

NEW REPORT – EXCERPT

SCALING UP GLOBAL CLINICAL TRIAL ACTIVITY: KEY TRENDS AND POLICY LESSONS

This report, from Pugatch Consilium, explains and quantifies the key factors that attract investment in clinical research. The report also benchmarks performance in the level of scope of clinical trial activity, providing a “who’s who” in global clinical research among countries and biopharmaceutical companies.

Below is an excerpt of the key findings of the report. Contact Pugatch Consilium at info@pugatch-consilium.com to request the full report and methodology.

Five policy-related facts to remember about clinical trials in your country

1 A dedicated environment for innovation, as measured by strong spending on research and development (R&D) and intellectual property (IP) protection, is just as, if not more, crucial as the intensity of physicians and hospital beds and the level of health expenditure to clinical trial activity.

- The clinical trial activity in 23 developed and developing countries is better explained by the level of R&D spending and IP protection than by the number of hospital beds or investment in health.
- Just around 30% of clinical trial intensity can be explained by factors relating to the capacity of the health system, such as the number of hospital beds and physicians, and the level of health spending, while over 40% can be explained by factors related to a pro-innovation culture – the level of R&D spending and IP protection.
- Countries that invest more than 1.5% of their GDP in R&D tend to be more active in terms of clinical trials relative to other countries. For example, the top 5 countries in terms of R&D spending host, on average, six times more clinical trials than the rest of the countries.

2 There is a positive correlation between a country’s IP environment and the level of clinical trial activity.

- Countries scoring highly in current standards for measuring biopharmaceutical IP protection (such as the U.S. Chamber’s GIPC IP Index) host 10-20 clinical trials per million population.
- In contrast, countries with low scores (below 60%) have 4 trials per million population or fewer.

3 North America and Northern Europe lead in global clinical trial activity.

- The US, Canada and the EU-5 host the highest gross number of clinical trials worldwide.
- Considering instead the number of clinical trials per capita, it is the Scandinavian and Northern European countries (along with the US) that hold the top positions globally.

4 Population size does not necessarily affect clinical trial activity.

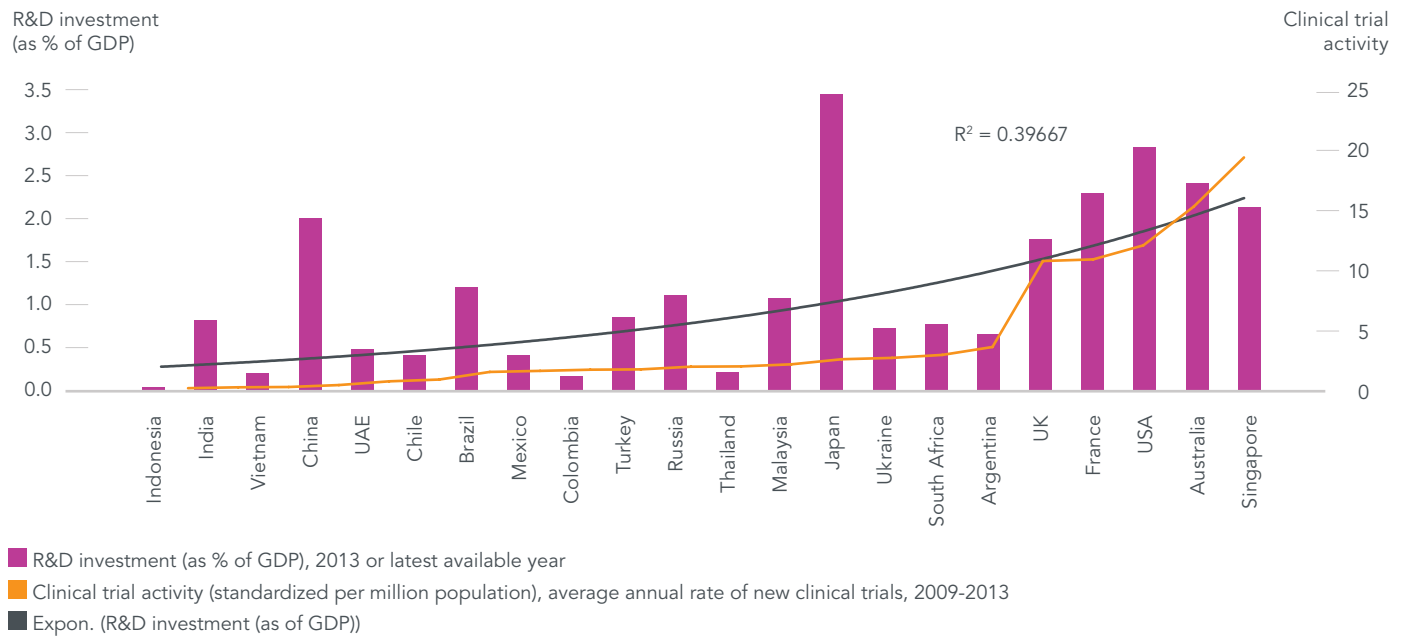
- The BRICs are among the world's leaders in population size, yet are among the weakest performers in clinical trial activity. With as little as 2 trials per million population, the BRICs fall in the bottom 5% of the selected countries.
- Smaller developed countries (for instance, Denmark, Norway, Sweden and Switzerland) have the highest levels of per capita clinical trial activity in the world.
- New Zealand has a relatively high per capita clinical trial intensity; factors of its performance may include ease of the regulatory environment for clinical research and a high quality clinical research system.¹
- Conversely, countries with large populations still achieve a high level of clinical trial activity relative to population, for instance the US, UK, Germany and France.

5 Cutting edge clinical trials (primarily defined as Phase I and II trials) are mainly conducted in developed countries, but the more active developing countries also experience a relatively high concentration of such trials.

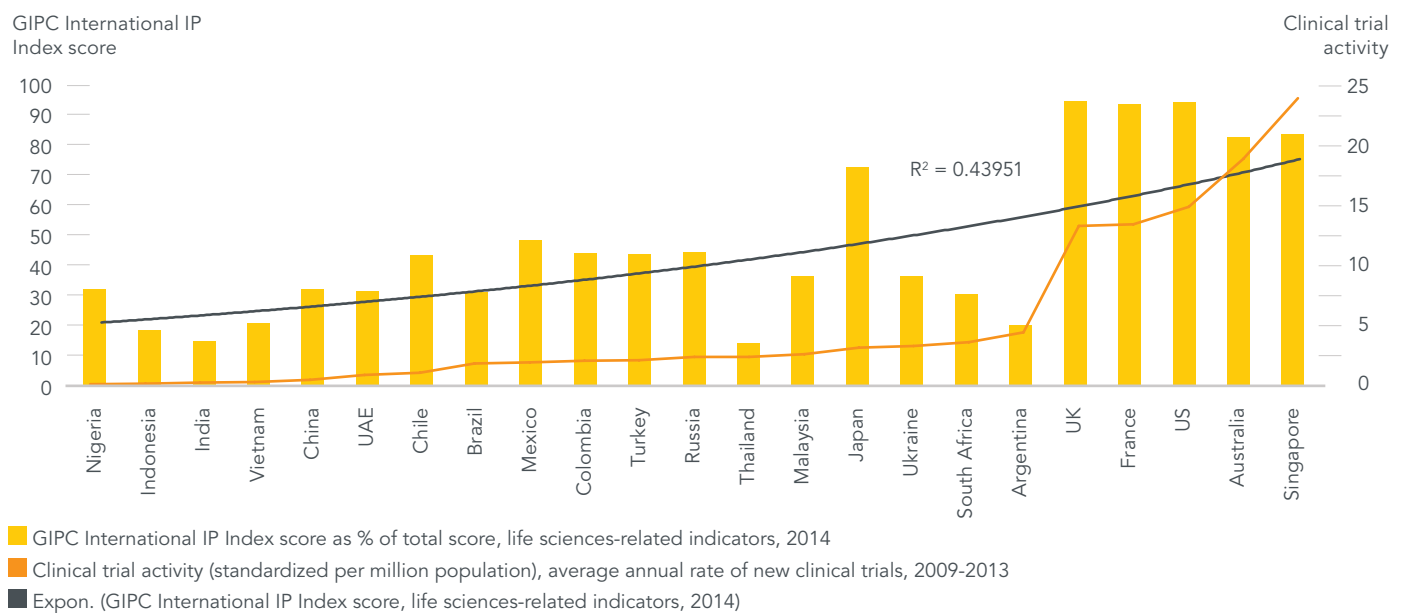
- Across the board, clinical trials tend to be concentrated in the larger, more established Phase III trials.
- The riskier, more complex trials (particularly Phase I) are mainly conducted in developed countries.
- On average developed countries host double the amount of early stage trials hosted by developing countries.
- Increasing the volume of total clinical trial activity is associated with an increase in the concentration of more advanced trials hosted in any given country: the greater the total volume of clinical trials the more likely a country is to host Phase I and II trials.
- Developing countries with strong clinical trial activity (more than 200 clinical trials annually) achieve three to four times more early-stage clinical trials than developing countries with relatively weak clinical trial activity (roughly 100 trials or fewer annually).

Assorted figures (see full report for complete set of figures)

FIGURE 1 Creating a pro-innovation culture is just as important as physical capacity for conducting clinical trials



Source: Pugatch Consilium, Clinicaltrials.gov, World Bank (2013), Vietnamese Ministry of Science and Technology (2014)²
 Note: Recent R&D spending data for Nigeria is not available



Source: Pugatch Consilium, Clinicaltrials.gov, GIPC International IP Index (2014)³

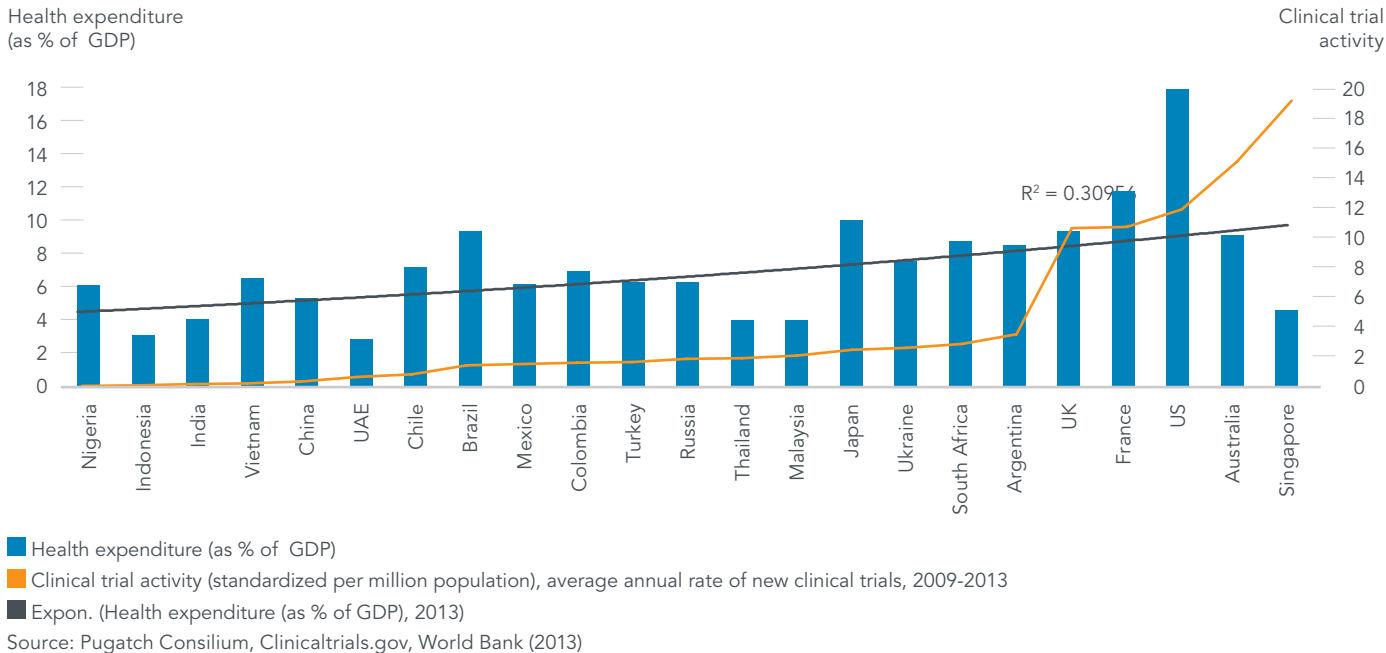
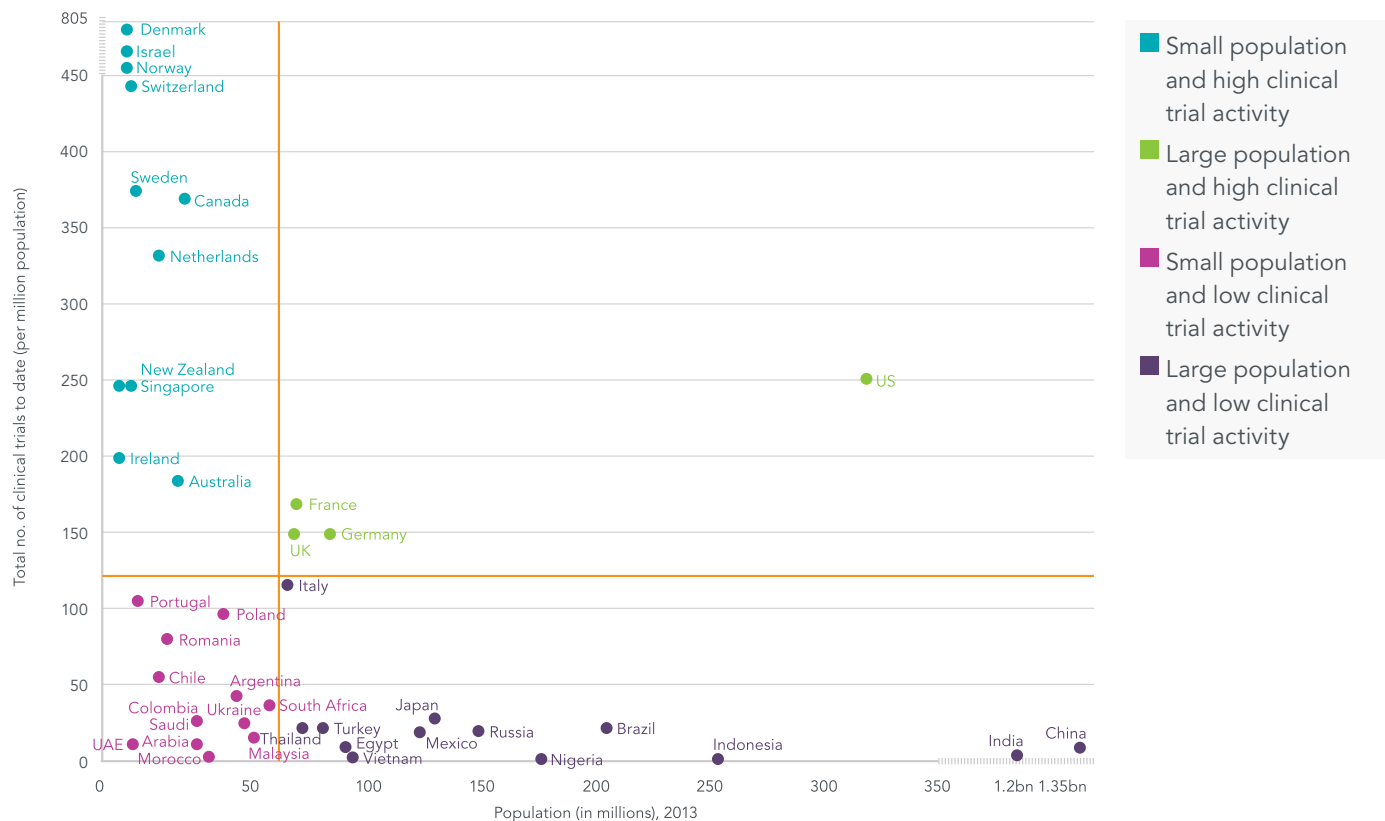


FIGURE 2 Population size does not always matter



Source: Pugatch Consilium, Clinicaltrials.gov, World Bank (2013)⁴

Note: Per capita clinical trial intensity based on number of clinical trials to date per million population

TABLE 1 Leaders versus laggards in clinical trial activity (2013)⁵

Country	No. of CTs (2013)	No. of phase I trials	No. of phase II trials	No. of phase III trials	No. of phase IV trials
US	3872	1223	1535	708	406
EU-5 (total)	3187	564	992	1280	346
Canada	740	105	232	312	85
Germany	733	154	235	279	63
UK	694	187	202	238	67
France	676	96	225	278	77
South Korea	551	114	126	208	101
China	529	66	179	148	136
Italy	527	55	164	229	79
OECD (average)	441	90	140	161	49
Belgium	428	83	114	178	52
Netherlands	371	86	88	148	46
Australia	350	69	93	172	16
Japan	305	53	81	146	24
Poland	293	10	77	184	20
Israel	289	43	84	122	34
Russia	266	25	60	161	20
Czech Republic	238	12	65	143	18
Brazil	233	27	47	120	38
Hungary	230	14	71	128	17
Turkey	151	3	23	87	36
South Africa	144	14	35	85	10
Mexico	140	7	22	93	16
Argentina	128	6	18	92	12
India	117	13	29	60	15
Thailand	117	8	35	48	26
Greece	108	4	25	65	14
Romania	107	5	15	83	4
Ukraine	92	0	17	72	3
Egypt	75	10	21	22	18
Colombia	61	2	17	36	6
Malaysia	57	3	10	36	8
Lithuania	47	1	11	33	2
Croatia	43	2	5	30	6
Vietnam	27	3	6	12	6
UAE	19	0	0	8	11
Indonesia	18	1	7	5	5
Saudi Arabia	18	1	6	4	7
Chile	16	1	3	9	3
Nigeria	6	2	4	0	0

■ 100+ CTs ■ 50-99 CTs ■ 0-49 CTs

Source: Pugatch Consilium, Clinicaltrials.gov

Note: Clinical trial activity based on number of clinical trials with a registered start date in 2013

Notes

- ¹ Clinical Trials – New Zealand, “About trials in New Zealand: Industry”, <http://clinicaltrials.health.nz/about-trials-in-new-zealand/industry/>
- ² Lexology, “Weak R&D in Vietnam, 8/6/2014, www.lexology.com/library/detail.aspx?g=48c49f54-4d3e-43a3-8529-2458034ddb39
- ³ Strength of intellectual property rights is calculated as the total score out of 16 life sciences-related indicators in the U.S. Chamber’s GIPC International IP Index, second edition (2013-14), which capture factors such as the scope of patentability, existence of effective pharmaceutical patent enforcement mechanisms and term of regulatory data protection.
- ⁴ World Bank Databank, Population, total, 2013, <http://data.worldbank.org/indicator/SP.POP.TOTL>
- ⁵ Based on number of registered trials within the *clinicaltrials.gov* database listed with a start date of 2013.

Note: Request the full report by emailing: info@pugatch-consilium.com