monitored, recorded and subject to high levels of scrutiny and evaluation. The clinical research process includes complying with a wide range of regulations governing international best practices related to the quality, safety and efficacy of drugs, for instance, Good Laboratory Practice guidelines on conducting toxicity studies, Good Manufacturing Practice and protecting the rights of patients through Good Clinical Practice.³ Without clinical trials it would be exceedingly difficult to test the safety, quality and efficacy of a proposed new medical technology. In this sense while the nature of clinical research has changed over the last few decades with new development technologies emerging, clinical research is still a fundamental cornerstone of modern medical development. On the following page figures 1 and 2 provide an overview of the drug development process and where in that process clinical trials take place.

The entire biopharmaceutical R&D process surrounding the creation of a new drug is a very involved and a financially risky process, with significant resources invested. The testing of drug candidates in human volunteers via clinical trials prior to market authorization,⁴ which is divided into 3 main phases, represents an undertaking of 6-7 years per drug candidate, or between 55% and 75% of the total R&D process.⁵ Various sources cite different figures for the length and cost of the clinical trials phase, ranging from USD845 million to USD1.17 billion.⁶ These numbers are continuously on the rise, and have doubled in the past decade.⁷ Phase II trials represent one of the riskiest segments of the R&D process, involving a substantial investment with 100-500 volunteers per trial but only a 40% success rate. Figure 2 shows the time and investment typically required for each stage of the clinical research process.

The benefits of clinical trials I: Provide advance access to innovative treatment and enhance medical care

First and foremost, clinical trials provide patients with access to innovative drugs, which may literally revolutionize existing treatments available domestically for prevalent diseases.⁸ In fact, clinical trials enable advance access to treatments that may continue beyond the duration of the clinical trial.⁹ In this sense the availability of a trial in a host country can be the difference between a patient gaining access to a given novel treatment in research or waiting for a number of years until the product has been fully developed and globally launched. For patients with rare and/or difficult and terminal diseases the availability of local trials can be a question of life or death.

Clinical trials also enable local physicians to participate in cutting-edge research as well as become members of multi-center research network. Such experience helps build R&D expertise, experience and prestige, and expands the ability of local researchers to publish their research and become key opinion leaders in their field. They often involve improvements to infrastructure – hospitals, clinics and health technologies – in local communities.¹⁰ Participation in multinational, cutting-edge research helps ensure that clinical trials and sites meet international standards of “Good Clinical Practice”, and exposes clinicians to new techniques and treatment strategies. In this sense the growth and conduct of clinical trials improves the overall medical research infrastructure and experience in a given country and region.

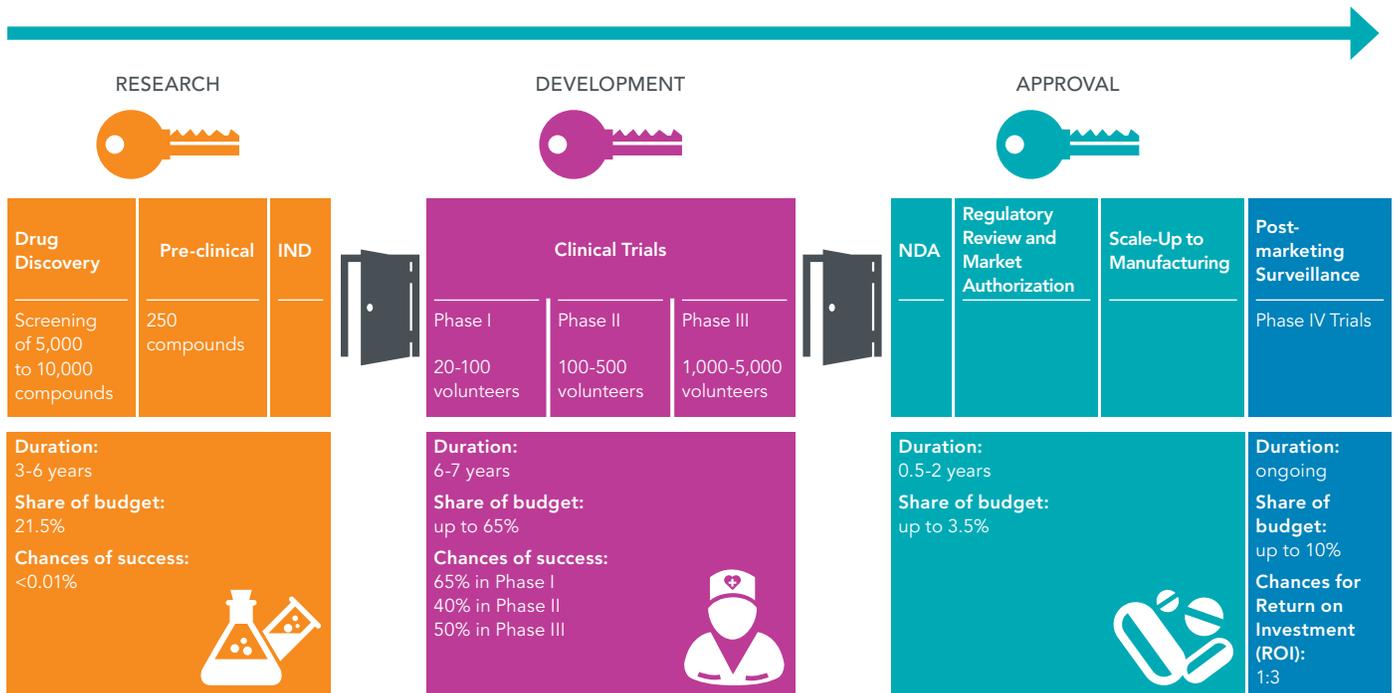
The benefits of clinical trials II: Provide macroeconomic benefits to hosting countries

Clinical research can have significant positive direct and indirect macroeconomic benefits. To begin with they represent a significant portion of the global R&D spending undertaken by the biopharmaceutical industry. In 2014 global life sciences R&D spending was estimated at around \$200 billion, with biopharmaceutical R&D investment by PhRMA member companies at over a quarter of that (around \$51 billion).¹¹

FIGURE 1 The biopharmaceutical R&D process

Source: Pugatch Consilium, based on FDA (2014)¹²

FIGURE 2 Pharmaceutical R&D process timeline



Source: Pugatch Consilium; adapted from PhRMA¹³ and Nature¹⁴

These figures place life sciences at the top of R&D spenders worldwide, second only to the ICT industry.¹⁵ And on a micro level, the biomedical and biopharmaceutical sectors spend more than double the amount on R&D per employee compared to the ICT sector.¹⁶ A significant portion of spending on biomedical manufacturing and wider operations also entails in-depth investment and high-value employment growth. According to a recent study by UNCTAD, cross-border mergers and acquisitions in the life sciences field were valued at over \$40 billion globally as of 2013.¹⁷ Moreover, “greenfield” FDI – foreign investments with no pre-existing operations or infrastructure – by pharmaceutical companies amounts to over \$13 billion globally.¹⁸ Additionally, by some estimates life sciences industries generate close to 4 million jobs in the U.S. alone (in the sector directly as well as in supporting sectors such as distribution and logistics).¹⁹

Apart from the above direct investments and sponsorship, with costs of a given product being researched and tests associated with the clinical trial often being borne by the study’s sponsor, clinical trials may lead to savings for healthcare

systems.²⁰ In addition, in some cases, the sponsor may continue to provide the treatment, for instance, at a preferential price.²¹

Clinical trials also provide financial value to governments through tax contributions derived from revenue earned on clinical trials by sponsors in a given country.²² Particularly internationally-sponsored clinical trials provide opportunities for the growth of a local clinical research industry, including clinical research organizations and site management organizations, with associated potential for increase of taxable revenue and employment.²³

Section summary

Having provided a detailed overview of the socio-economic benefits of conducting clinical trials to a host country the next few pages will examine some of the best practices and policy measures aimed at enhancing domestic attractiveness for clinical research as adopted by four countries which are now considered leaders in the global clinical research arena. The four countries studied are: Denmark, Singapore, South Korea and Israel.



Denmark

Denmark is the world's 34th largest economy with a population of 5.6 million.²⁴ Denmark is considered a global leader in the fields of innovation within the life sciences sector, ranked 2nd in the Scientific American Worldview Scoreboard of 2015,²⁵ and 12th (out of 140 economies) in the World Economic Forum's Global Competitiveness Report of 2015-2016.²⁶

Clinical research overview

In the field of clinical research, Denmark is considered an attractive location with a supportive environment. Among the reasons are its strong healthcare system, a robust regulatory framework, high standards of clinical research, and high levels of participation and compliance.²⁷ Indeed, Denmark is a global leader in clinical trials intensity – the gross number of clinical trials to date per million population – with more than 800 clinical trials per

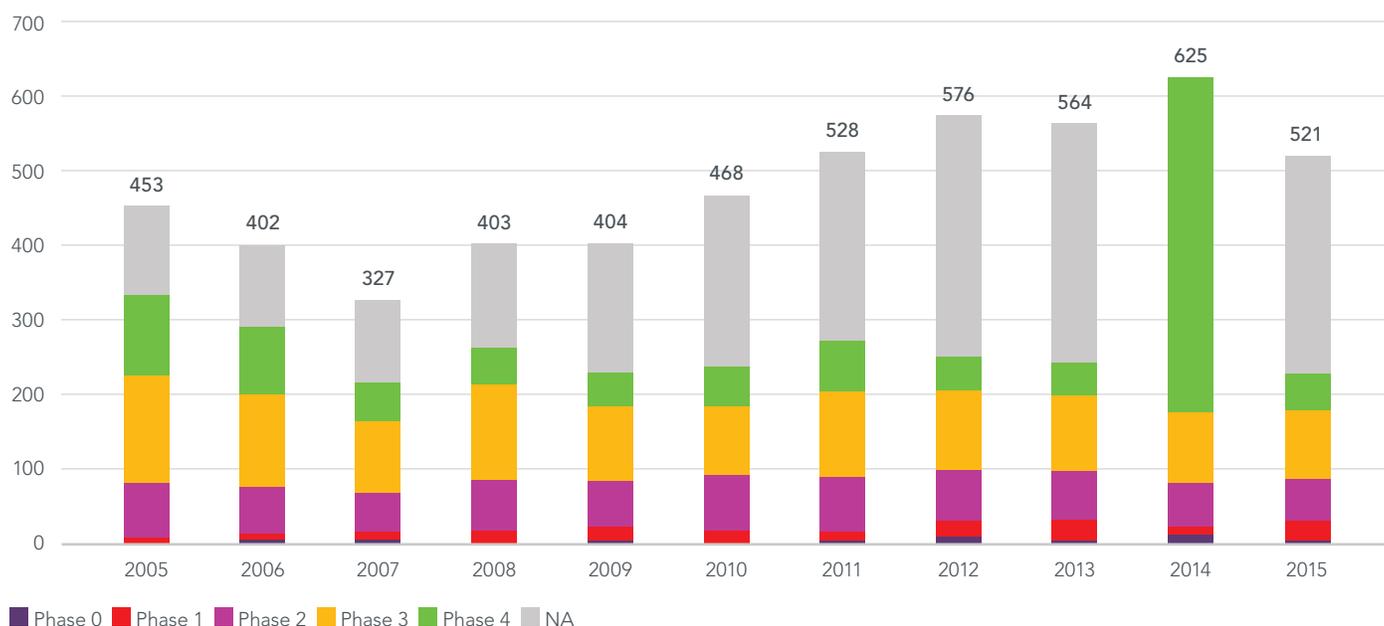
million population,²⁸ and over 100,000 Danish citizens participate annually in clinical research.²⁹

Pursuant to section 88 of the Danish Medicines Act and to the Act on Scientific Ethical Committee System and the Processing of Biomedical Research, a clinical trial must be approved by the Danish Medicines Agency (DKMA) and by one of the 11 regional Scientific Ethical Committees.³⁰ The regional Scientific Ethical Committees follow guidelines issued by the national Committee on Health Research Ethics (established in 2012), which also coordinate their activities.³¹ The DKMA follows ICH guidelines on clinical research, and liaise with national and regional ethics committees, regional GCP bodies (all clinical trials in Denmark must adhere to its GCP standard), medical organizations and the private sector.³²

Clinical trials policy framework

During recent years Denmark has taken several steps to create a supportive clinical trial environment. In 2011 the Clinical Trials Office Denmark was established as a joint project of Denmark's five regional healthcare authorities and the pharmaceutical industry, with the intention

FIGURE 3 Clinical trials in Denmark, by phase, 2005-2015



Source: Clinicaltrials.gov, 2016; analysis: Pugatch Consilium

of creating a simple and efficient communication channel for planning clinical trials and recruiting subjects in Denmark. The Clinical Trials Office Denmark acts as a mediator for clinical trials' sponsors, offering a nationally-standardized service in recruitment of subjects, advising on the best ways to conduct clinical trials in Denmark, and assisting in concluding contracts and agreements.³³ The Danish MoH has also launched a website which informs citizens on new and on-going clinical trials in order to assist in the recruitment process.³⁴

Additionally, since 2012 the DKMA has offered a fast-track approval pathway for clinical trials on investigational drugs which are: authorized for use in the EU or the EEA, tested under a licensed indication, and not involving an additional risk to the subjects beyond the existing treatment. Clinical trials which satisfy these criteria are assessed in a period of only 14 days.³⁵ While pursuant to the Danish law the DKMA has an assessment timeframe of 60 days, most trials are authorized within a significantly shorter period. In 2015, over 80% of all clinical trial applications were reviewed within a period of 43 days.³⁶

Furthermore, in 2014 the DKMA has launched the DKMAnet, a designated portal which enables companies to submit, using a digital certificate and signature, clinical trial applications, amendments, notifications and other safety-related material electronically and directly to both the DKMA and the Scientific Ethical Committees.³⁷ The shared platform relies on available data from the pan-European EudraCT database, and automatically selects the relevant information for the DKMA and the Scientific Ethical Committees.³⁸ This initiative essentially renders the clinical trials' regulatory approval process into a 'one-stop shop' for sponsors.

In addition, under the Danish government's INNO+ initiative which aims to place Denmark as a preferred location for conducting riskier, early-phase trials the National Experimental Therapeutic (NEXT) partnership was formed in November 2014. This public-private partnership joins the Capital region of Denmark, public hospitals and pharmaceutical companies in order to invest in the establishment of cutting-edge national research centers.³⁹

It is important to note that pursuant to the new Clinical Trials Regulation (CTR) EU No 536/2014 the EMA is developing a new portal which is designated to centralize all clinical trials applications for the EU.⁴⁰ While Denmark has initiated several legislative and institutional changes in accordance with the new CTR, its entry into force is now expected only in 2018, due to delays in the preparation of the new portal and database.⁴¹



Singapore

Singapore is the world's 36th largest economy and 8th wealthiest in GDP per capita in 2014, with a population of 5.5 million.⁴² Singapore is considered both a regional and global leader in the fields of innovation within the life sciences sector: it is ranked 5th in the Scientific American Worldview Scoreboard of 2015.⁴³ Singapore is the world's second most open and competitive economy according to the World Economic Forum, ranked 2nd (out of 140 economies) in the Global Competitiveness Report for 4 consecutive years.⁴⁴ It is also heralded as the most pro-business country, ranked 1st (out of 189 economies) in the World Bank's *Ease of Doing Business* of 2016.⁴⁵

Clinical research overview

Singapore is a striking example of a country that in the last fifteen years has built up an active biomedical science system from almost no base at all before 2000. As a result of research collaboration and reciprocal government investment, Singapore has transformed itself into a key player in biomedical R&D, especially in translational and clinical research. It has boosted its science base, attracting national and foreign scientists to its new research institutes, built state-of-the-art infrastructure and developed key partnerships with many established biopharmaceutical companies.⁴⁶ As a result, the number of clinical trials has increased from only 2 in 2000 to an average of 151 clinical trials each year since 2010.⁴⁷

Singapore has also created a specific body to liaise between universities, public research institutes and industry needs, called the Biomedical Sciences Industry Partnership Office. This body seeks to catalyze and promote partnerships between industry and public sector research, linking upstream public sector research with downstream commercialization partners.⁴⁸ Building up a high quality biomedical research base has allowed Singapore to attract a number of multinational pharmaceutical companies, which are now supporting the further development of a domestic biomedical industry, particularly in fields of biologics and translational and clinical research.⁴⁹

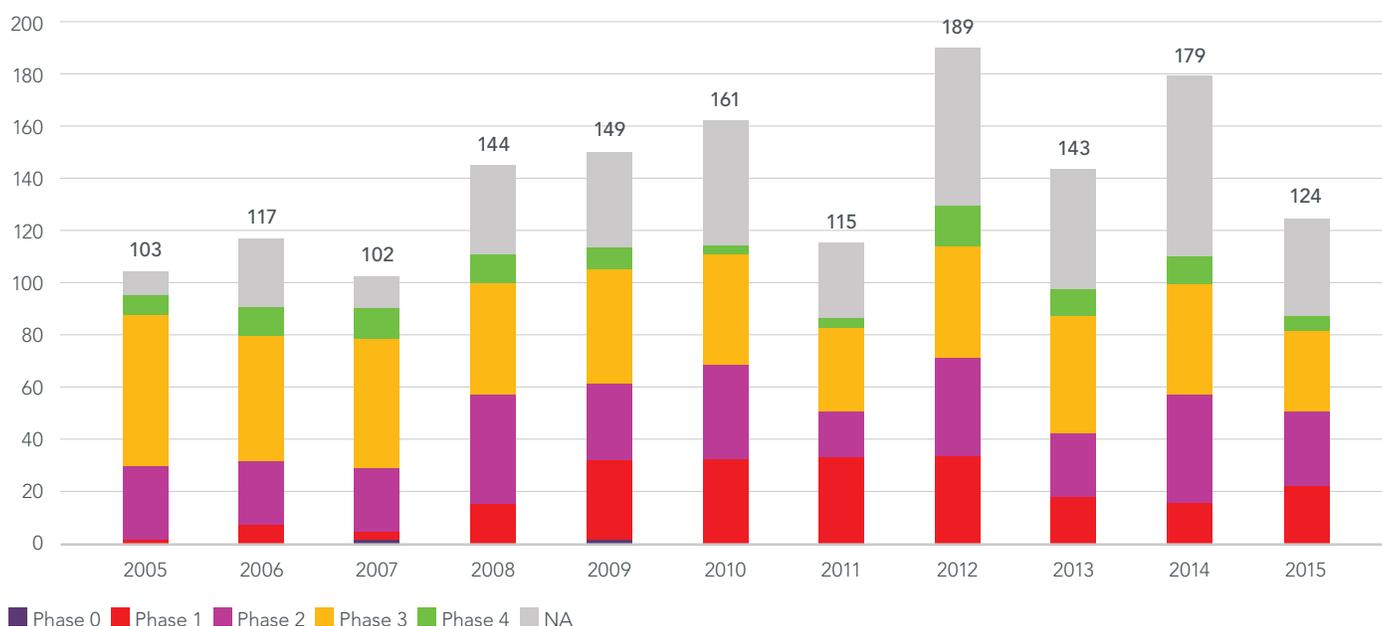
Clinical trials policy framework

The legislation governing clinical trials in Singapore requires separate authorization from the Health Sciences Authority (HSA) and from an Institutional Review Board, which provides the ethical approval. Since 2006 applications can be made in parallel to these bodies, thus decreasing the time taken for regulatory approval significantly.⁵⁰ Indeed, clinical trial applications are usually processed within a

timeframe of 30 days, and small-scale clinical trials (such as for the assessment of bioequivalence or food-drug/drug-drug interactions) are processed within a timeframe of only 15 days.⁵¹ Additionally, clinical trials that test drugs (or a drug indication) which are already approved for marketing are exempt from the process and must only submit a notification to the HSA.⁵²

To better optimize the regulatory approval process, the HSA has implemented a Pharmaceutical Regulatory Information System (PRISM) – an electronic system which enables clinical trials’ sponsors to submit applications and other supporting documents online, using a secured electronic authentication system. The system validates the submissions, provides guidance on the regulatory approval process, and has online payment and tracking options.⁵³ In 2012 the HSA also launched a local Clinical Trials Register, which enables access to ongoing clinical trials by therapeutic areas and the trial’s drug, sponsor and site.⁵⁴

FIGURE 4 Clinical trials in Singapore, by phase, 2005-2015



Source: Clinicaltrials.gov, 2016; analysis: Pugatch Consilium



South Korea

South Korea is the world's 13th largest economy and 29th in GDP per capita in 2014, with a population of over 50 million.⁵⁵ South Korea ranked 23rd in the Scientific American Worldview Scoreboard of 2015,⁵⁶ and 26th (out of 140 economies) in the World Economic Forum's Global Competitiveness Report of 2015-2016.⁵⁷

Clinical research overview

South Korea has established itself as a global competitor in the field of biomedical research and a leader in clinical trials. This was made possible by systematic government support in establishing a state-of-the-art biomedical and IT infrastructure, sustained pro-innovation government policies and the quality of researchers and medical staff.⁵⁸ Biomedical R&D is a primary strategic field in South Korea: under the "Pharma 2020 Vision"

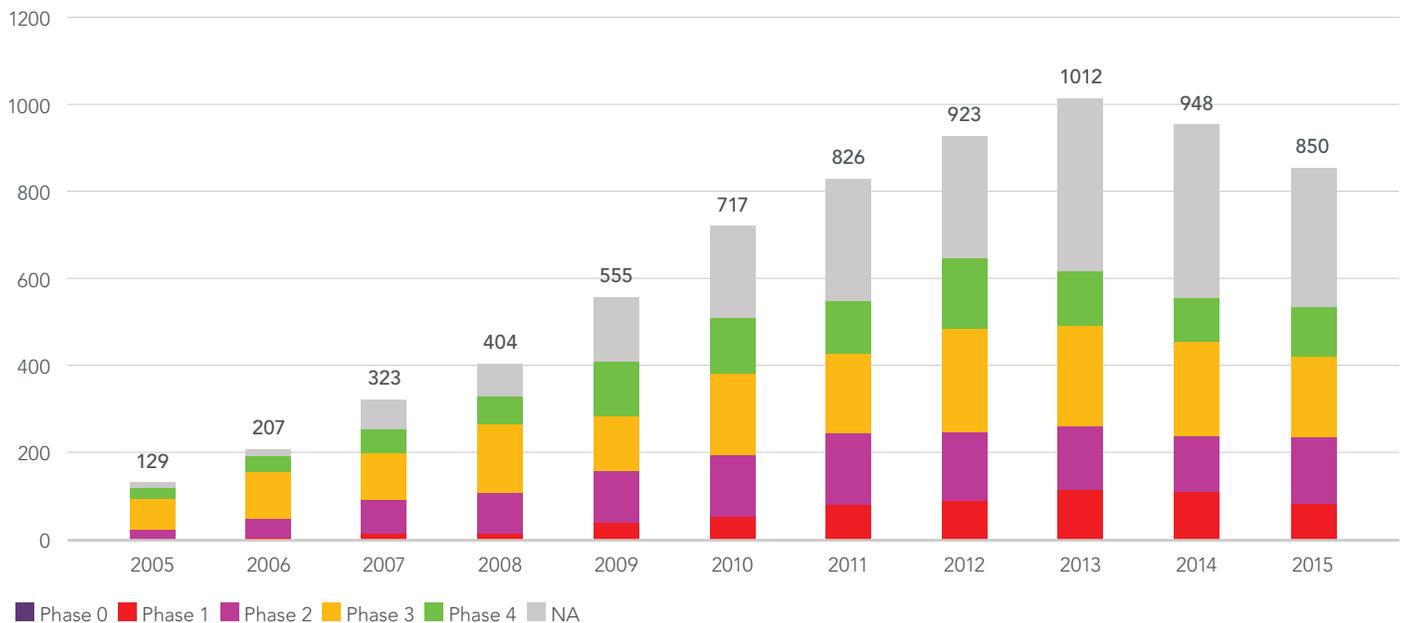
program of 2010 the Korean Government will invest approximately USD8.9 billion over 10 years in strengthening the biomedical R&D structure and train 10,000 new researchers.⁵⁹ Over the years, the number of clinical trials has increased from only 2 trials in 2000 to an average of 877 trials each year since 2010.⁶⁰

Clinical trials policy framework

Similar to Singapore, in order to conduct a clinical trial in South Korea approval must be obtained from the Ministry of Food and Drug Safety (MFDS) and from an Institutional Review Board of the relevant medical facility. Application submissions can be made in parallel and online, using a designated portal.⁶¹ Since 2010 applications can also be submitted in English. These and other considerable efforts by the MFDS has reduced the timeframe of clinical trials' regulatory approval process to only 30 days, and even 14 days for special circumstances.⁶²

There are over 170 accredited medical facilities approved by the MFDS for clinical research, and some 80% of these operate an electronic medical

FIGURE 5 Clinical trials in South Korea, by phase, 2005-2015



Source: Clinicaltrials.gov, 2016; analysis: Pugatch Consilium

record system, with the remaining 20% in the process of implementation. GCP inspections are carried out by an independent body – the Korea Good Clinical Practice for Pharmaceutical Products (KGCP) agency.⁶³

In 2004 the MFDS (then KFDA) established 15 Regional Clinical Trials Centers (RCTCs) with the support of government investments.⁶⁴ In 2007 the Korea National Enterprise for Clinical Trials (KONECT) was established with three responsibilities: managing the 15 RCTCs, developing human capital for clinical research (Clinical Trials Training Academy), and forging public-private partnerships with multinational CROs and pharmaceutical companies.⁶⁵ In 2011 the Korean Ministry of Health and Welfare launched the Clinical Trials Technology Development funds for fostering innovation in the biomedical field.⁶⁶ In addition, the Korea Innovation and Collaboration Center (KICC) was established to provide sponsors with advisory services and support.⁶⁷

Clinical trial sponsors are also given the option to extrapolate from early clinical trial data from global clinical trials in the regulatory appraisal and

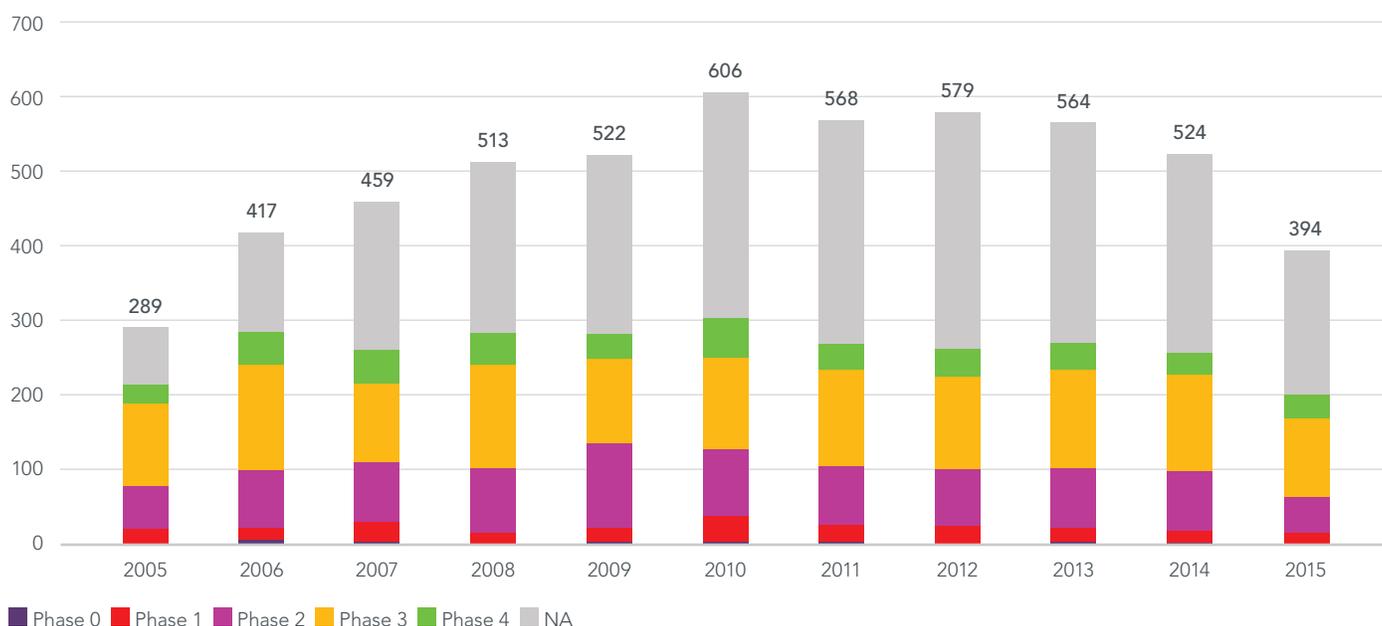
approval process of novel drugs in South Korea. By relying on safety, efficacy and dosage regimen data garnered from clinical trials conducted specifically on Asian population in Western countries, companies can plan local clinical trials in accordance with specific ethnic variations and adjust the compound to fit the local population. This option, known for “Ethno-bridging”, was enabled under ICH guidelines, and is primarily being used by South Korea, China and Japan, and is used to reduce the lag in drug approval in these countries, thus enabling quick market access of innovative treatments for their patients.⁶⁸



Israel

Israel is the World’s 37th largest economy, with a population of 8 million.⁶⁹ It is one of the very few developed, high-income economies in its region, and is an OECD member since 2010. Israel is ranked 18th in the Scientific American Worldview

FIGURE 6 Clinical trials in Israel, by phase, 2005-2015



Source: Clinicaltrials.gov, 2016; analysis: Pugatch Consilium

Scoreboard of 2015,⁷⁰ and is the world's 27th most open and competitive economy according to the World Economic Forum for 3 consecutive years.⁷¹

Clinical research overview

In the global biomedical arena Israel is considered a strong competitor: it is experiencing a continuous growth in the field for the past two decades with nearly 280 global multinational R&D centers and a rate of 658 clinical trials per capita, among the highest in the world.⁷²

The clinical research environment in Israel is attractive: there are 29 high-grade medical facilities (10 of which are university affiliated), all maintain high standards and operate a unified electronic medical records system which supports Electronic Data Capturing for clinical trials; the quality of human capital (physicians, researchers, CRO personnel and medical staff) is high and research-oriented; costs are relatively low compared to the US and EU; and a large, ethnically-diversified pool of patients is accessible and retention rates are high.⁷³

In addition, the government views the life sciences sector in general and clinical research in particular as a strategic areas of development. The life sciences sector takes up as much as 30% of the Office of the Chief Scientist's budget, more than USD 100 million annually.⁷⁴ Furthermore, clinical trials agreements with Israeli hospitals summed up to over USD 100 million in 2013 alone.⁷⁵

Clinical trials policy framework

The regulatory approval process for clinical trials in Israel includes two authorities: an Institutional Review Board of the medical facility and an additional review board of the Pharmacy Division within the MoH. Up until recently later-phase clinical trials only required an IRB while early-phase trials necessitated an approval by the MoH. The timeframe for approval was usually 3-6 months.⁷⁶ In an effort to further increase clinical research intensity in Israel the government has issued an optimization plan in 2013 which was initiated in 2014. The plan included a revised timeframe of 60 days for the regulatory approval process for clinical trials, an option for parallel and online

submissions of clinical trial applications, increasing transparency and predictability in the regulatory process and added positions for advisory experts and regulatory personnel.⁷⁷

In addition, recent changes to tax law introduces two financial incentives for foreign companies conducting clinical trials in Israel. First, the mandatory VAT (17% as of 2015) has been cancelled for services rendered in the field of clinical research. Second, the VAT and importation fees for pharmaceutical products for clinical trials have been cancelled as well.⁷⁸



Colombia

Clinical research overview

Despite having the potential of becoming a regional leader and a major global competitor in the field of clinical research, Colombia currently lags behind its regional competitors. To date, Colombia hosted only 924 clinical trials as opposed to Chile (1,144 CTs), Argentina (2,059 CTs), Mexico (2,575 CTs), and Brazil (4,976 CTs).

Furthermore, a relatively small proportion of Colombia's newer trials (since 2013) are in the realm of riskier, more complex trials (particularly Phase I). Here, Colombia currently has only 2 Phase I trials in operation; significantly less than the OECD average of 90.17.⁷⁹

Looking at the adjusted number of clinical trials per million population, Colombia stands at 18.56 CTs per million population, a rate which is similar to the BRIC-TM countries average of 18.35, but is considerably lower than the regional average of 29.3 and the EU top 3 countries average of 82.42.⁸⁰

Clinical trials policy framework

During recent years the government of Colombia and the DRA INVIMA have dedicated efforts to improving the clinical research environment to international standards and enhancing its relative

attractiveness. In 2008, Resolution 2378 established the roles and responsibilities of actors involved in clinical research (sponsors, investigators, regulators and medical facilities), covering site accreditation, GCP inspection in accordance to ICH standards, trial protocol evaluation, and approval of the trial's agreement by the IRB.⁸¹ The regulatory framework has since been further expanded with additional definitions and responsibilities, revised timelines and more.⁸²

Today there are 63 GCP-certified institutional ethics committees and over 120 medical facilities approved by INVIMA for clinical research. A clinical trial application must be reviewed by both bodies, except for phase 4 trials which only require an IRB approval. Colombia's medical facilities rank highly in regional comparison, and a pool of nearly 50 million people with adequate health coverage is accessible.⁸³ In addition, a number of global and local CROs operate in Colombia and maintain an open communication with INVIMA.⁸⁴ Recently, a US-based clinical development company entered into an agreement with the Government of Colombia to position Colombia as a preferred destination for conducting clinical trials by US-based sponsors.⁸⁵

Challenges

However, despite the efforts taken to enhance Colombia's attractiveness in the global clinical research arena, challenges still exist.

First, evidence suggest that approval times for clinical research are marred by significant delays. Trial approval times-frames in Colombia are currently very long. According to recent research conducted by the local biopharmaceutical trade association AFIDRO the regulatory approval of a clinical trial in Colombia takes no less than 225 days: some 50-60 days for an approval by the Ethics Committee, and an additional 165 days for the approval by the regulatory agency.⁸⁶ As Table 1 suggests, this is among the longest timeframes for approving clinical trials, both regionally and globally.

This is echoed by older studies which found that the clinical trials approval process usually takes between 3 and 6 months and sometimes even

more.⁸⁷ These studies also found that, while the level of education, physician-patient relationship, adherence to trial protocol and the patients' enrollment and interest in the research are all perceived as high, the regulatory framework is perceived as cumbersome and costly.⁸⁸

Second, the framework of collaboration between sponsors and local investigators, including start-up companies and university hospitals, is lacking.⁸⁹

Finally, while the number of medical facilities approved for clinical research by INVIMA has grown substantially in the past few years, only a fraction have adequate infrastructure and skilled staff for clinical research requirements.⁹⁰ Indeed, while hospitals within main cities (and particularly those with universities affiliations) have an electronic medical records system in place, some of the rural hospitals and clinics do not have a constant, reliable internet connection.⁹¹

Regulatory reform

In April 2016 Colombia's DRA INVIMA announced significant changes to the regulatory approval process of clinical trials.⁹² First, the timeframe for approval would be reduced to only 2 calendar months, or 60 days. This would be achieved by two significant administrative changes:

- enabling parallel submissions of clinical trials applications; and
- transferring the trial protocol evaluation of clinical trials on biologic drugs, which require particular expertise, to a designated group within INVIMA (*Sala Especializada de Medicamentos y Productos Biológicos al Grupo de Investigación Clínica de la Dirección de Medicamentos y Productos Biológicos*).⁹³

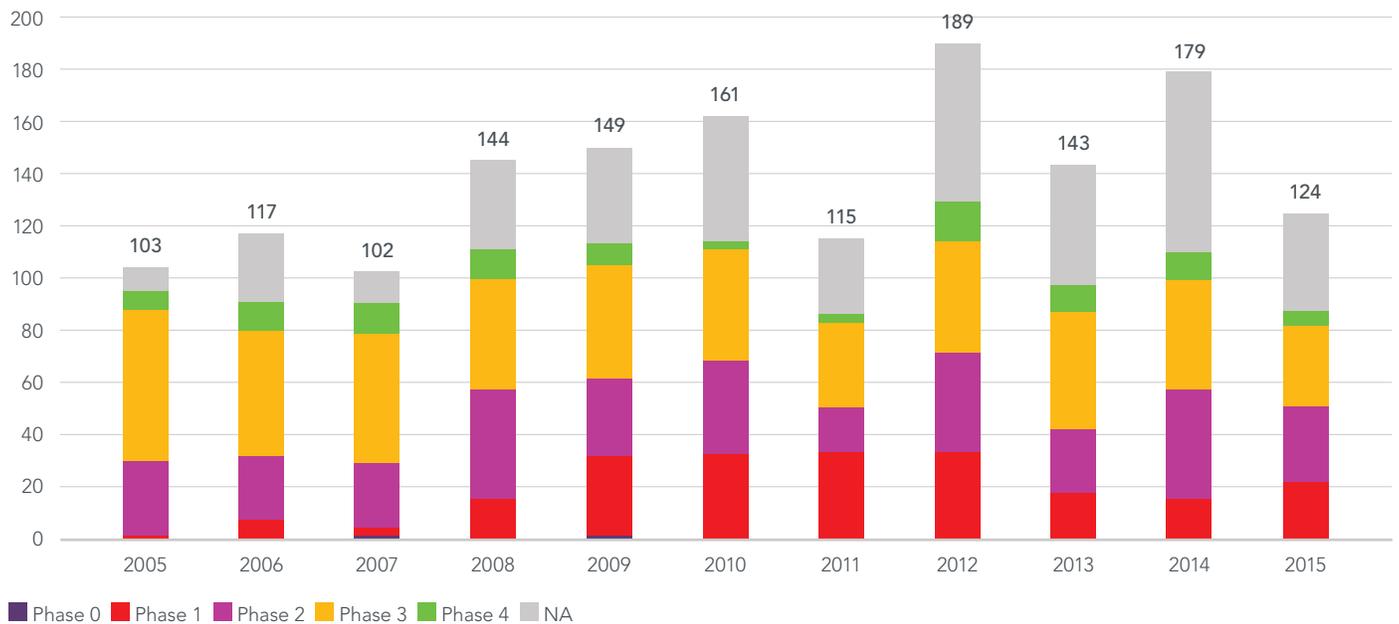
A reduction from the current 225 days for approving a clinical trial to 60 days would significantly improve Colombia's attractiveness in the global clinical research arena.

TABLE 1 Timeframe for regulatory approval of clinical trials in selected countries

	Regulatory Agency approval time	Ethics Committee approval time	Application submission hierarchy	Total timeframe for approval
Singapore	30 days	30 days	Parallel submission	30 days
Australia	50 days	10-50 days	Parallel submission	50 days
South Korea	60 days	8 weeks	Parallel submission	60 days
India	90 days	60 days	Parallel submission	90 days
Russia	55 days	60 days	Ethics Committee approval first	115 days
Canada	30 days	120 days	Parallel submission	120 days
South Africa	120 days	45 days	Regulator's approval first	165 days
Argentina	150 days	30 days	Ethics Committee approval first	180 days
Brazil	120 days	60 days	Ethics Committee approval first	180 days
Colombia	165 days	50/60 days	Ethics Committee approval first	225 days
Peru	195 days	42 days	Ethics Committee approval first	237 days

Source: EFPIA, 2013; AFIDRO, 2015; analysis: Pugatch Consilium

FIGURE 7 Clinical trials in Colombia, by phase, 2005-2015



Source: Clinicaltrials.gov, 2016; analysis: Pugatch Consilium



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IMPROVING COLOMBIA'S ATTRACTIVENESS FOR CLINICAL RESEARCH: LESSONS LEARNED FROM THE WORLD'S TOP PERFORMERS

This Annex has provided a brief overview of some of the best practices and policy measures aimed at enhancing domestic attractiveness for clinical research as adopted by a sample of four countries now considered leaders in the global clinical research arena.

Key lessons: Fast-track and digitization

It's clear that two of the key policies that all four countries have adopted to improve their attractiveness are fast-track approvals and digitizing the application process. All countries seek to make the clinical trials application process as simple and fast as possible. Introducing 'one-stop shops', simplifying application procedures and ensuring a speedy review process are at the heart of Denmark's, Singapore's, Korea's and Israel's clinical trials regulatory framework.

Comparative overview

The table on the following page provides a comparative side-by-side overview of the different best practices and policy measures adopted by these countries. It shows that while Colombia has dedicated considerable efforts to improve its clinical research environment, room for improvement still exists, particularly in improving the public-private collaboration framework, providing incentives for clinical research, and in further improving the regulatory framework by optimizing the approval process and enhance its accessibility to sponsors, researchers and patients alike.

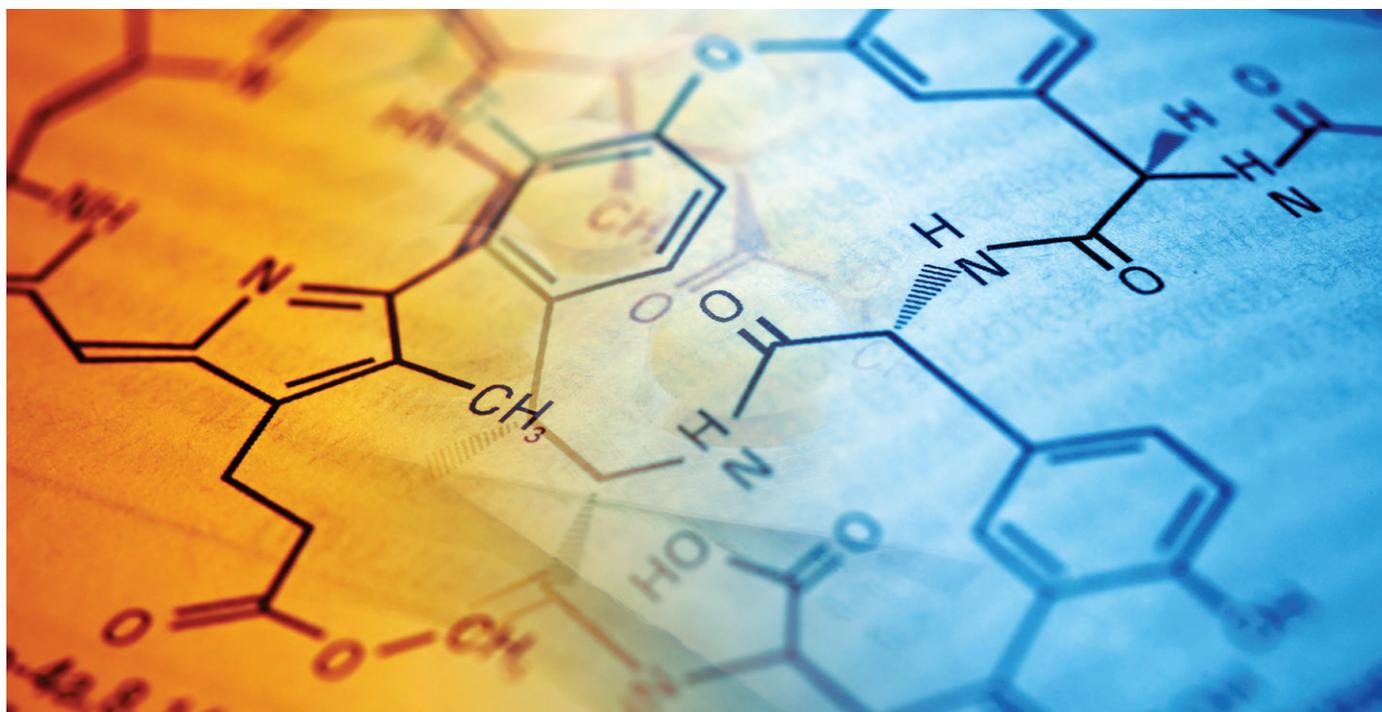


TABLE 2 Encouraging clinical research: Policies in place – Colombia and top-performers

		Denmark	Singapore	South Korea	Israel	Colombia
Governmental support	Clinical research recognized as a strategic field	Yes	Yes	Yes	Yes	Yes
	Direct incentives for clinical research					
Institutional framework	Clinical research requires accreditation / approval of medical facilities by the relevant authority	Yes	Yes	Yes	Yes	Yes
	An electronic medical records system in place	Yes	Yes	Yes	Yes	Partial
	International standardization (i.e. GLP, GCP)	Yes	Yes	Yes	Yes	Yes
Regulatory framework	A centralized approval process	Yes	No Trials must be approved by the HSA and IRB	No Trials must be approved by the MFDS and IRB	No Trials must be approved by the MoH and IRB	No Trials must be approved by INVIMA and IRB
	Fast-track procedure for certain clinical trials	Yes Clinical trials on investigational drugs which are: authorized for use in the EU or the EEA, tested under a licensed indication, and not involving an additional risk to the subjects beyond the existing treatment. Clinical trials which satisfy these criteria are assessed in a period of only 14 days	Yes Small-scale clinical trials, such as for the assessment of bioequivalence or food-drug/ drug-drug interactions, are processed within a timeframe of only 15 days	Yes Trials under special circumstances can be approved in a period of 14 days; later-phase clinical trials only require an IRB approval	Yes Later-phase clinical trials only require an IRB approval	No

Source: EFPIA, 2013; AFIDRO, 2015; analysis: Pugatch Consilium

TABLE 2 Encouraging clinical research: Policies in place – Colombia and top-performers (continued)

		Denmark	Singapore	South Korea	Israel	Colombia
Regulatory framework	Applications can be made in parallel	Yes	Yes	Yes	Yes	Until recently No; from 2016 Yes
	A designated portal for online submission of applications and tracking	Yes	Yes	Yes	No	No
	Official timeframe of approval process	40 – 60 days	15 – 30 days	14 – 30 days	60 days	Until recently 3-6 months; a goal of 60 days has been set recently
	A designated website for patients	Yes	Yes	No	No	No

NOTES

- ¹ See Pugatch Consilium, (2015). *Scaling Up Global Clinical Trial Activity: Key Trends and Policy Lessons*.
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