



FIFARMA represents innovation in the Latin America Region

Why? Because supports the development of policies that foster the access to high quality pharmaceutical innovations that prolong, preserve and improve live for patients



For what purpose?

To unlock the potential of **Advanced Therapies**, they are medicines for human

which are obtained from:

- ✓ Cells (cell therapy)
- ✓ Genes (gene therapy)
- ✓ Tissue (tissue engineering)

These new therapies are pushing the boundaries of science and challenging expectations of what medicine can achieve

Why is it important?

Because they have the potential to

- ✓ Address major unmet health needs
- ✓ Change the courses of diseases
- ✓ Even cure certain conditions

However, this requires changes in mindset and approach by all stakeholders, which can be addressed by regulatory system strengt hening



FIFARMA sees three keys area of opportunity to make these changes:

- ✓ **Establishment of regulatory frameworks**-> adoption of international regulations and guidelines
- ✓ **Adoption of Reliance Procedures** -> adopt reliance procedures to increase efficiencies and improve regulatory capacities
- ✓ **Regulatory Capacity Building** -> multi-stakeholder partnership approach in delivering capacity training for regulators, officials and health care professionals on Advanced Therapies

