BIO Latin America - Regenerative Medicine & Cell Therapy

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Techtrials International - Chief Executive Officer
Commitment, Flexibility and Speed

(*) TTI = Techtrials International
Clinical Research Overview - Brazil

- Main Reasons to run Clinical Research Projects:
  - New product/technology registration;
  - Renewal of registration;
  - Post Approval Safety Monitoring;
  - Marketing strategy and data;
  - Epidemiology Studies;
  - Others;
Clinical Research Overview - Brazil

- Pharma Outsourcing growing globally – Brazil is not different;
- 2.1% of Total Global Clinical Trials = 1434 Open Studies in Brazil (clinicaltrials.gov);
- Potential = 4 to 6%;
- Current Brazil Market Size = not audited = R$ 600 Millions at least (rough estimate for total clinical research outsourcing)

Players:
- Sponsors – Government, Multinational Pharma and Biotech, Local Pharma and Biotech, Device Companies, Academia;
- Service Providers – CROs, Clinical Sites/Institutions, Central Labs, Logistics Operators, Consultancy Co, several others;
- Study Subjects;
- Regulators (ANVISA, CONEP);
Therapeutic Areas

% of studies per therapeutic area (source ABRACRO)
Why Running Trials in Brazil

- Large Population over 200 million
- Faster Enrollment, High Enrollment
- Highly Qualified Sites and Investigators
- Consistently cheaper than developed countries
- Improving Regulatory Timelines

Responsiveness

Quality

Cost
Regulatory Timelines

Prazos de Análise de Estudos Clínicos pela ANVISA (Dados ABRACRO)

Datas / Períodos de submissão dos estudos

Prazos de Análise de Estudos Clínicos pela CONEP (Dados ABRACRO)

Datas / Períodos de submissão dos estudos
Stem Cell Studies

- Brazil = 27 studies = 1.9% of total country studies = Stem Cell Studies
- USA = 875 studies = 3.8% of total country studies = Stem Cell Studies
- Targets:
  - Bring more International Studies to Brazil;
  - Foster implementation of more Brazilian projects;

Source: clinicaltrials.gov
Regenerative Medicine Product Intelligence & Strategy

RM and Cell Therapy Companies will need support related to Intelligence & Strategy of biological product development, such as:

1. Analysis of the client case to define the best strategy for the product
2. Identify the specific studies and procedures steps that are required for new RM products registry
3. Support to the client on follow-up with ANVISA through meetings and discussions, providing assistance on presentations, if needed
4. Providing all information about the operational steps and prices of all required activities related to the project (planning, timelines, costs)
Regenerative Medicine Clinical Trials News

Australia: world first stem cell trial for Parkinson's disease starts

By Elena Conroy on Sep 21, 2016

In a bid to cure Parkinson's disease, medical researchers at The Royal Melbourne Hospital...

Positive results for Asterias Biotherapeutics’ SCiStar study for cervical spinal cord injury patients

By Elena Conroy on Sep 09, 2016

Asterias Biotherapeutics announces positive safety data from the initial cohorts of the...

First patient randomized in STEMRA trial for traumatic brain injury

By Lauren Pulling on Jul 15, 2016

SanBio, Inc. (CA, USA) have announced the randomization of the first patient in the stem...

Source: Regenerative Medicine Network
Opportunity to innovate in Prevention and Treatment for Chronic Diseases.
Use of apps & wearables doubled in past 2 years.

Source: Accenture 2016 Consumer Survey on Patient Engagement (across 7 countries, including Brazil)
Global Market for wearable devices is booming.

448 Currently available wearable devices.

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Source: Wearable Technology Database, Vandrico Inc.
Multichannel Digital Initiative to foster healthcare promotion through prevention and treatment including Cell Therapy projects.

Unique PSP
The beauty of Data

When offering wearables and medical devices, sensors e mobile apps, Pharma Industry can collect data remotely. Thousands of data points per day…
Example Diabetes
Health
Sensors like the Kenzen Smart Patch determine the blood **glucose concentration** in the subcutaneous tissue.

Example Cardio
Fitness and Prevention
Fitness trackers like the Fitbit Charge HR use light-sensitive photodiodes to capture the heart rate.

Example Arthritis
Wellness
Smartphone Apps like All4One or Longevidade use sensors and geolocation to monitor steps, calories burnt and arthritis improvement.
Let’s bring the Cell power to renew our treatment options!

Thank you!

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