



QuintilesIMS™

Synergies and collaboration to drive clinical research The Brazilian case

Vitor Harada
Vice President / R&D Solutions Operations Head - LatAm

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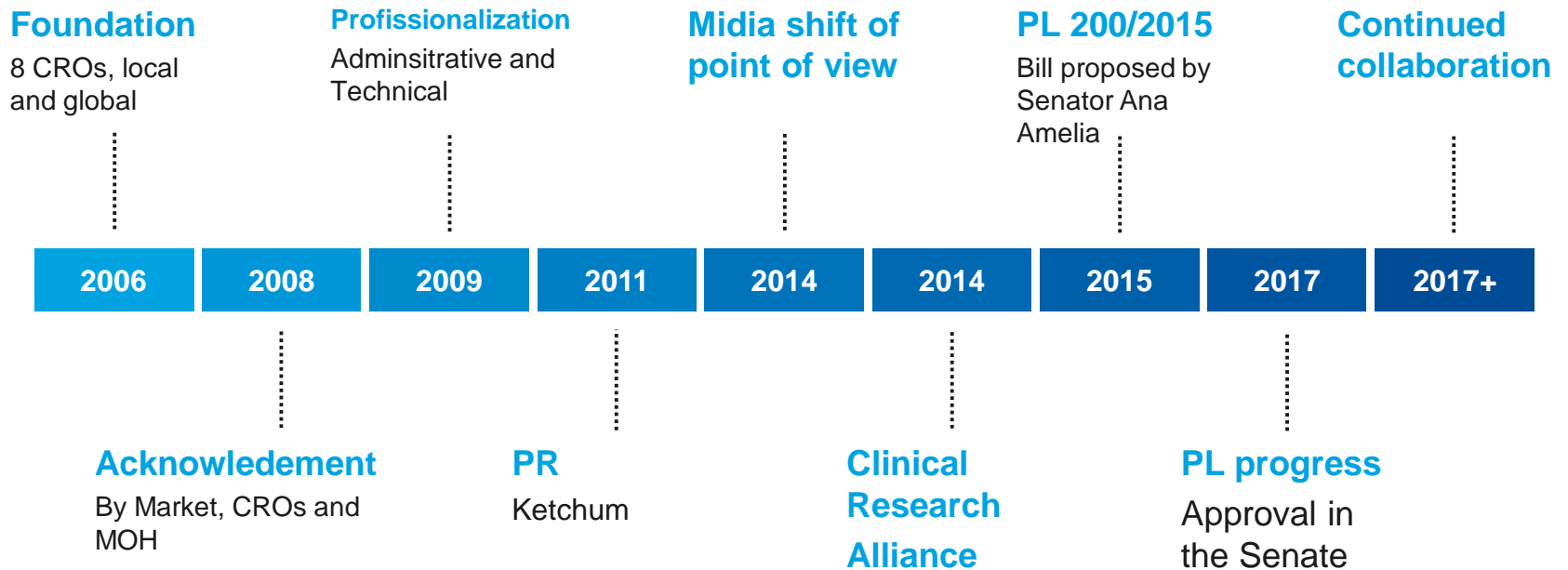
Vice President / R&D Solutions Operations Head - LatAm



Profile overview

- 19 years of experience in the pharmaceutical industry (8 years in pharma companies and 11 years in CROs)
- PharmD degree - University of São Paulo, BR
- MBA - Fundação Getulio Vargas, BR
- Executive Coaching - Columbia University, NY, US
- Former Director of ABRACRO (Brazilian CRO Association) as president (2008-2012) and vice-president (2013-2016)
- Former teacher and coordinator of the Santa Casa Medical School Post Graduation in Clinical Research (2009-2014)
- Co-Founder and first President of the Clinical Research Alliance Brazil

History of the CRO association impact in Brazil



ABRACRO – Collaboration examples

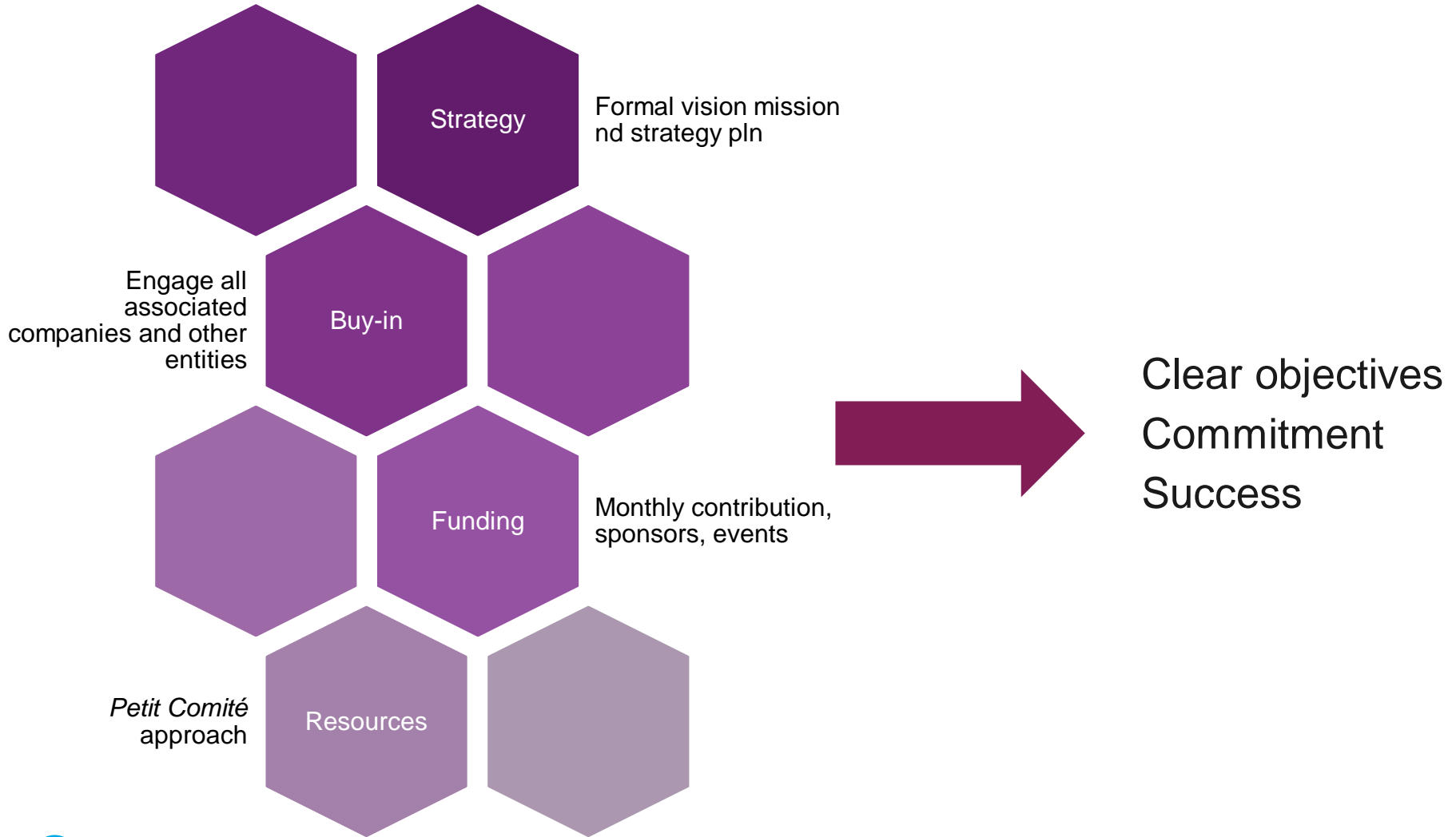
- ANVISA
 - Collaboration for controlled substances rules for clinical trials
 - Debate for the RDC09/2015 implementation
 - Discussion and alignment for PK data submission for biosimilars (ongoing)
 - Regulatory agenda discussion (2017/2020)
 - Alignment meeting with GPAF
 - Review of ICH E11 guidance implementation
 - DDCM (ANVISA´s NDA) Training – 19/May
- CONEP
 - Manual of frequent contingencies
 - Real World studies fórum/discussion
 - 2 Post-trial drug access fórum (first open meeting with CONEP / with Harvard representatives)
 - Annual meetings to discuss process, common contingencies and others

Lessons learned: added value



Achievements, acknowledgment and visibility brings value to CROs, sponsors and regulators.

Lessons learned: Professionalism



Lessons learned: Change management



Lessons learned: Change management (cont.)

Kotter's model of change management

Step 1: **build sense of urgency**

a. Things can be better



b. Things will be worse



Other actions

- Partnership with Post Graduation in Clinical Research with Santa Casa Medical School in São Paulo since 2009
- Clinical research report
- “Premio ABRACRO”
- Open positions and newsletter
- Strong social media presence (3-4 times a week in LinkedIn and Facebook)
- Guidelines:
 - Post-trial drug access report
 - ANVISA Inspection support for trials sites

WORKSHOP ABRACRO: DDCM – UM PACOTE COMPLETO

A ABRACRO realizará workshop sobre a montagem de DDCMs.

[SAIBA MAIS](#)



NEWSLETTER

Cadastre-se e receba nosso informativo mensal

DADOS REGULATORIOS

ABRACRO ANALYTICS

OPORTUNIDADES

Confira as vagas disponíveis

PESQUISA ABRACRO

SETOR de PESQUISA CLÍNICA

Dados Regulatórios - Acompanhamento de processos ético-regulatórios

Imprimir

Seleção o período:

jan/2010 até mai/2017

Área Terapêutica:

Todos selecionados (20)

Seleção:

- Ambos
- CONEP
- ANVISA

Pediátrico:

- Ambos
- Sim
- Não

Medicamento órfão:

- Ambos
- Sim
- Não

Fase do Estudo:

Todos selecionados (5)

Tipo de Medicamento:

Todos selecionados (4)

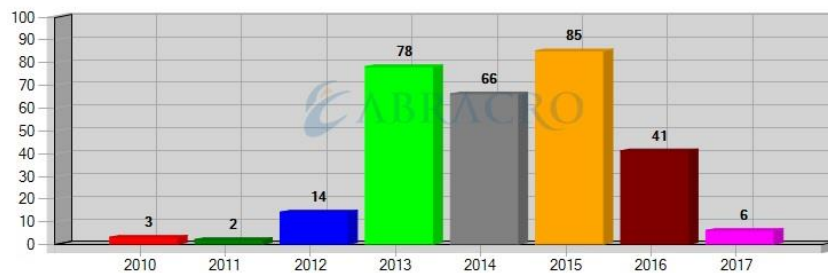
Apenas dados ANVISA anteriores às RDCs 09 e 10/2015

Linguagem dos gráficos:

Português

Buscar

Estudos Enviados



Percentual:

- Sim
- Não

Trimestral

Status dos Estudos

Percentual:

- Sim
- Não

Tempo Decorrido (dias)

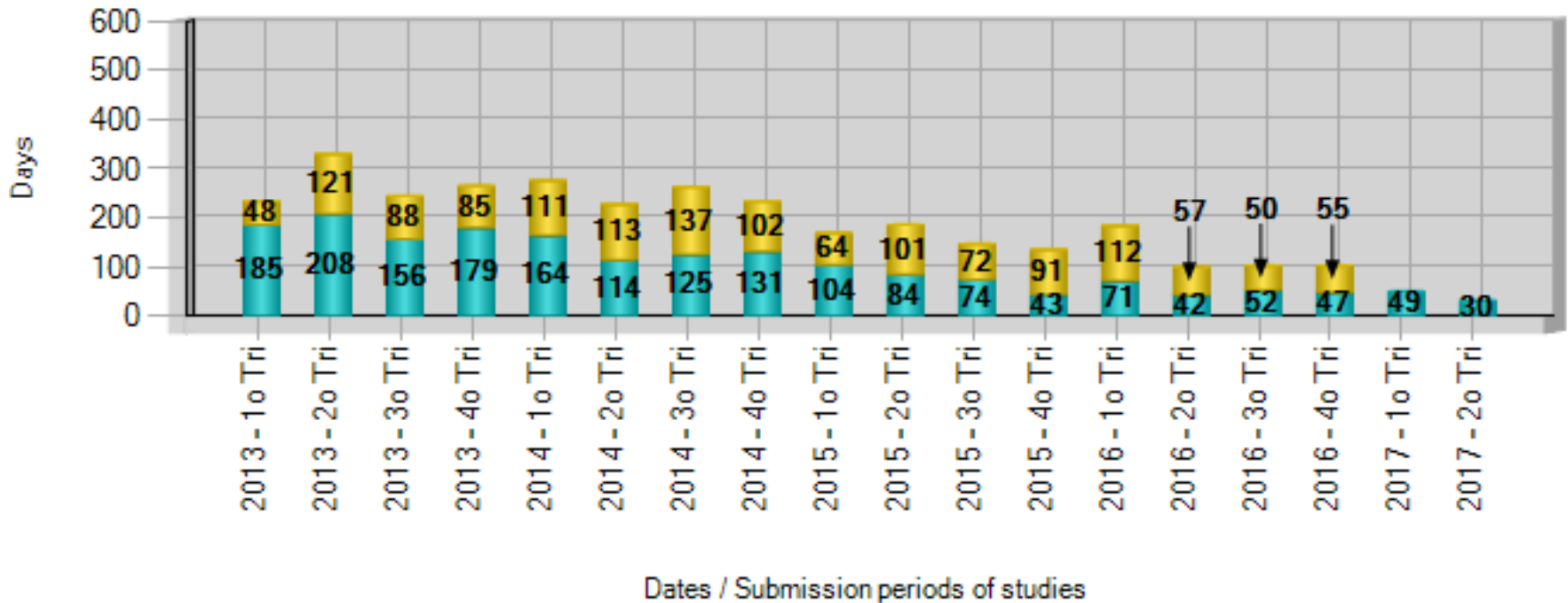


Other entities



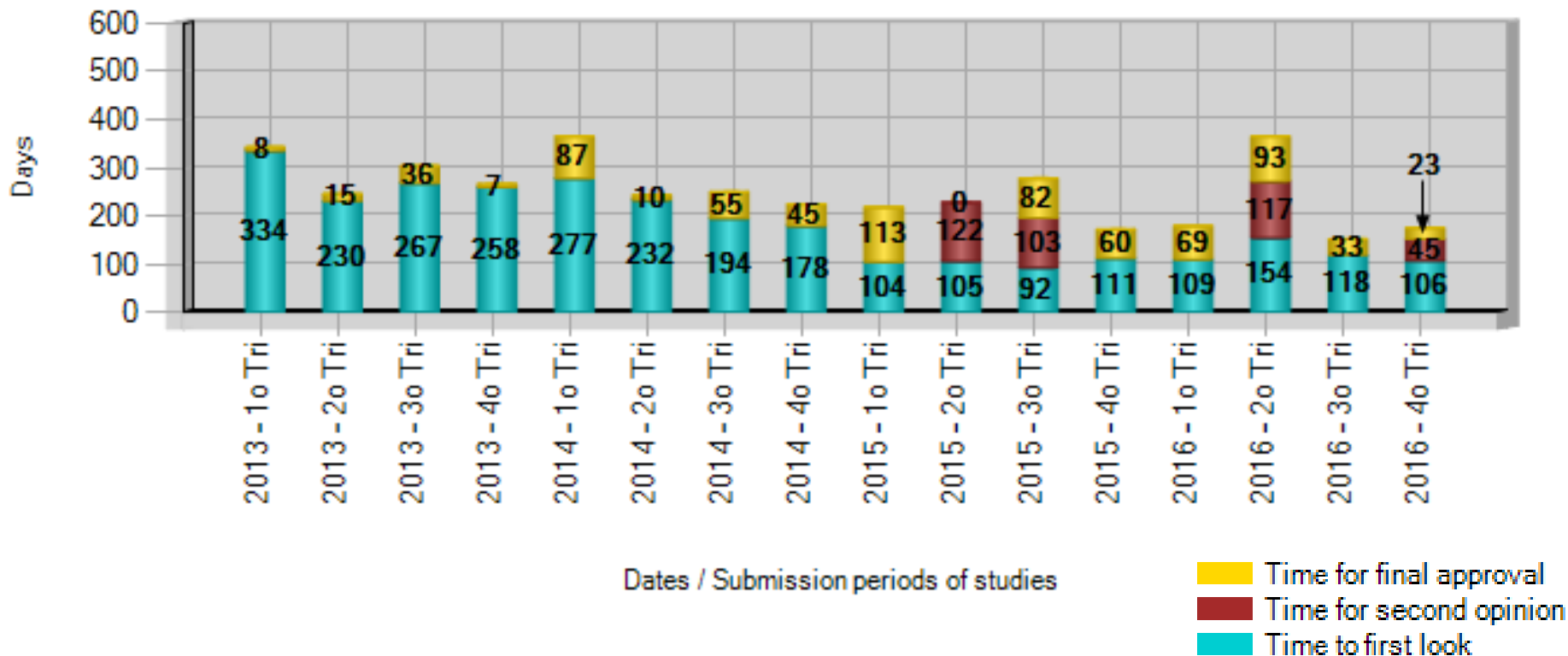
Brazilian Regulatory Times – CEC (CONEP)

Deadlines Analysis of Clinical Trials by CONEP (ABRACRO Data)



Brazilian Regulatory Times – RA (ANVISA)

Deadlines Analysis of Clinical Trials by ANVISA (ABRACRO Data)



Final message

