RDC 09/2015 and the Clinical Development Dossier

Experience, results and challenges

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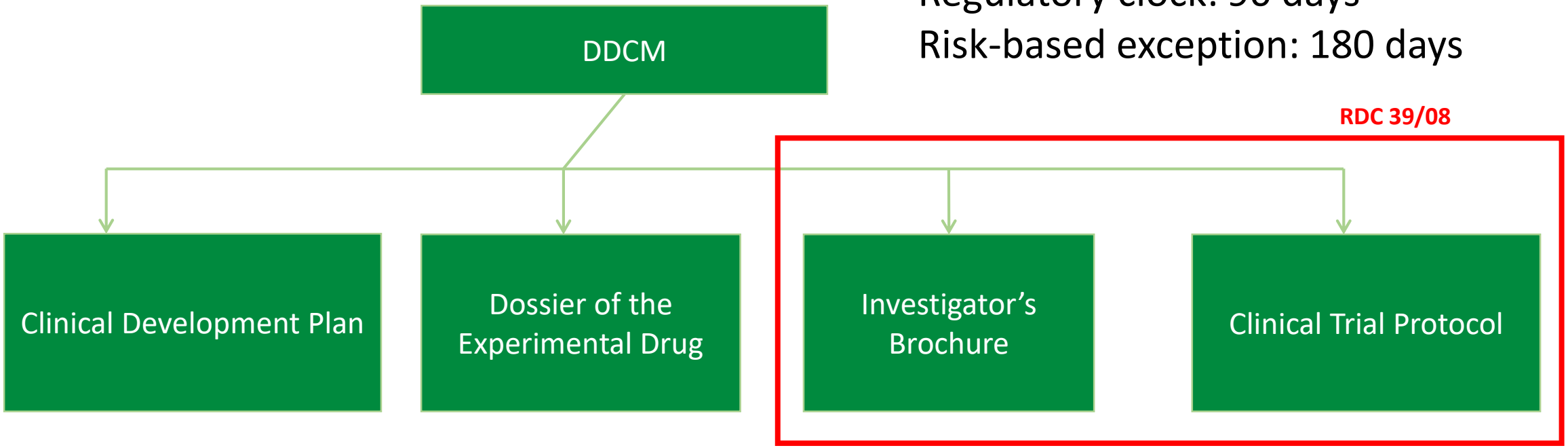
ANVISA
Agência Nacional de Vigilância Sanitária

Regulatory clock: 90 days
Risk-based exception: 180 days



How big was the step forward?

- Timeline predictability
- Importing and customs done *in loco*
- Evaluation of the Clinical Development Plan
  - Necessary steps for the next clinical phase
  - Rationale for the development course
  - Roadmap
- CMC information evaluated before MA

Direct impacts:

- Reduced timelines for customs processing
- Backlog from previous normative eliminated
- Closing in with MA departments
- Risk-based analysis
- Subsequent trials quickly evaluated

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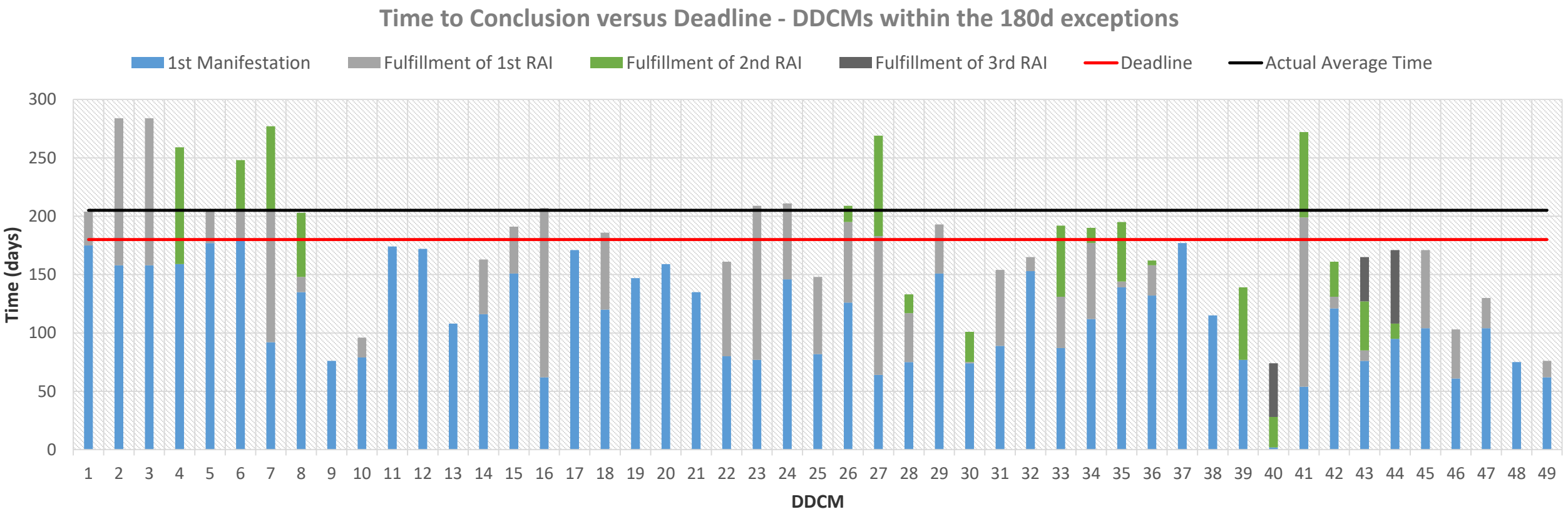

Source: Term Paper presented to the *Lato Sensu* Post-Graduation Program in Clinical Research from the Health Science Education Faculty, Oswaldo Cruz German Hospital. Adriane Alves de Oliveira, 2016; unpublished data.

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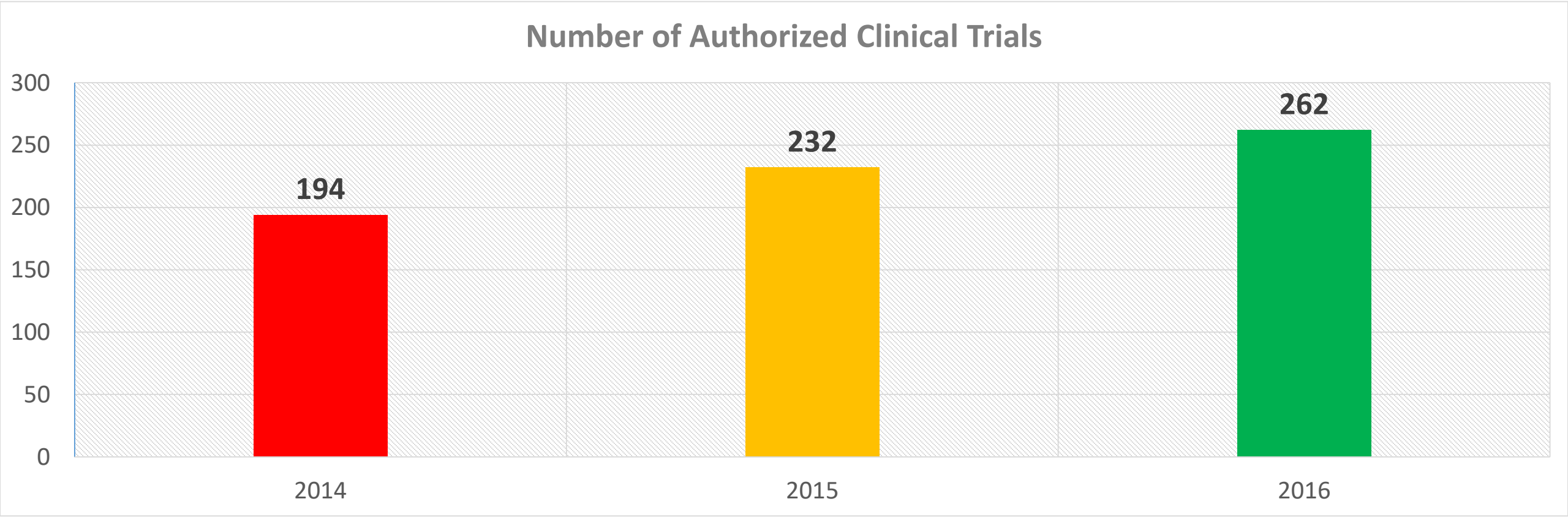

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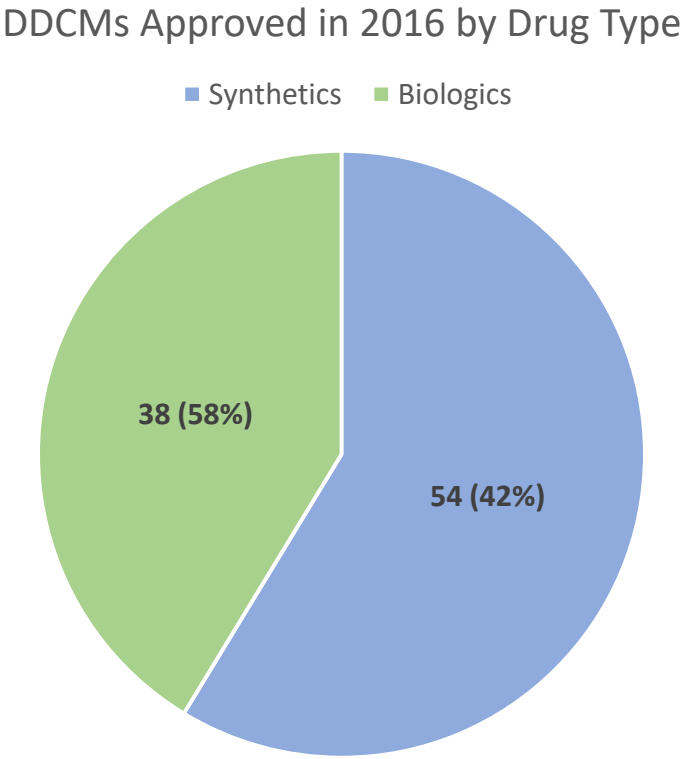
- 8 (8,7%) were immuno-oncologics
- 5 (5,4%) targeted neglected/rare diseases
- 2 (2,2%) were biosimilars
- 18 (19,6%) already had valid MAs in Anvisa
- 20 (21,7%) had pediatric trials in the clinical development plan
  - 14 (70%) out of the 20 had such trials planned to be run in Brazil
- 25% had MAs in other global-level agencies



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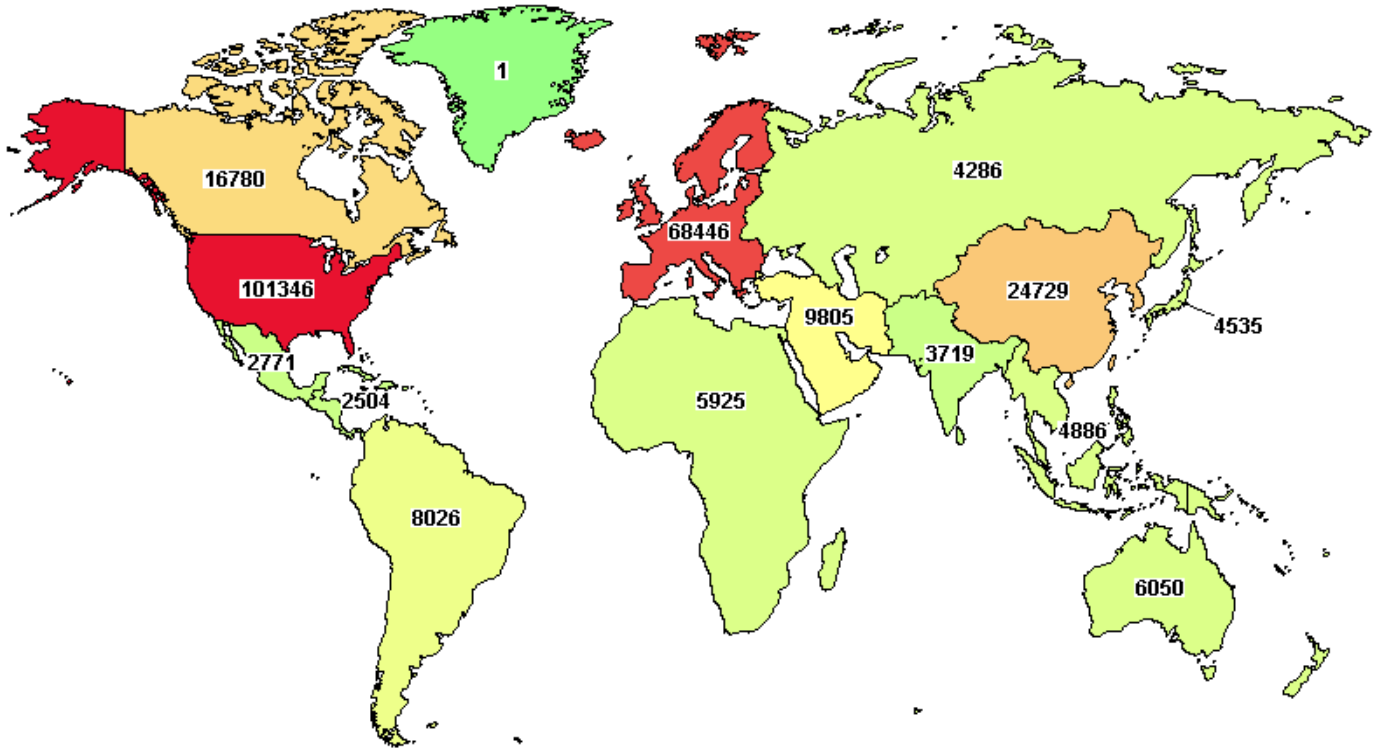

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Source:https://ClinicalTrials.gov

Country*	Trials
China	9.537
South Korea	7.978
Israel	6.121
Brazil	5.610
Australia	5.604
Taiwan	4.787
Japan	4.535
Russia	3.562
India	3.075
Mexico	2.771
Turkey	2.468
South Africa	2.360

*Excludes USA, Europe and Canada

Data accessed on 27-Apr-2017

- Art. 71: *...Anvisa poderá realizar inspeções em BPC nos* ***centros de ensaios clínicos, patrocinador, ORPC, laboratórios e em outras instituições envolvidas no desenvolvimento do medicamento experimental*** *para verificar o grau de adesão à legislação brasileira vigente e o cumprimento das BPC...*

- 2016 to now: 7 GCP Inspections
  - 1 Sponsor inspected
  - 1 CRO inspected – 8 trials

THANK YOU

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