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# **Stempeucel: the Journey from Bench to the Market**



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There are no Conflicts of Interests



## Learning Objectives

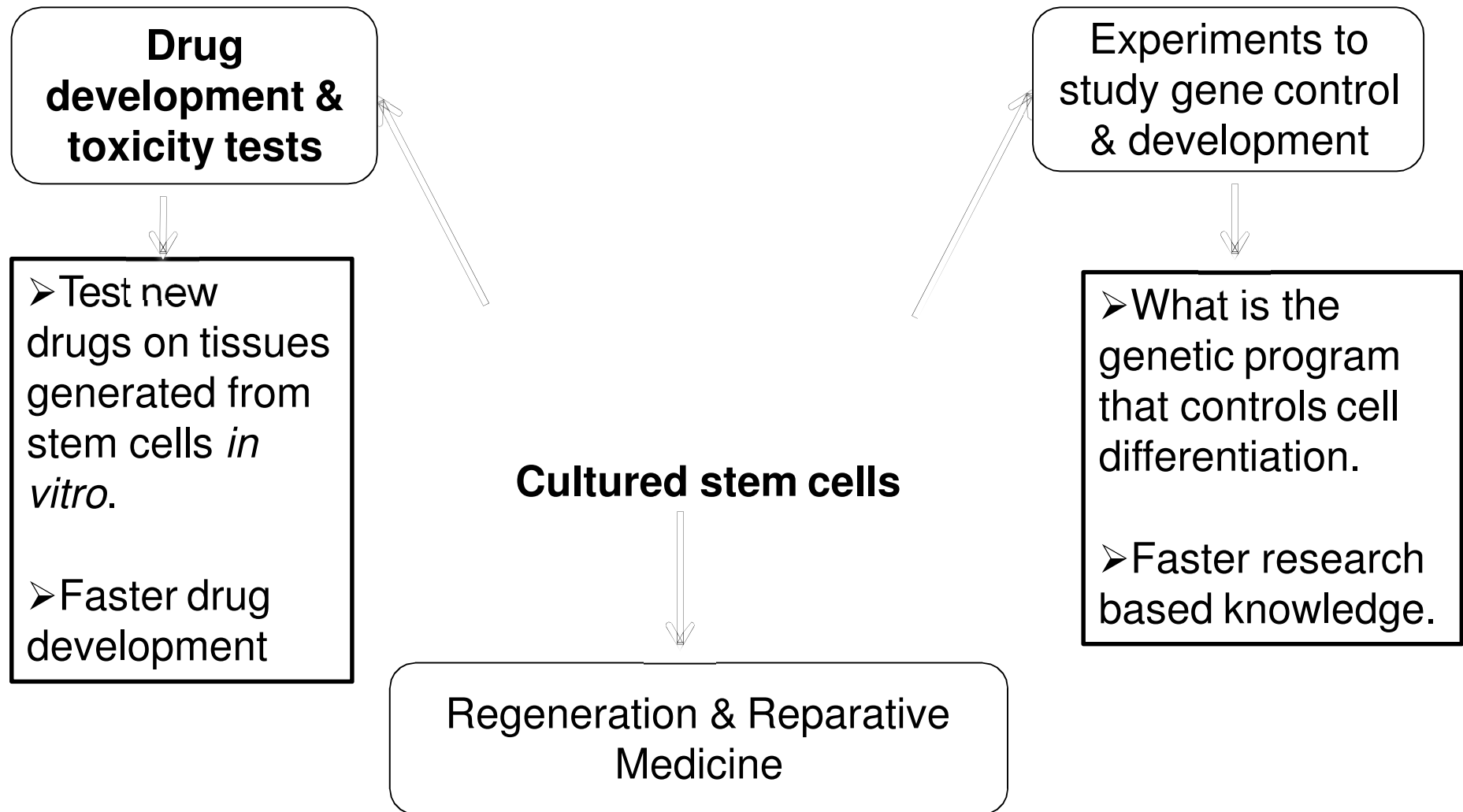
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At the end of the webinar, participants are expected to

- Understand how Mesenchymal Stromal cells are preferred source for drug product development
- Explain the various applications of Stem Cells
- Compare Autologous and Allogeneic Therapy
- Understand How to arrive at Target Product Profile (TPP)
- Ascertain role of Cell Banks for therapeutic product development

# Applications of Stem Cell Research



- The risk of a stem cell therapy generally increases as the source changes.
- The safest cells are your own adult stem cells.
- Newer induced Pluripotent Stem Cells (iPSC), are artificial stem cells manufactured in a lab and as such are considered the most dangerous.

# Target Product Profile (TPP)

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- A **Target Product Profile (TPP)** is a planning tool for therapeutic candidates based on FDA Guidance for Industry and Review Staff. **The goal of drug *product* development is commercial success.**
- A dose of **Glybera** contains trillions of viruses harboring correct copies of the lipoprotein lipase gene. The company that developed Glybera, UniQure, based in Amsterdam and Lexington, Mass., has given European sales to the Italian drug maker Chiesi Farmaceutici, which calls selling the drug "challenging." The drug cost is US\$1.4 million
- In May 2012, Osiris Therapeutics received approval to market "Prochymal" first stem cell drug to treat graft-versus-host disease, a devastating breakdown occurring after a bone marrow transplant that kills around 80% of children affected. The approximate cost of treatment is US\$ 200K.

## Approved cell based products for PMS study in India

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<b>Product</b>	<b>Manufacturer</b>
Autologous adult live cultured Osteoblasts for Avascular Necrosis of hip joint	M/s Regenerative Medical Services, Mumbai
Autologous adult live cultured Chondrocytes for Articular Cartilage defects of knee joint	M/s Regenerative Medical Services, Mumbai
Autologous dendritic cell immunotherapy for carcinoma of Ovary & Lung	M/s APAC Biotech Pvt Ltd, Gurgaon
Bone marrow derived, cultured, pooled, allogeneic mesenchymal stromal cells for Critical Limb Ischemia due to Buerger's disease	M/s Stempeutics Research Pvt Ltd, Bangalore

**Other indications like Diabetes type 2, CLI due PAD, OA amongst others in clinical trial phase in India**





# Stempeucel Status

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Completed

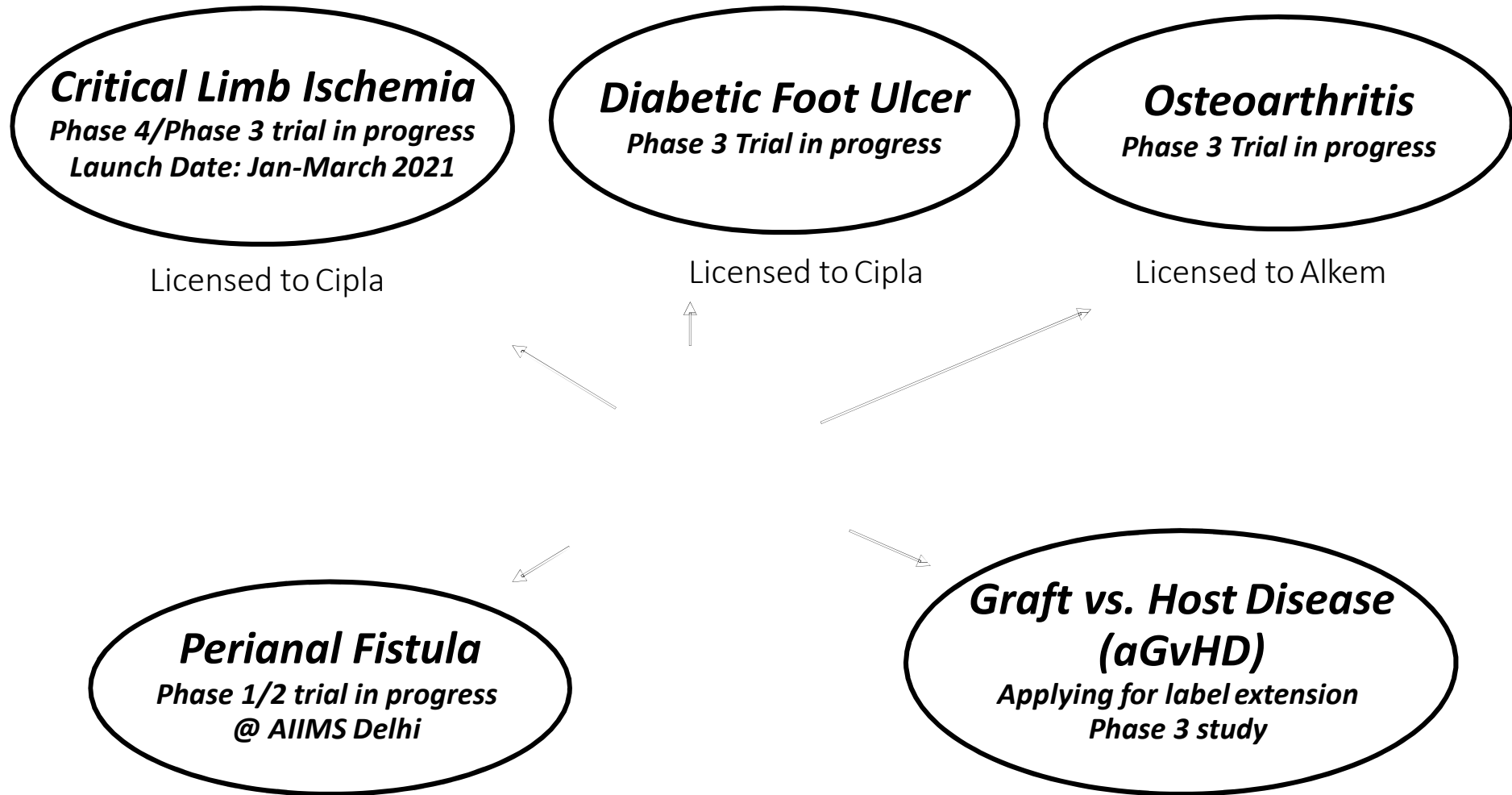
MA granted

Completed

MA granted

# Product Development

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## Critical Limb Ischemia – Clinical Trial Sites

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City	Hospital	Investigator
Chennai	Vijaya Hospital	Dr Rajkumar
	SRMC	Dr Radhakrishnan
	MMC	Dr Sritharan
Bangalore	Jayadeva	Dr Muralikrishna
	MS Ramaiah	Dr Sanjay Desai
Hyderabad	KIMS	Dr VK Reddy
Kolkata	Health Point	Dr Mahapatra
	Bellevue Clinic	Dr Santanu Dutta
Delhi	AIIMS	Dr Anita Dhar
	Medanta	Dr Rajiv Parakh
Kanpur	GSVM Medical College	Dr Sanjay Kala Dr Vinay Krishna
Chandigarh	PGIMER	Dr Behera

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# CLI Phase 1 & Phase 2 Trial data Published

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- **Cellular Therapy is an emerging field of Bio-Therapeutics**
- **Adult stem cells are preferred source for product development as they are safe**
- **Full potential of stem cells is yet to be exploited, which is the hope for millions of people**

# References

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**Thank you**