GHTF to IMDRF

What next?

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Introduction

- Personal reflections
- Early days for IMDRF
- Questions, concerns, opportunities

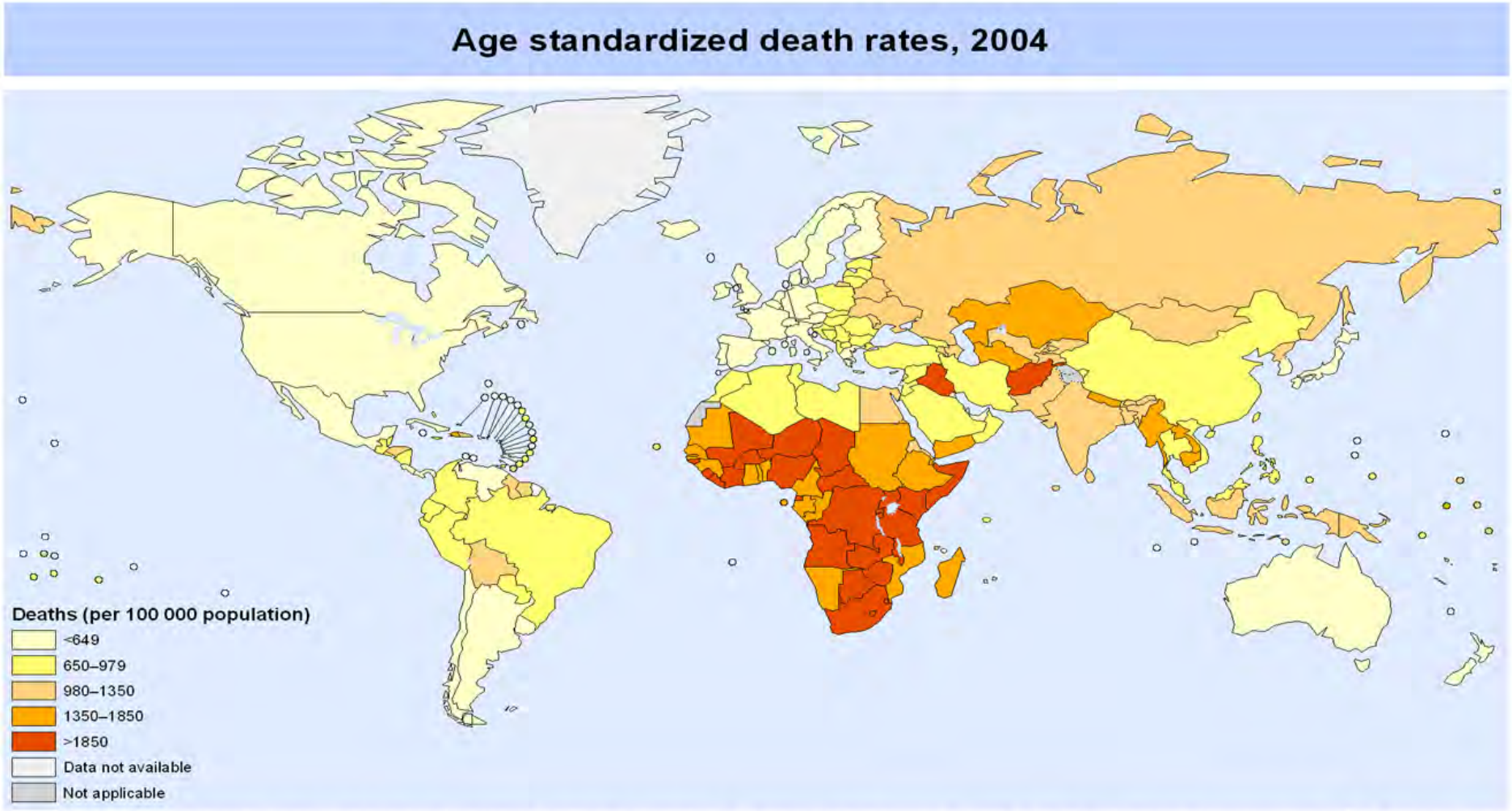
Background trends

- Worldwide population continues to grow
- Infant mortality continues to decrease
- Life expectancy increases
- Ageing populations
- Growing policy focus on healthy ageing and assistive technologies
- Shift of burden of disease from communicable to non-communicable conditions
- Reduction in poverty -- but not evenly distributed

Background trends

- Challenges to fiscal sustainability of current social models
- Changing models of health care delivery
- Growing public access to information on health
- Growing public awareness of medical technology
- Rapid expansion of access to enabling technologies such as mobile telephones and Internet

Why seek regulatory convergence?



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Data Source: World Health Organization
Map Production: Public Health Information and Geographic Information Systems (GIS)
World Health Organization

World Health Organization

Thesis

Access to safe and effective health care technologies of high quality is an important contributor to economic and social progress in countries at all stages of development

Thesis

Enlightened, appropriate, judiciously applied regulation of health care products is a public good

- Protection and promotion of public health
- Good governance
- Expectation of citizens
- Public confidence in products and health care

Thesis

Regulation and regulatory practice are determinants of successful life sciences innovation

- Regulators are on the life sciences “critical path”
- The efficiency and effectiveness of regulatory authorities in fulfilling their public health mandate is therefore critical to achievement of desired life sciences outcomes
- Importance of international regulatory harmonisation and use of international standards in contributing to life sciences innovation

Thesis

Growing public discussion about needs in less developed countries for “available, accessible, appropriate, and affordable” medical technologies highlights the concomitant need for appropriate and affordable regulation

Why seek regulatory convergence?

- More efficient use of regulator and industry resources
- More efficient use of taxpayer funds
- Spread compliance costs over more markets
- Develop and promulgate regulatory best practices
- Pooling of expertise
- Regulatory capacity-building

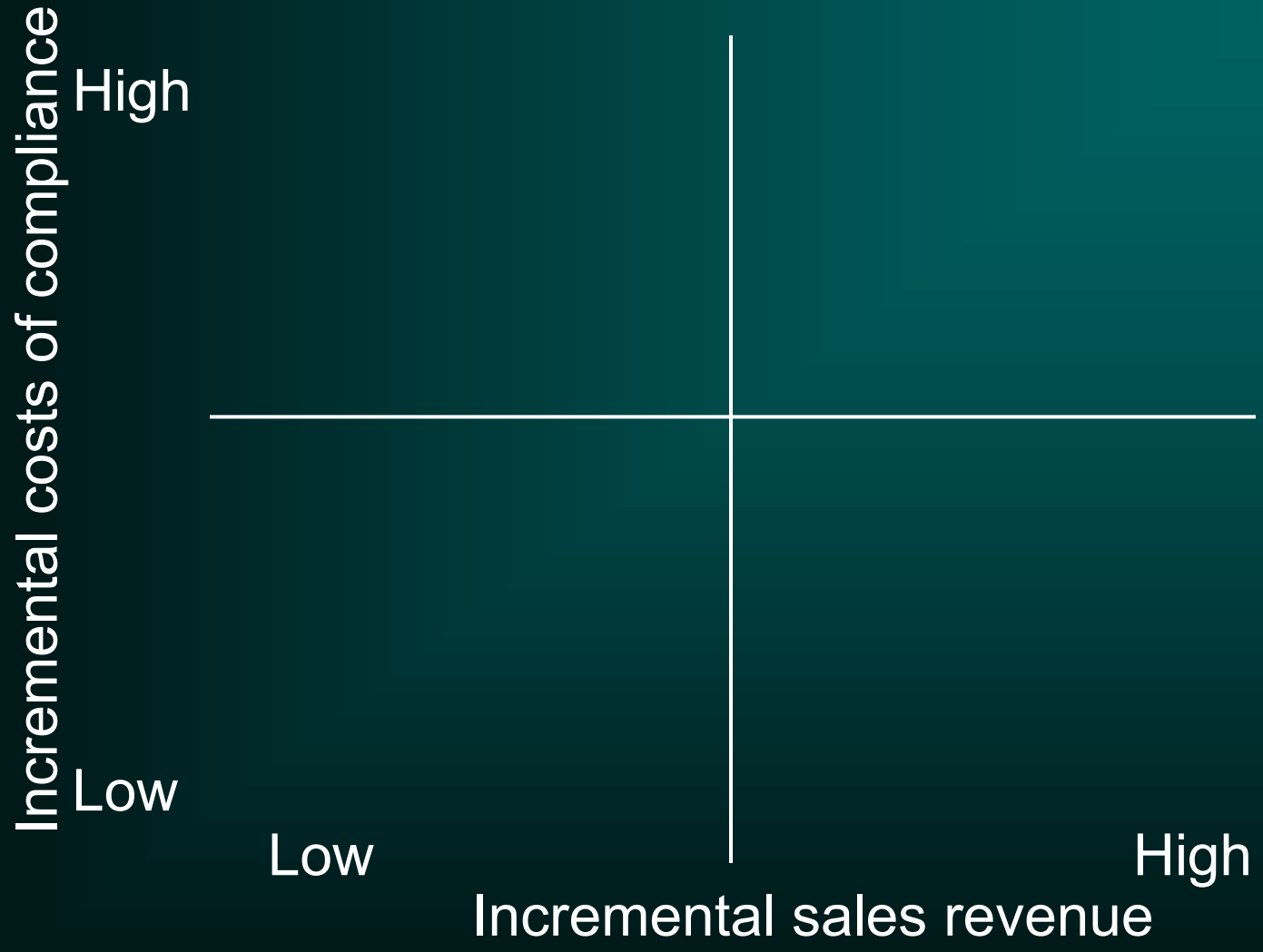
Why seek regulatory convergence?

- Protect and promote public health
  - Directly in-market
  - Indirectly in other markets

Why seek regulatory convergence?

- Protect and promote public health
  - Directly in-market
  - Indirectly in other markets
- Promote investment in innovation
- Facilitate international trade

Costs of regulatory divergence



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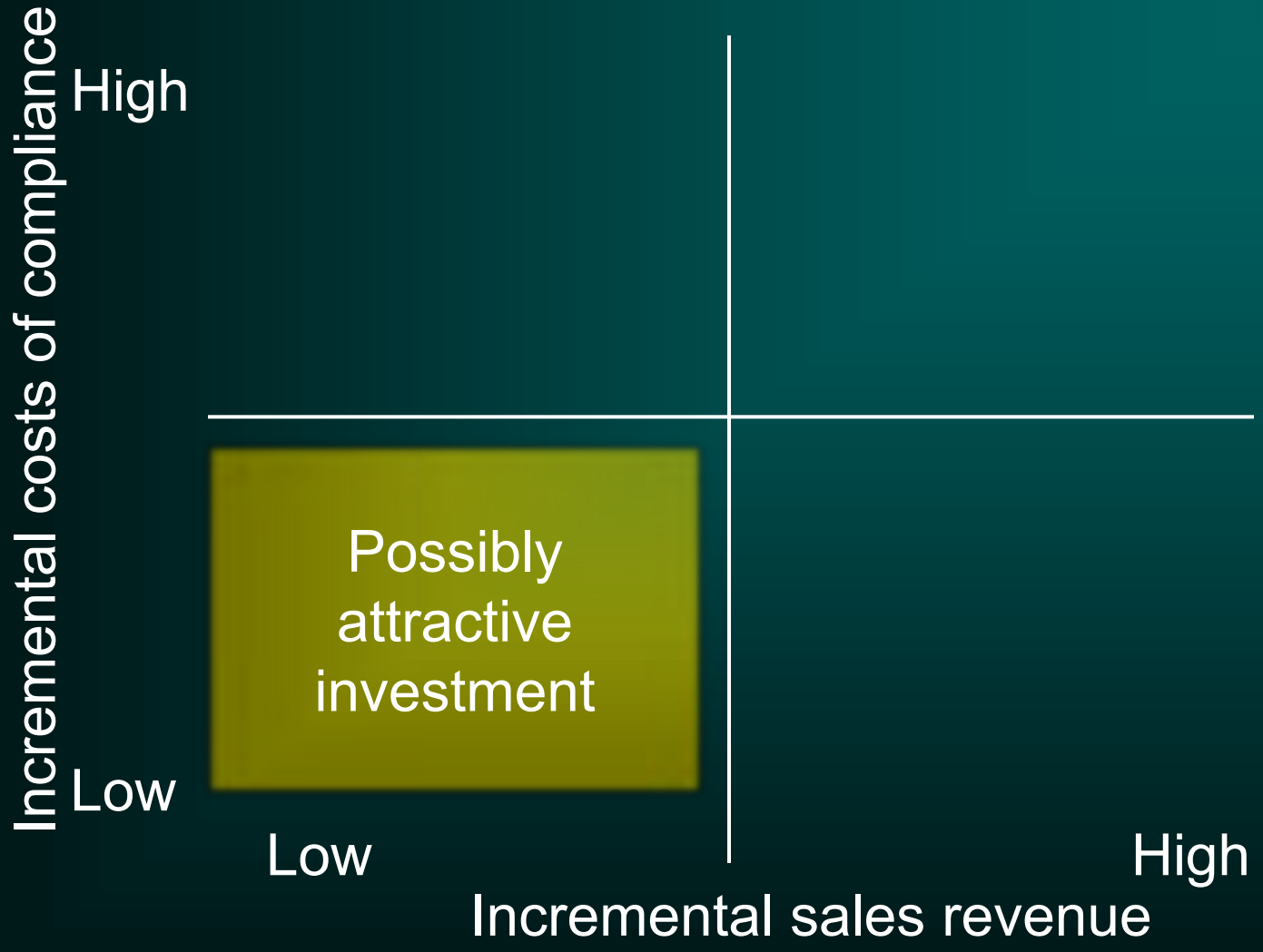

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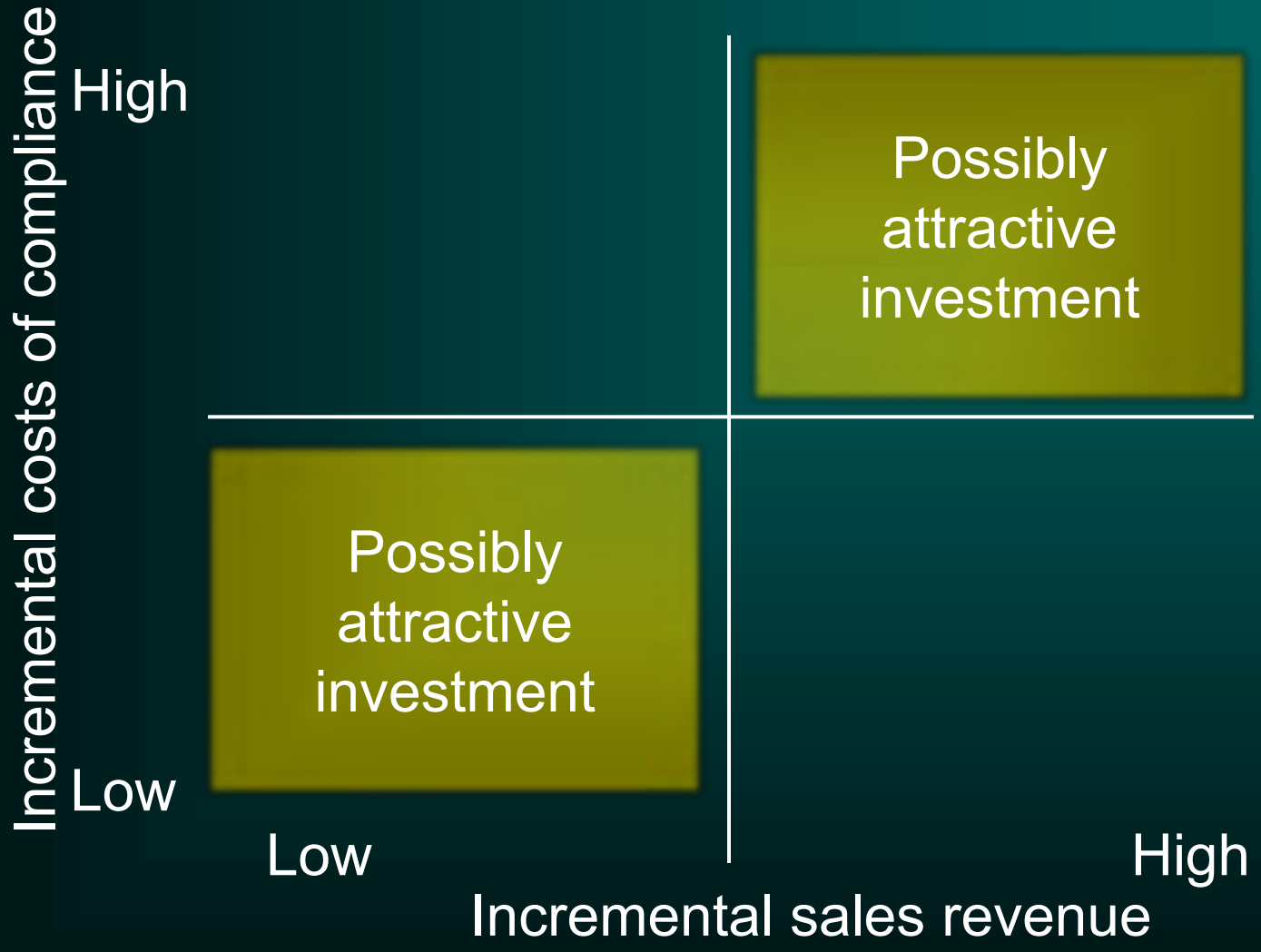

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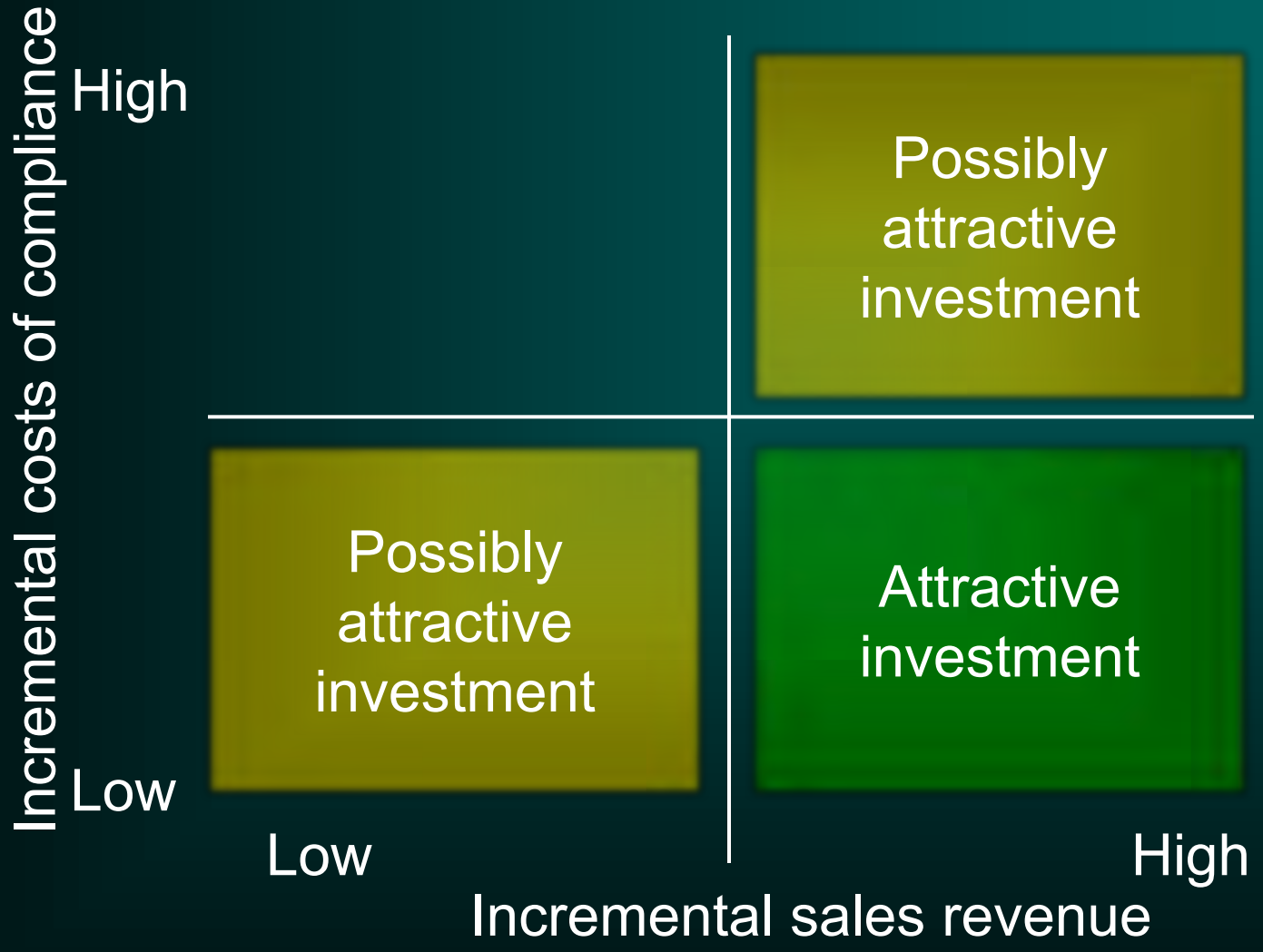

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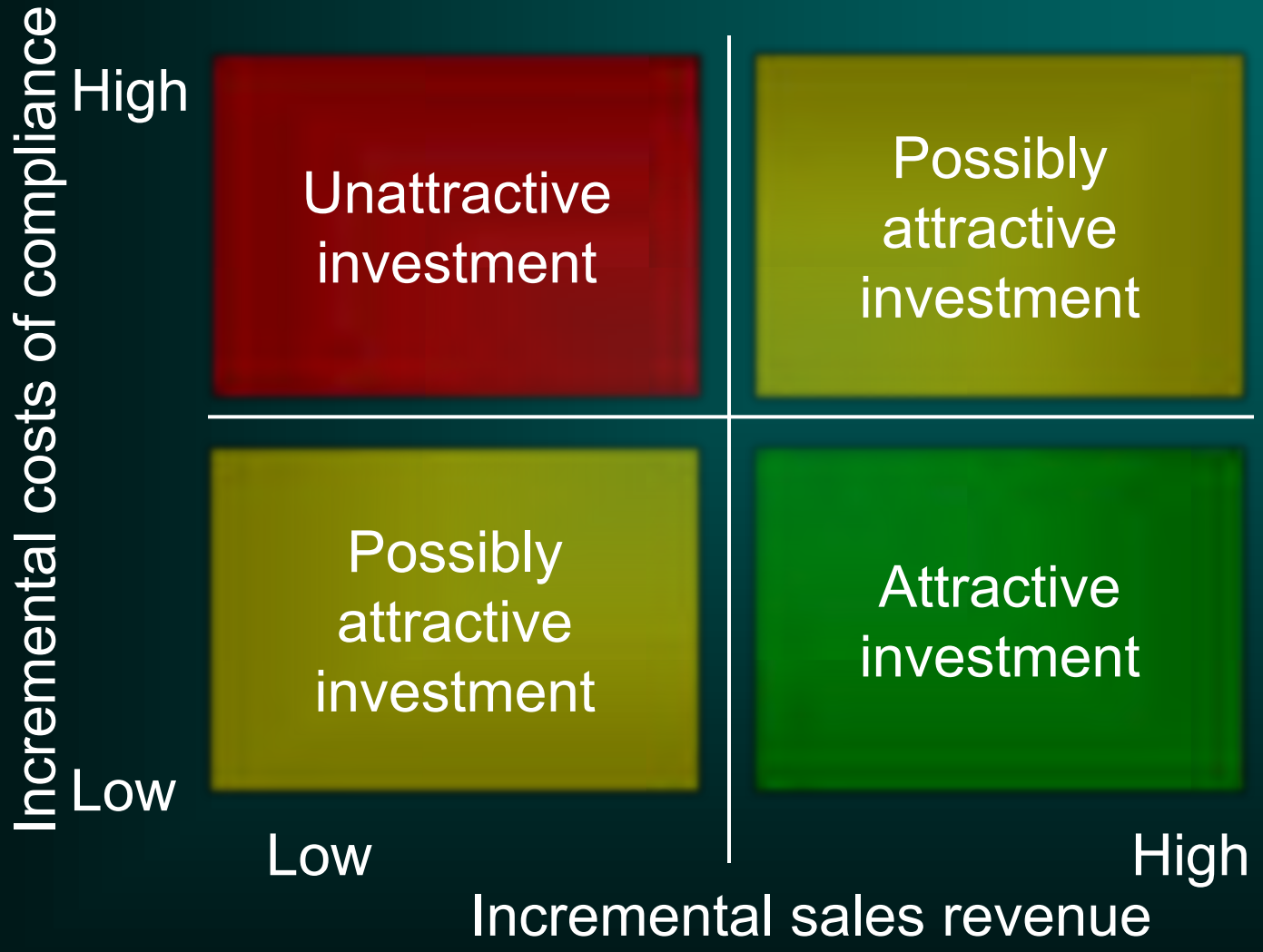

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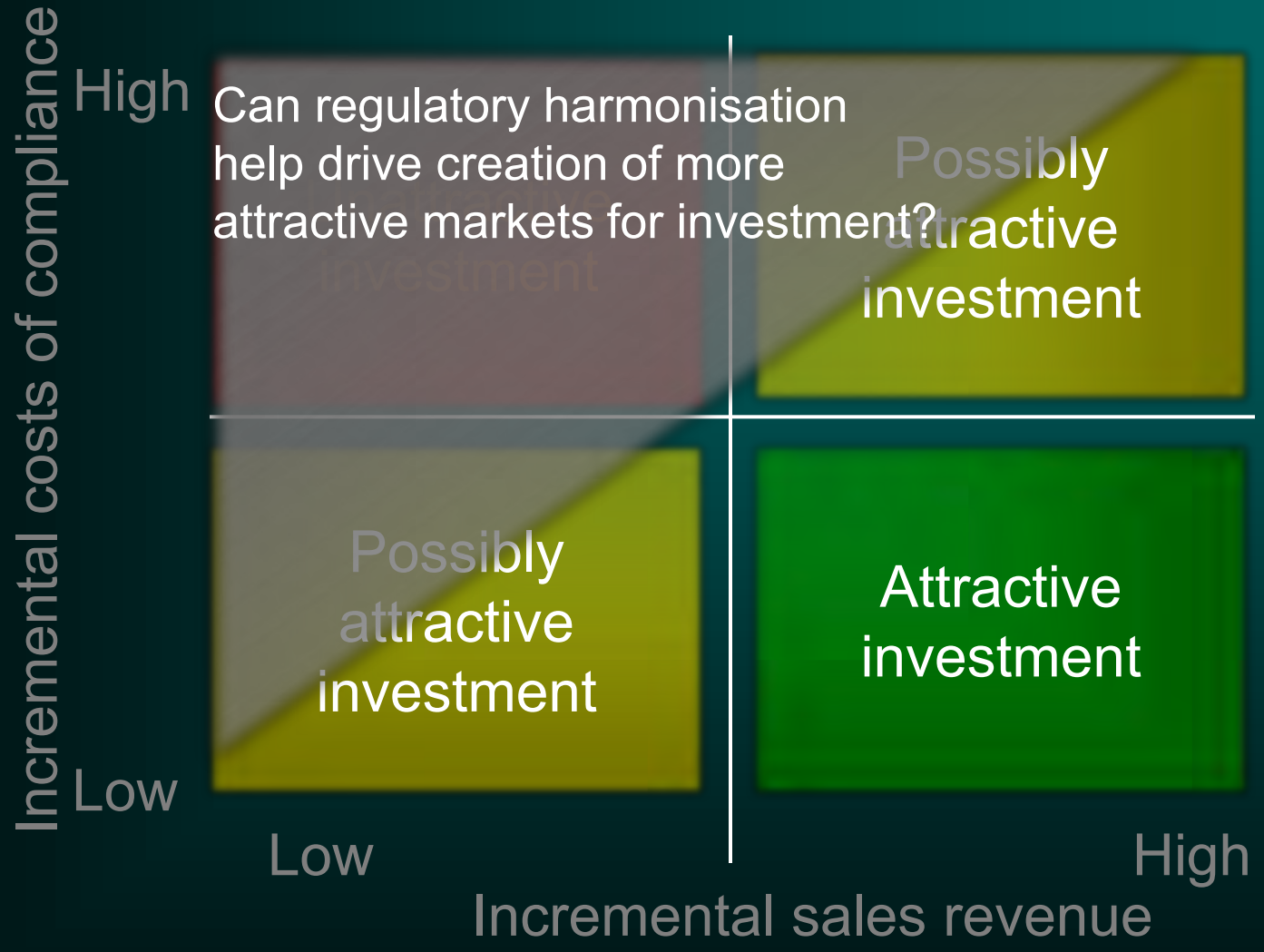

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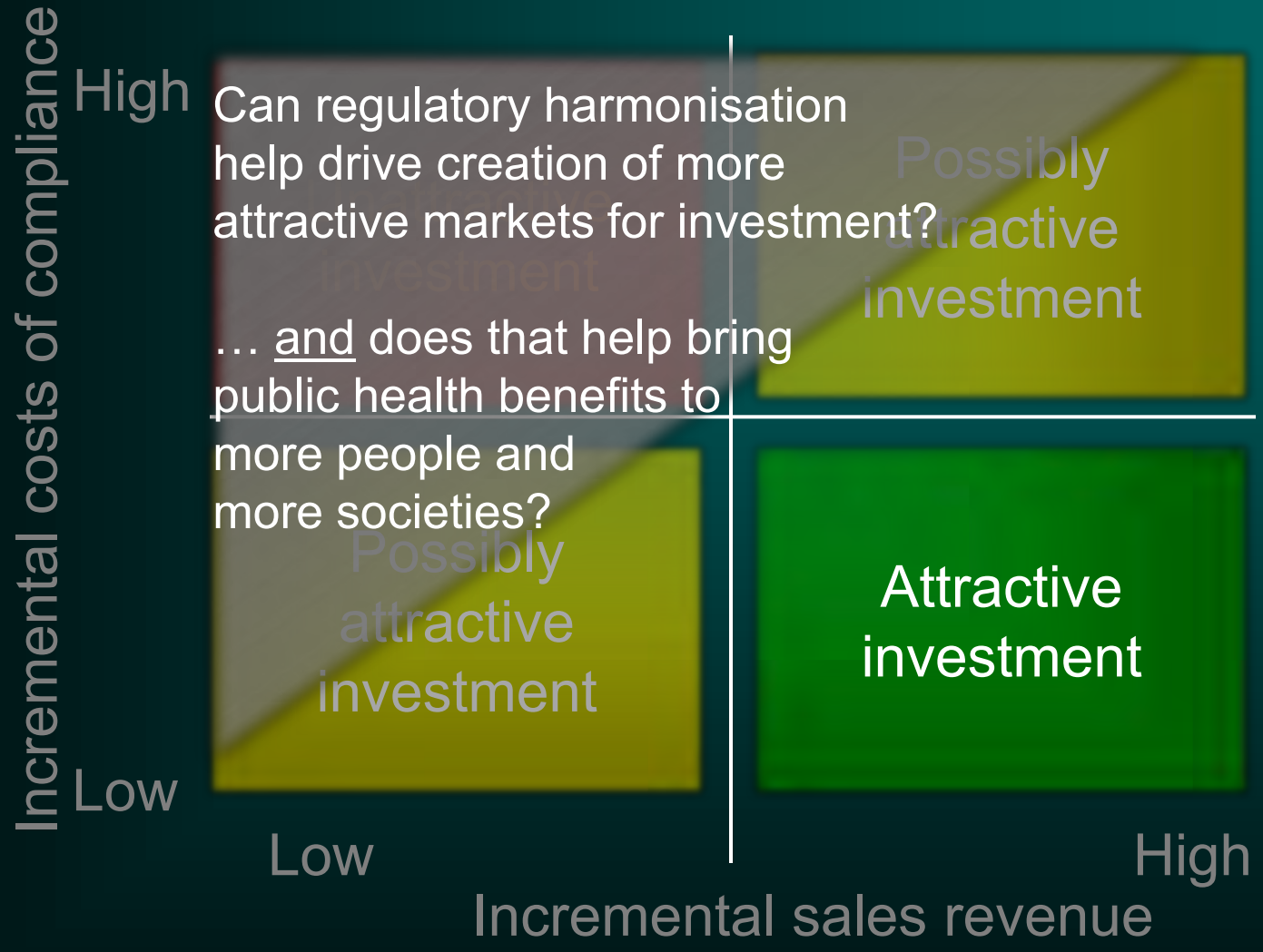

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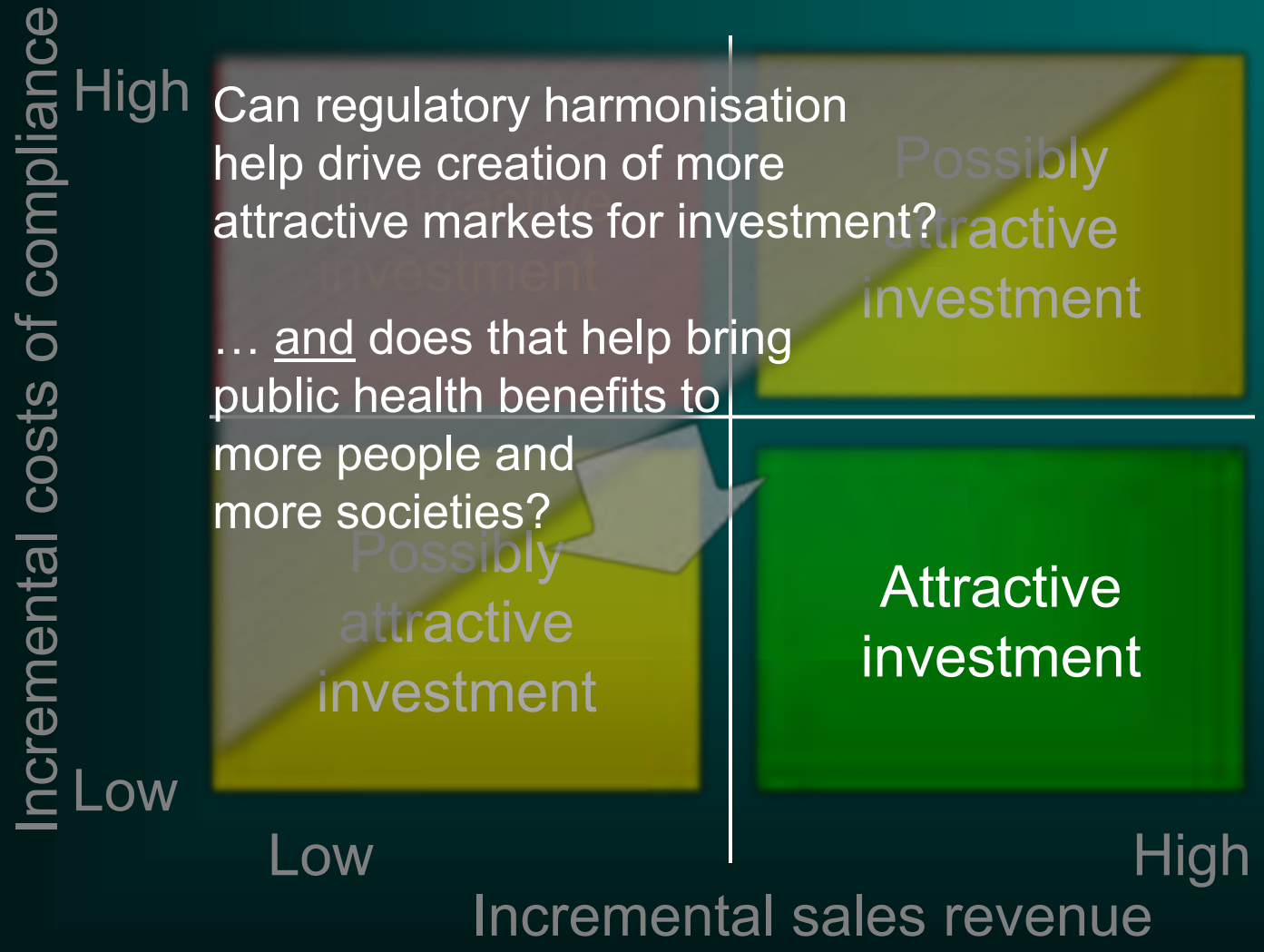

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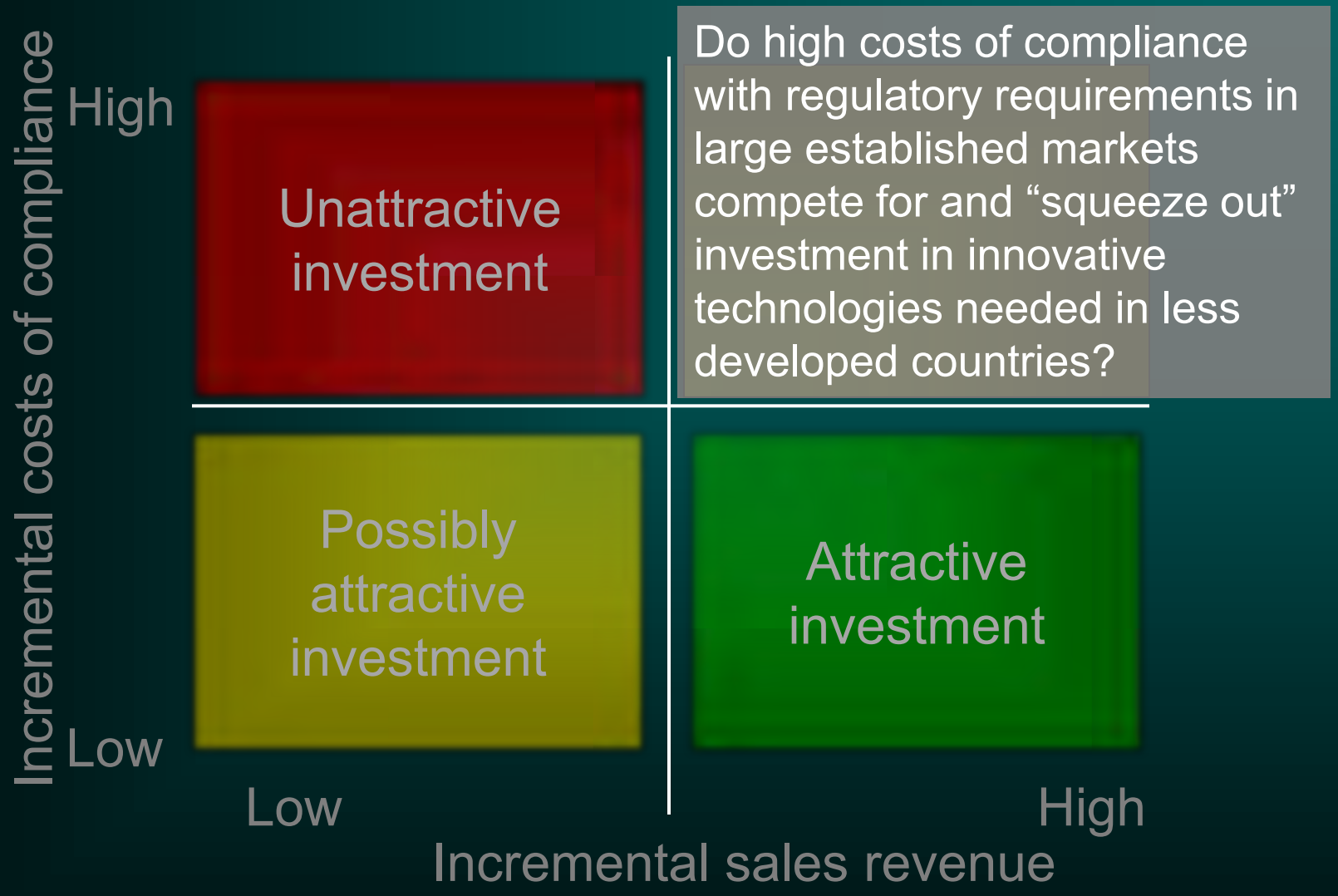

Now is the time

- ≈ 85 countries today regulate medical devices
- More developing regulations
- To what regulatory model(s) will they turn?
- Prospective regulatory convergence easier than retroactive

GHTF guidance as rootstock

- International harmonisation initiatives based upon GHTF guidance documents

GHTF guidance as rootstock

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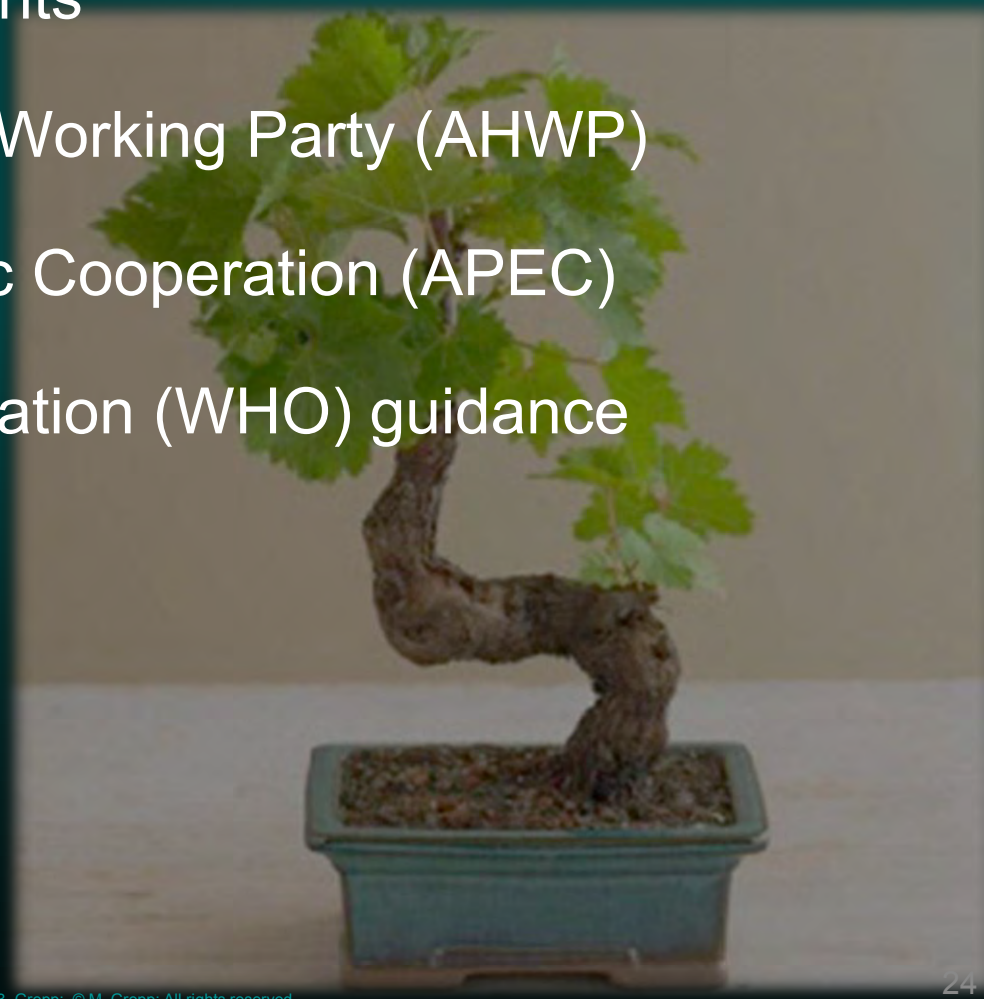
  - Asian Harmonization Working Party (AHWP)
  - Asia Pacific Economic Cooperation (APEC)
  - World Health Organization (WHO) guidance

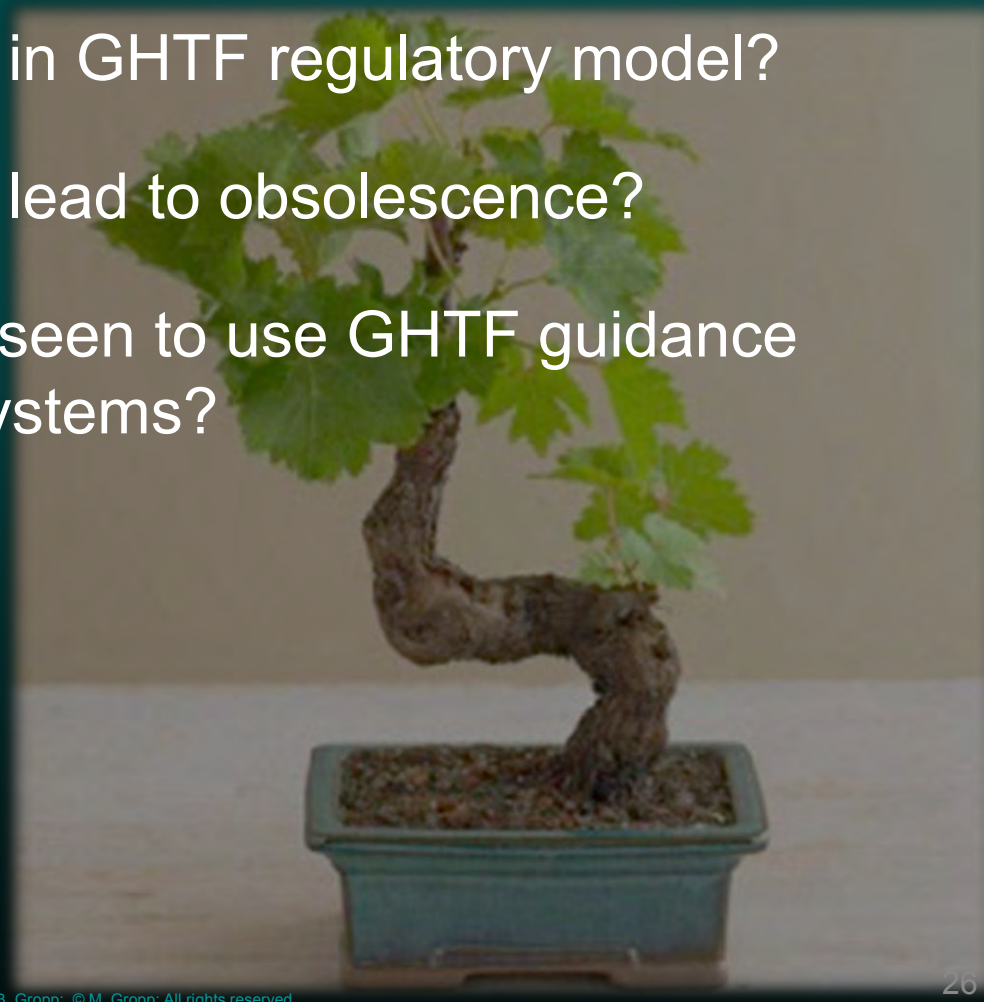


GHTF guidance as rootstock

- New national and regional regulations based upon GHTF guidance documents
  - Association of Southeast Asian Nations (ASEAN) medical device directive
  - South Africa (?)
  - Saudi Arabia
  - India (?)

GHTF guidance as rootstock

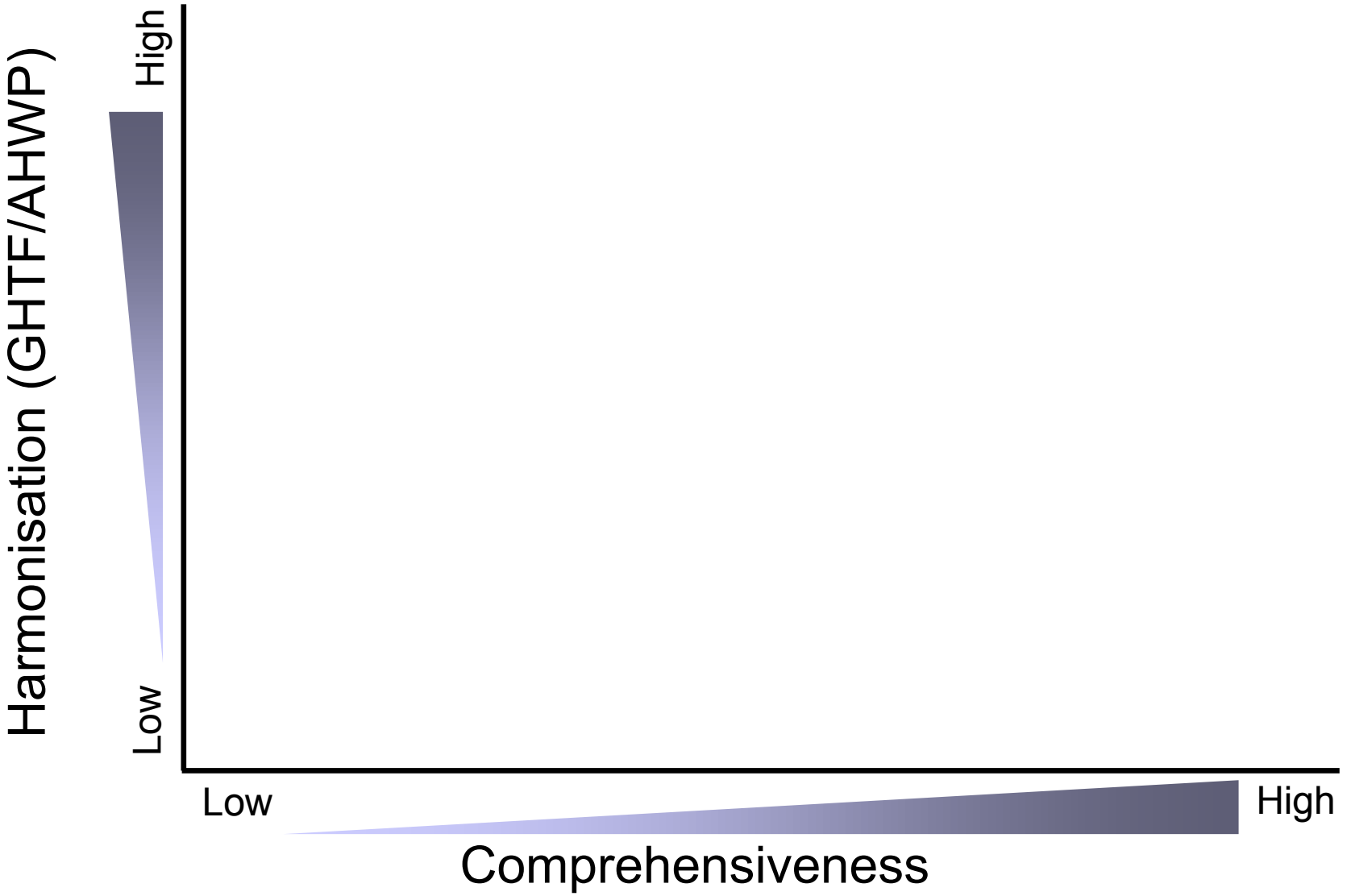
- How will GHTF guidance be maintained?
- How will IMDRF fill gaps in GHTF regulatory model?
- Will lack of maintenance lead to obsolescence?
- Will IMDRF founders be seen to use GHTF guidance in their own regulatory systems?



Vision of “success”?

- What will be different in 3-5 years as a result of IMDRF’s work?
- Can “convergence” be measured?

Vision of “success”?



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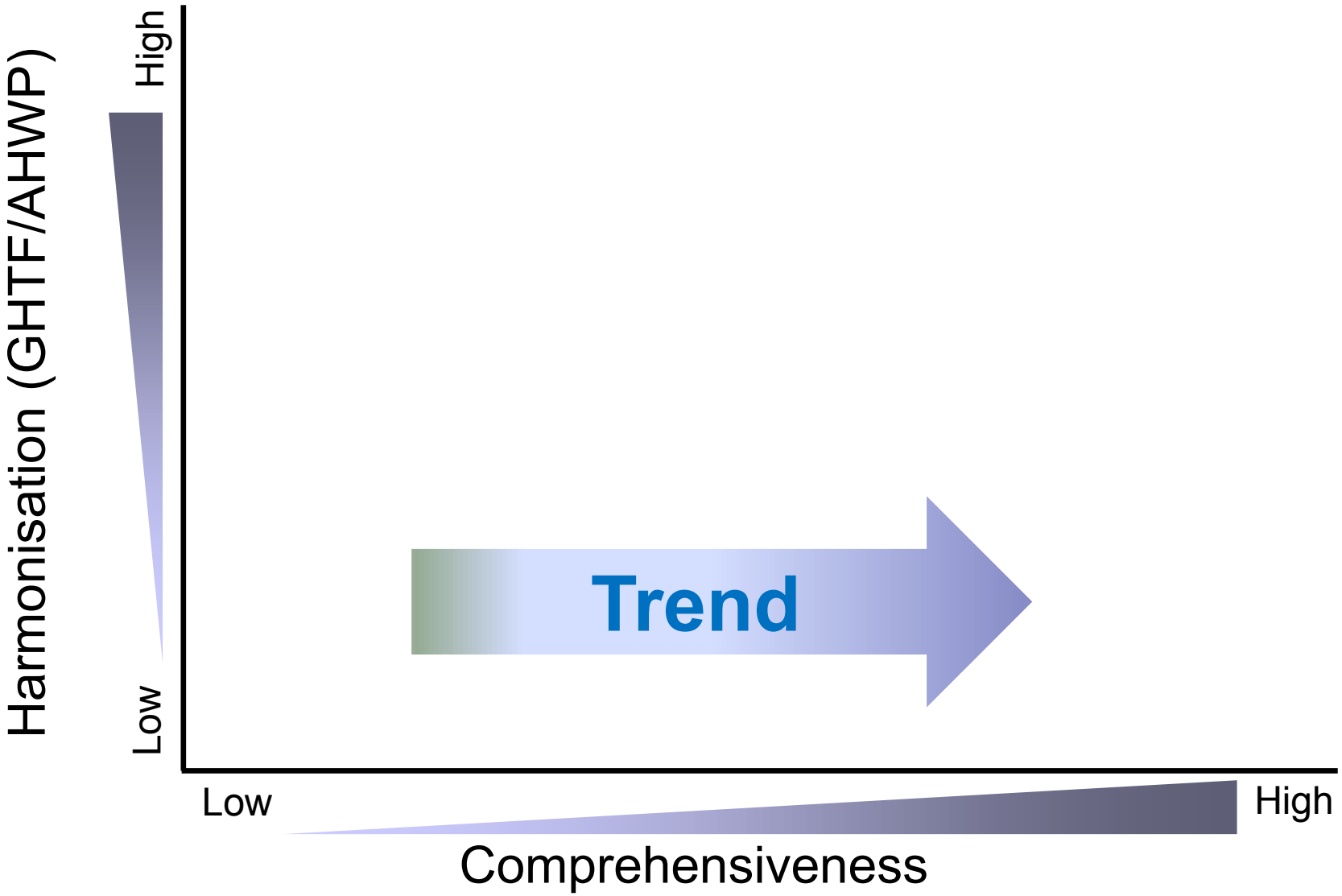

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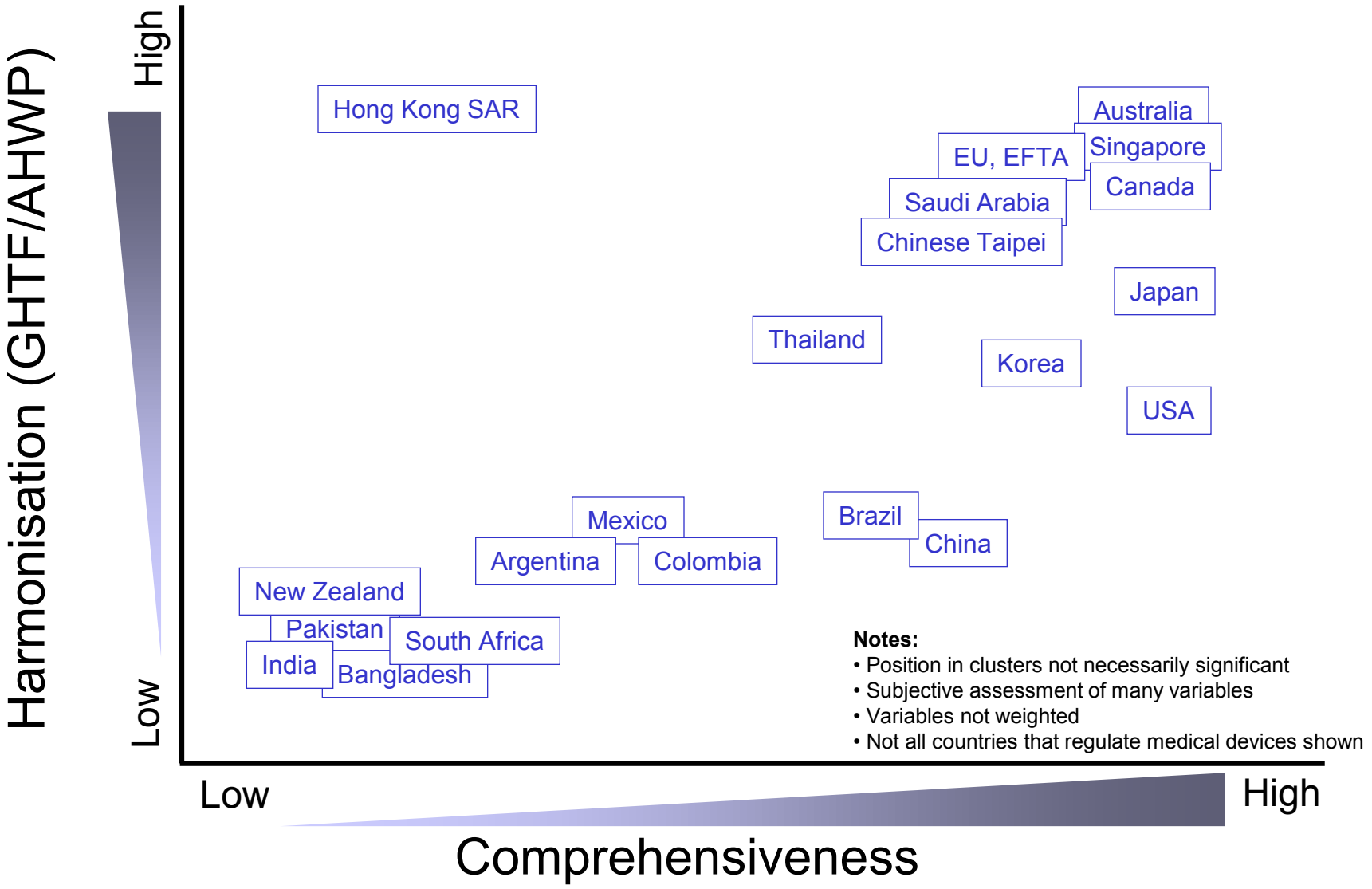

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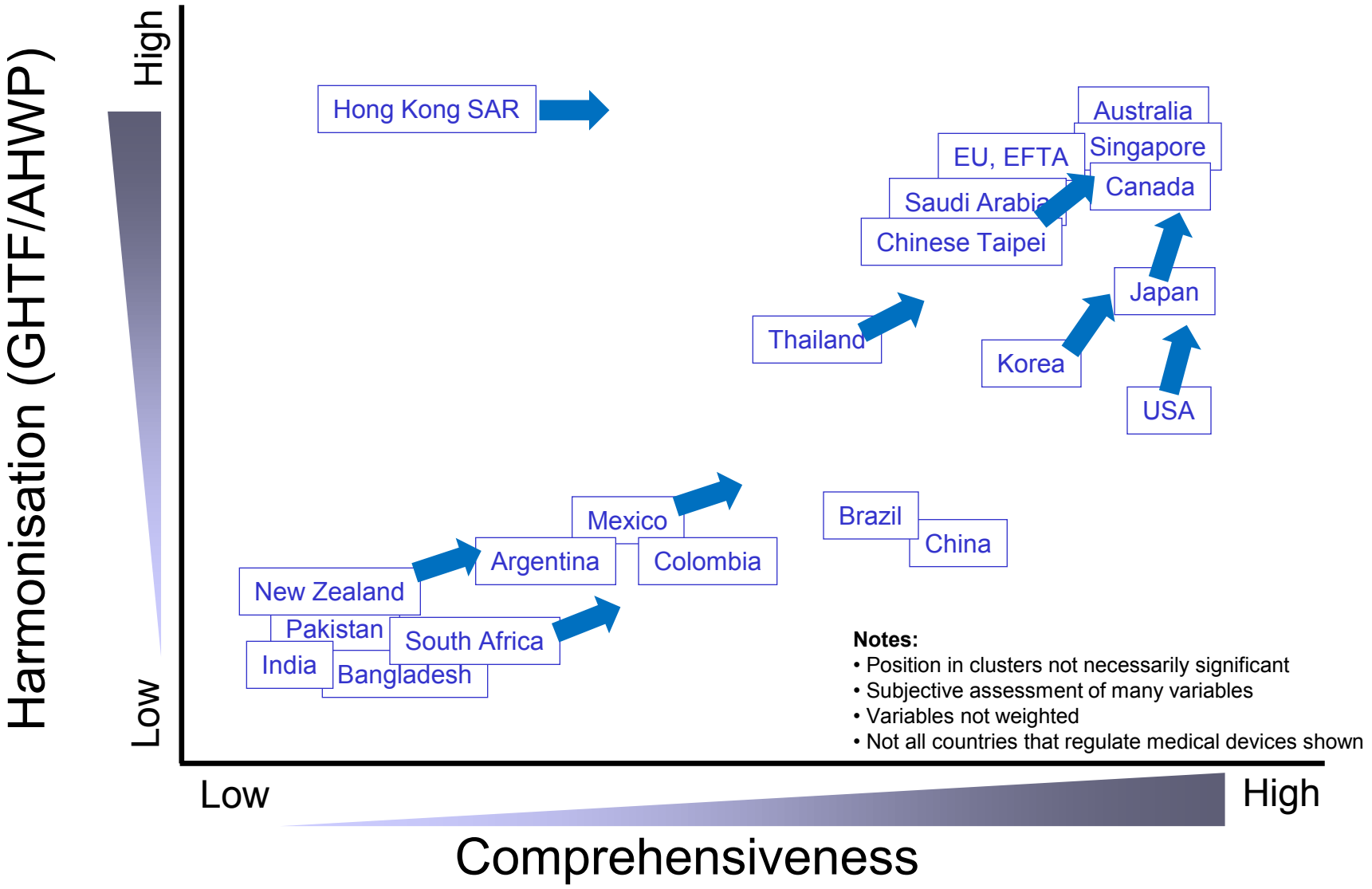

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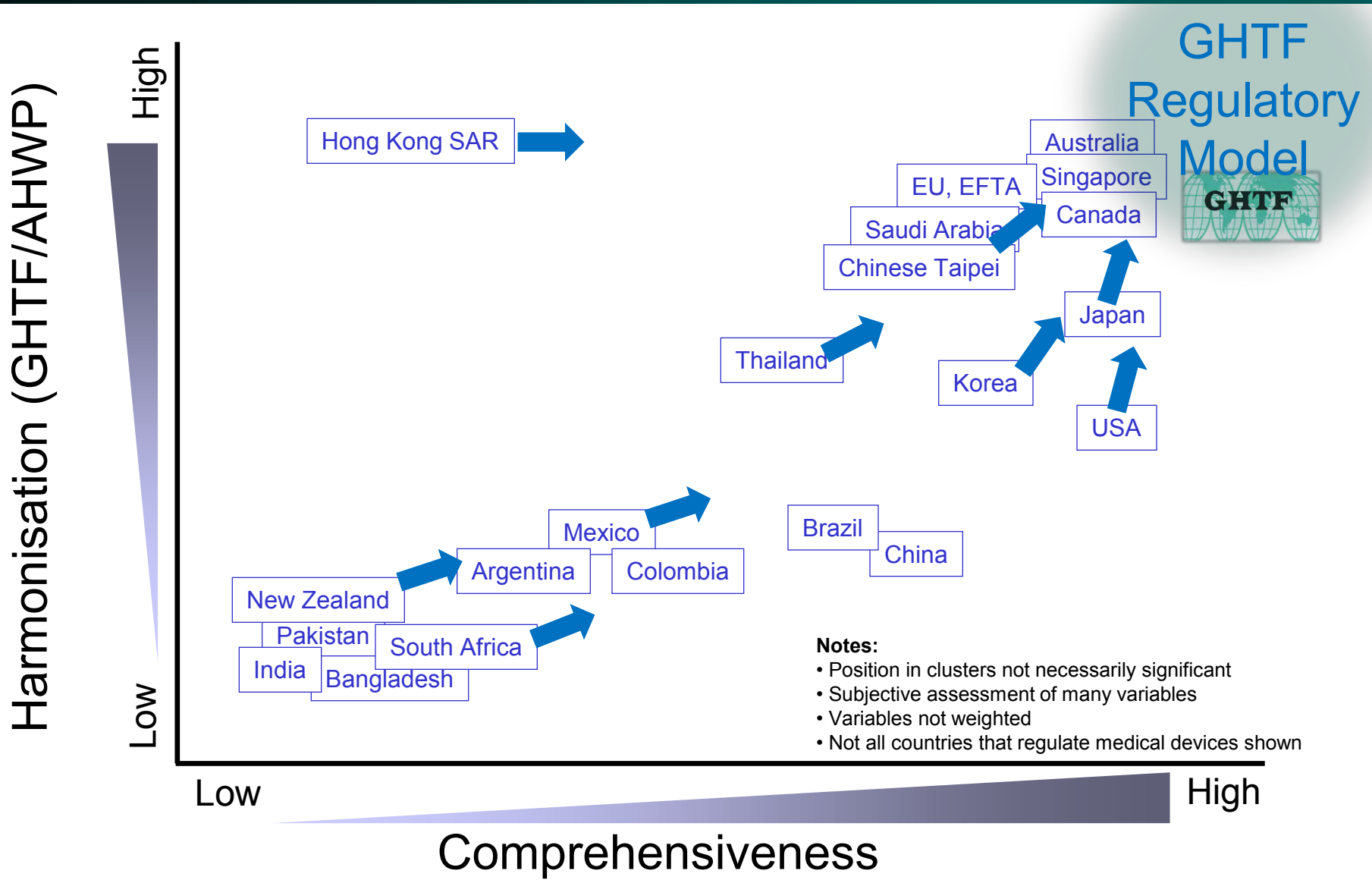


GHTF regulatory model

GHTF/AHWG-GRM/N1R13:2011

GHTF

Final Document

Title: The GHTF Regulatory Model

Authoring Group: Ad Hoc GHTF SC Regulatory Model Working Group

Endorsed by: The Global Harmonization Task Force

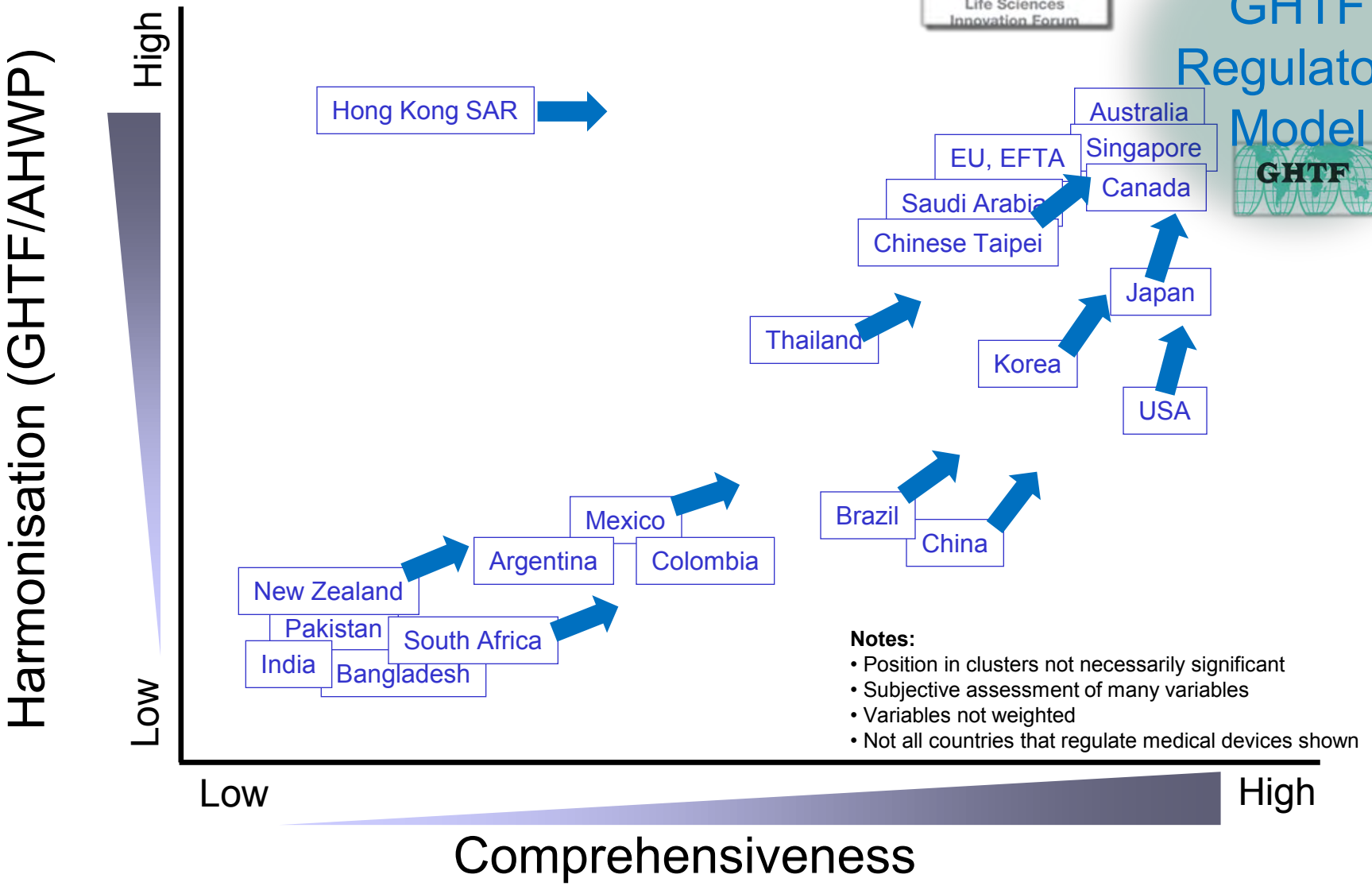
Date: 13 April 2011

[Signature], GHTF Chair

This document was produced by the Global Harmonization Task Force, a voluntary international group of representatives from medical device regulatory authorities and trade associations from Europe, the United States of America (USA), Canada, Japan and Australia.

The document is intended to provide *non-binding* guidance to regulatory authorities for use in the regulation of medical devices, and has been subject to consultation throughout its development.

What follows?



GHTF Regulatory Model

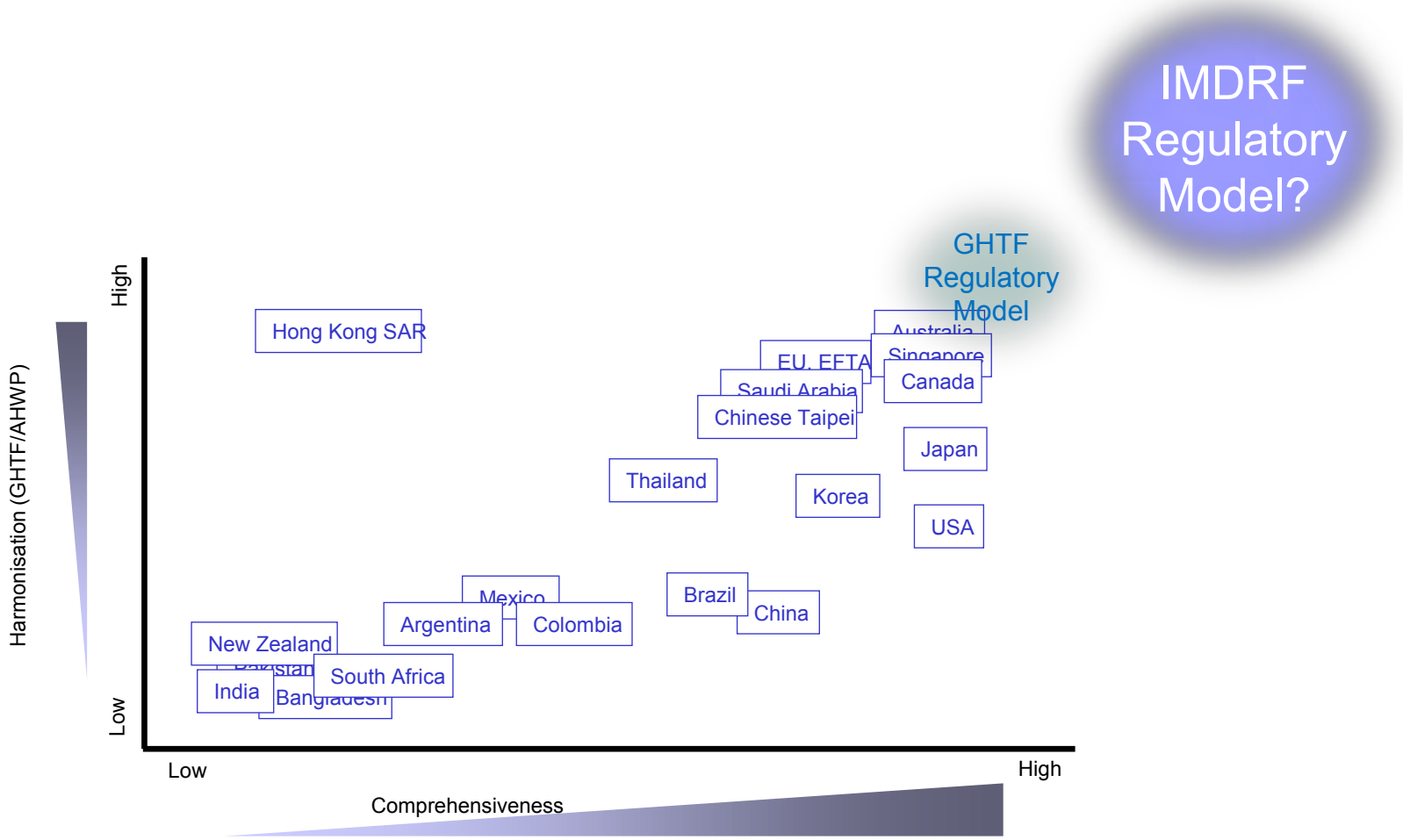
Vision of “success”?

“ … The process of convergence represents an important form of regulatory cooperation which in turn makes possible additional, enhanced forms of cooperation and collaboration between regulatory authorities.”

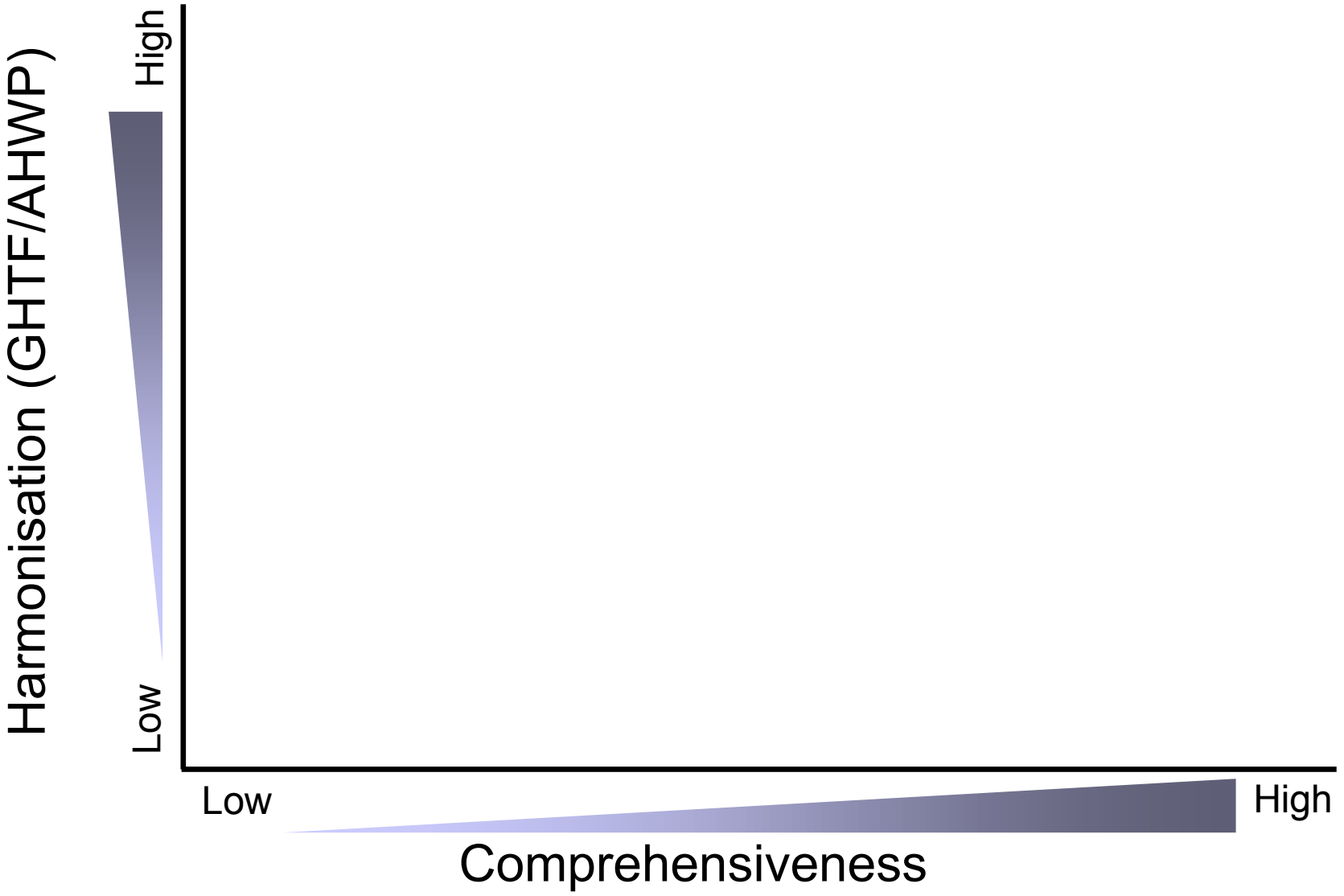
- Functional network of regulators, rather than individual regulators?

Source: IMDRF Terms of Reference, 1 March 2012

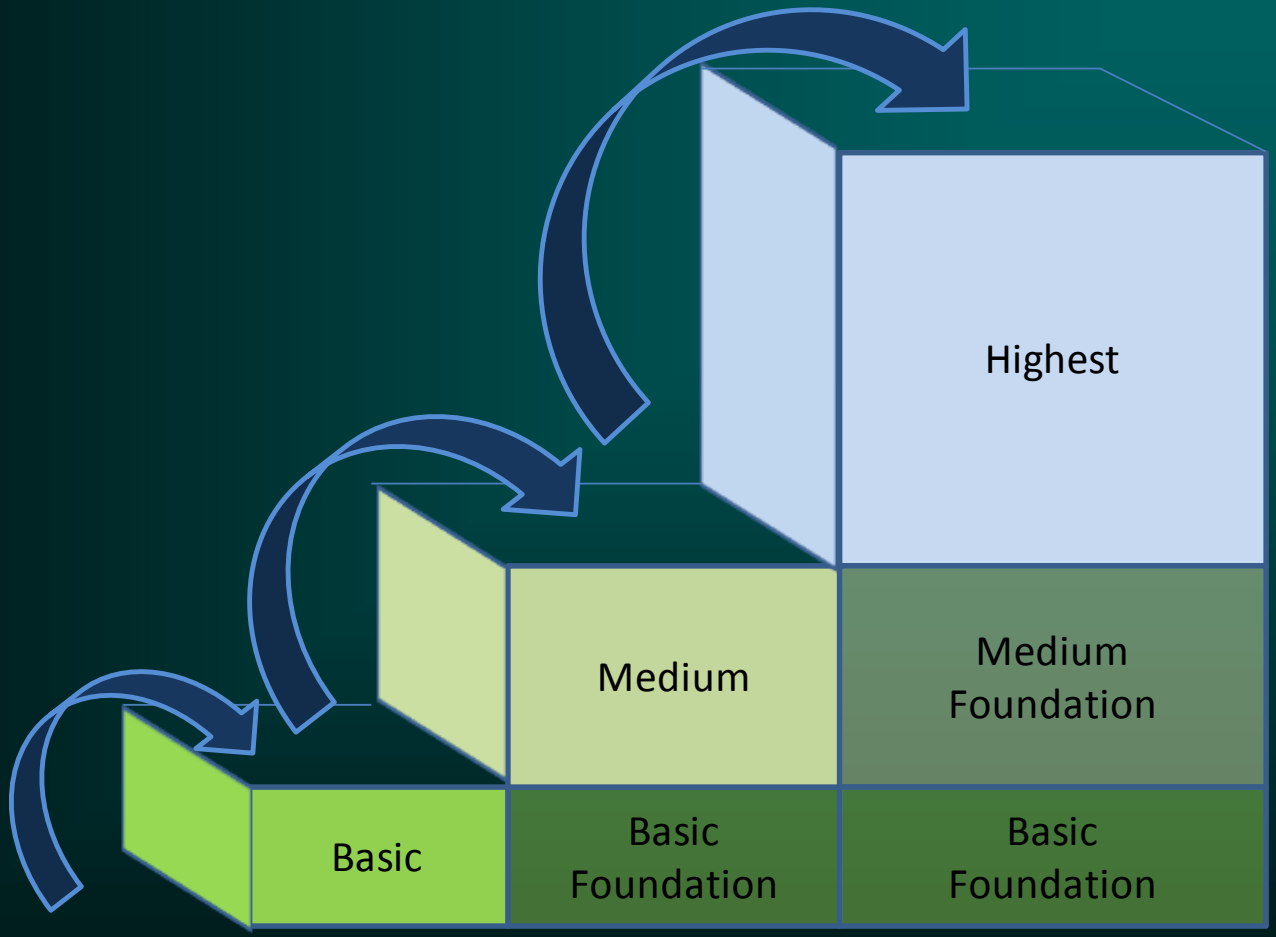
What follows?



Converge on all elements of models?



Different levels of regulatory control



Source: GHTF: *GHTF Regulatory Model*; GHTF/AHWG-GRM/N1R13; 2011

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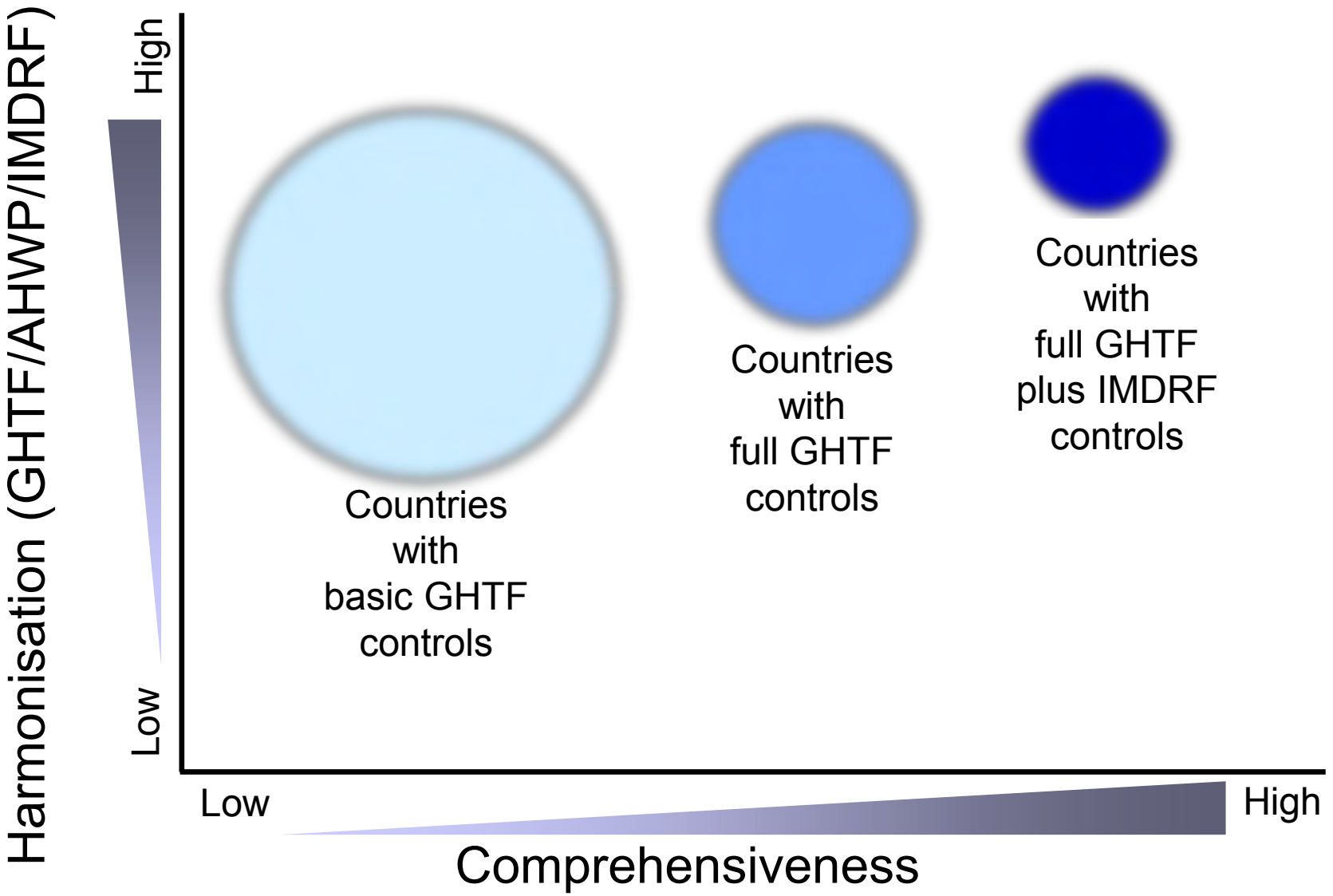

What next?

- Who is the intended user of GHTF guidance and IMDRF work products?
- Who will develop guidance for less developed regulatory systems?
- How will implementation of guidance be supported in less developed regulatory systems?
- How will harmonisation forums be coordinated?
- Is there a need for ‘good harmonisation practices’?

Vision of “success”

Are there measurable public health gains?

"… one of the biggest challenges today is to make scientific innovation improve the lives of the poorest"

-- Bill Gates, Philanthropist

Source: *Landscape analysis: of barriers to developing or adapting technologies for global health purposes;* Global Initiative on Health Technologies; Department of Essential Health Technologies; World Health Organization, Geneva; 2010