



Global Medical
Technology Alliance
Innovating for a Healthier World

GMTA

- ***Getting innovative medical technologies to patients –***
 - ***How IMDRF matters -***



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Innovating for a Healthier World



Who Are We?

1990s Origins date s as informal network

2010 Formally established

2013 Became legally constituted in Switzerland as an
“association”

2015 WHO approved as official NGO

- **Governed by Articles of Association, Governance Rules, Elected Board of Directors**

◆ **Membership open to medical technology associations
(not companies)**

- **willing to accept GMTA governance rules**
- **with functioning code of ethical business practices**



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Countries Represented by GMTA



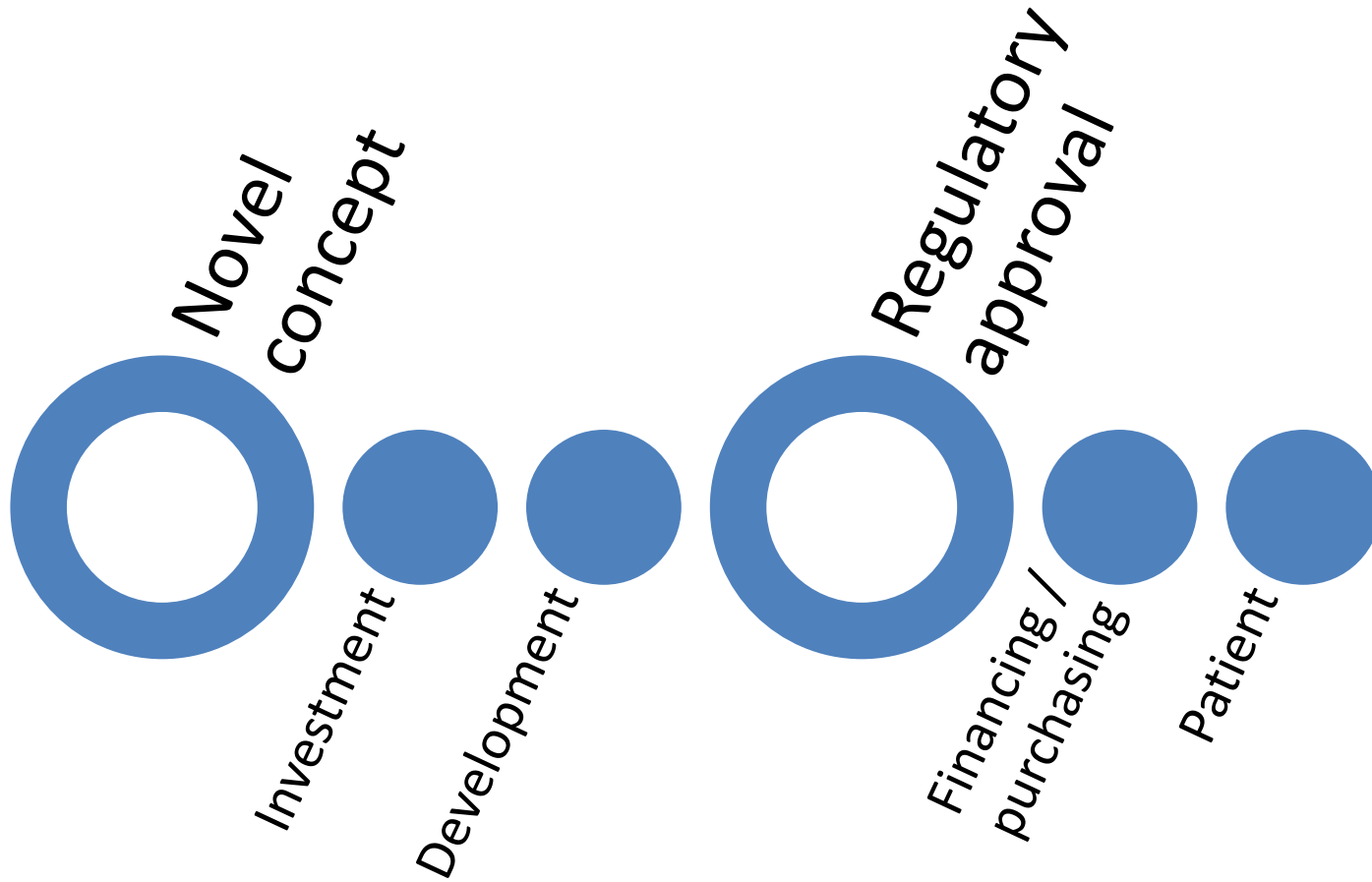
IMDRF Strategic Plan

“The mission of the IMDRF is to strategically accelerate international medical device regulatory convergence to promote an efficient and effective regulatory model for medical devices that is responsive to emerging challenges in the sector while protecting and maximizing public health and safety.”

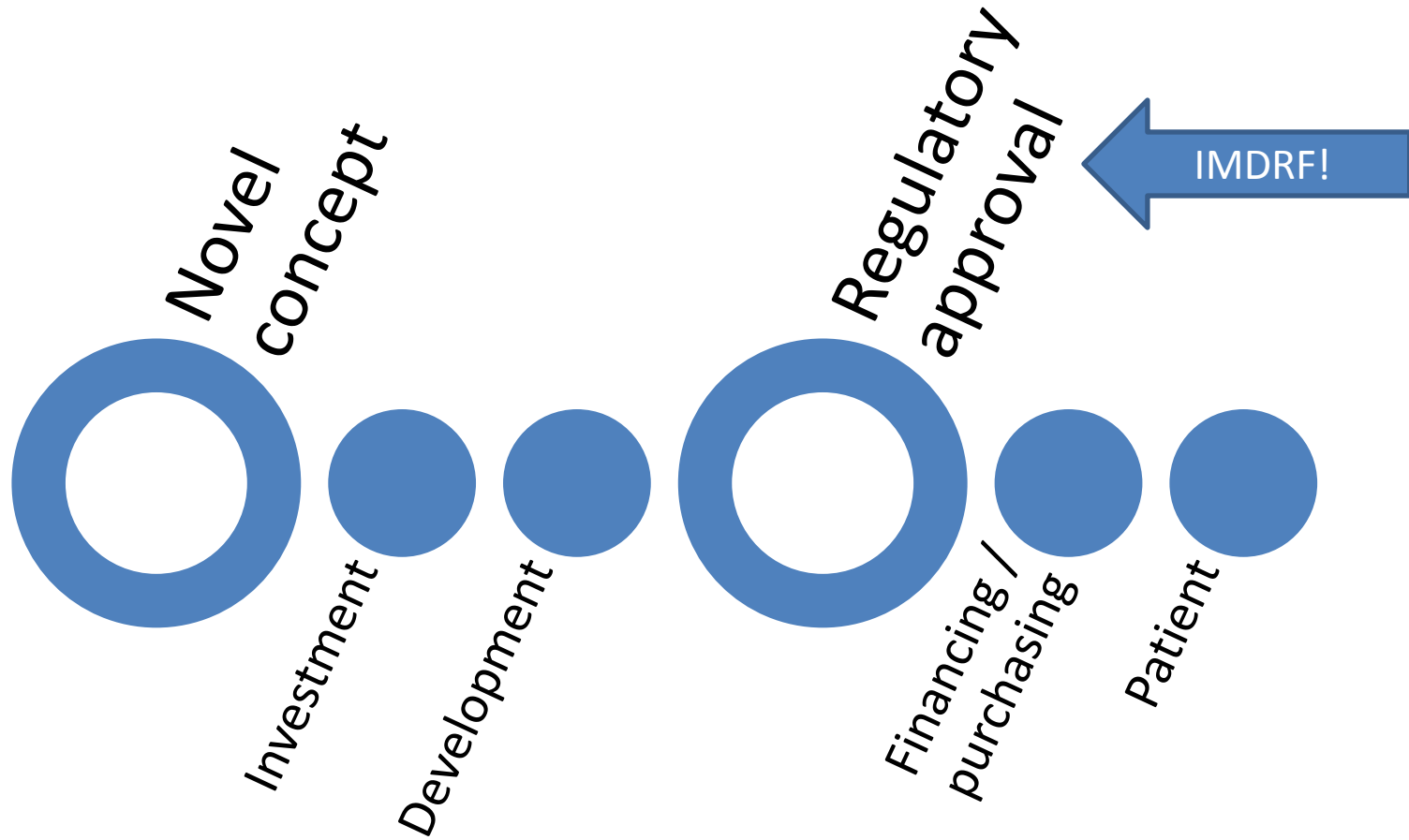


the Management Committee (MC) intends to put particular focus on the objective, “Support innovation and timely access to safe and effective medical devices”

MedTech Innovation to Patients

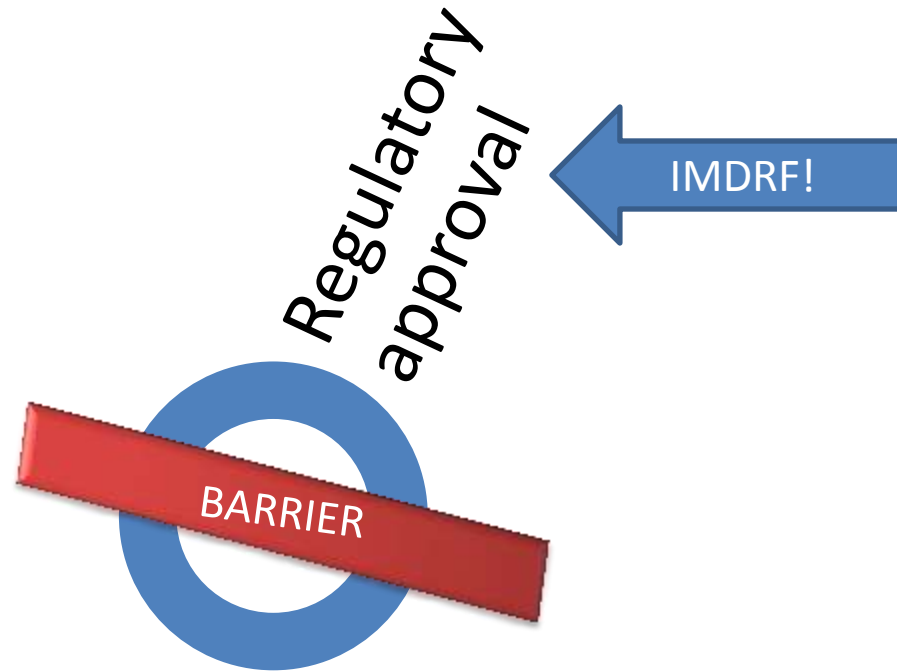


MedTech Innovation to Patients



Regulatory Challenge?

When do regulatory systems risk becoming a barrier to supporting health systems having access to safe and effective medical devices?



Beyond IMDRF and in the news...



Zika outbreak & IMDRF members

**Vector
Present:**

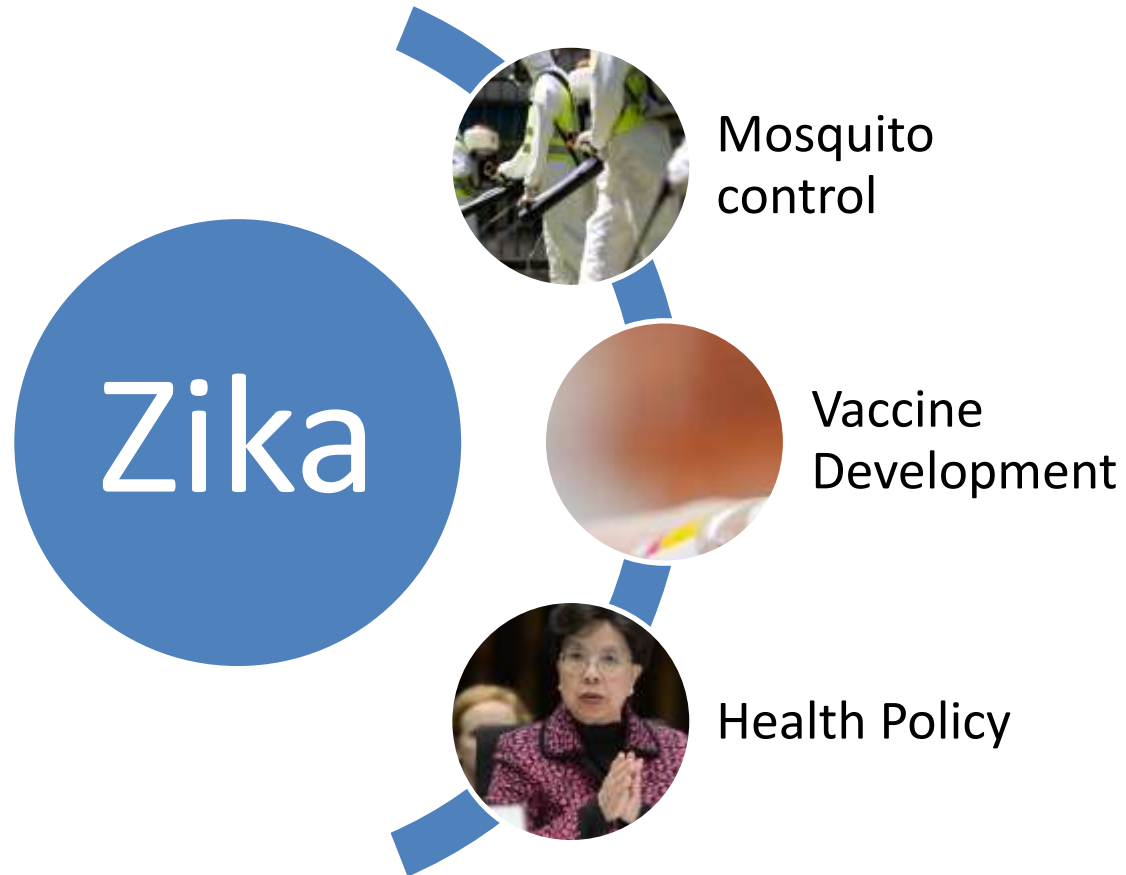


**Australia
Brazil
China
EU
Japan
Russia
USA**

**Vector
Free:**

Canada

What we hear about Zika?



But... Medical Technologies are critical



Are they all available?

Novel

Investment in new technologies

- Very strong investment in new technologies
- Focused on a single jurisdiction (sometimes even a single hospital)

Existing

Critical technologies exist but...


- Not all are available around the world – regulatory approval a concern

Emergency

Diverging issues

- Emergency approvals are very different
- Hard to see how to get an emergency approval in all relevant jurisdictions

Conclusion



IMDRF has a pivotal role in the access pathway for innovative technologies

GMTA Actively supports the IMDRF 2020 Strategic Plan

Access to innovative medical technologies remains a challenge

When dealing with a global health crisis innovation in Medical technologies is essential



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Muito obrigado!

Thank you for your time!