Trinity College Dublin
Coláiste na Tríonóide, Baile Átha Cliath
The University of Dublin

The emerging specialty of regulatory science

CORE-MD webinar

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Agenda

So what is regulatory science?

Regulatory science and medical devices

Future directions

So what is regulatory science?

regulation

/ˌrɛgjʊˈleɪʃn/

noun

a rule or directive made and maintained by an authority.

Ref. Oxford languages definition

science

/ˈsʌɪəns/

noun

the systematic study of the structure and behaviour of the physical and natural world through observation, experimentation, and the testing of theories against the evidence obtained.

DALL-E search for 'regulation' and 'science'

US FDA description

Regulatory Science is the science of developing new tools, standards, and approaches to assess the safety, efficacy, quality, and performance of all FDA-regulated products.

Ref. *https://www.fda.gov/science-research/science-and-research-special-topics/advancing-regulatory-science*

Regulatory science and Public Health

"Regulatory science (RS)" is the science of developing **methods** to quantitatively and/or qualitatively **analyze and understand** the causal relations and mechanisms of the **substances and the phenomena around us**, and measuring their positive and negative effects. Their efficacy and safety are appropriately predicted, evaluated and judged using the methods developed and the results obtained in the RS, finally **contributing to public health**.

Ref. Division of Regulatory Sciences, The Pharmaceutical Society of Japan - What's Regulatory Science
https://www.nihs.go.jp/dec/rs_en/whats_rs.html

Regulatory science as a subset of translational science

- **Translational science** is the application of the scientific method to address a health need.

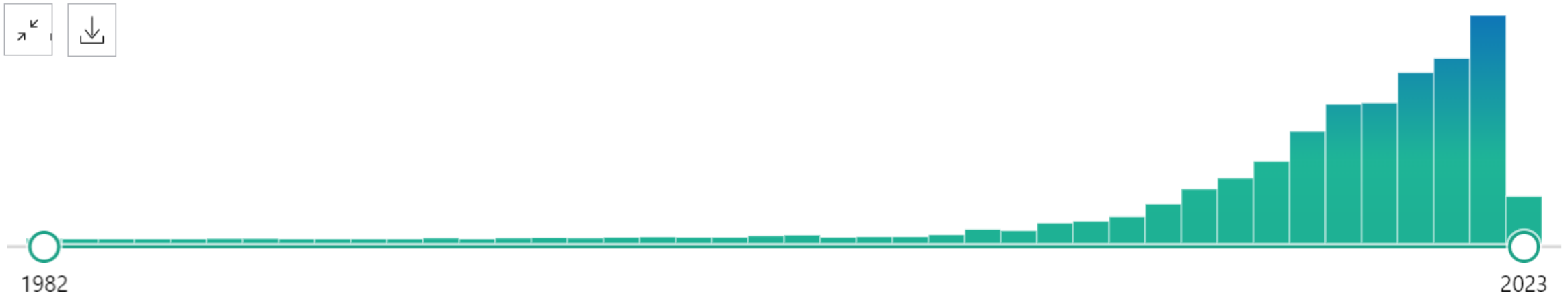
- **Regulatory science** is the application of the **scientific method** to improve the **development**, **review**, and **oversight** of new drugs, biologics, and devices that require regulatory approval prior to dissemination.

Institute of Medicine (US). Strengthening a Workforce for Innovative Regulatory Science in Therapeutics Development: Workshop Summary. Washington (DC): National Academies Press (US); 2012. 3, Defining a Discipline of Regulatory Science and Core Competencies for Its Workforce. Available from: https://www.ncbi.nlm.nih.gov/books/NBK92887/

‘Regulatory science’ versus ‘regulatory affairs’

"Regulatory science" is contrasted with regulatory affairs and regulatory law, which refer to the administrative or legal aspects of regulation, in that the former is focused on the regulations' *scientific* underpinnings and concerns – rather than the regulations' promulgation, implementation, compliance, or enforcement.[*citation needed*]

https://en.wikipedia.org/wiki/Regulatory_science



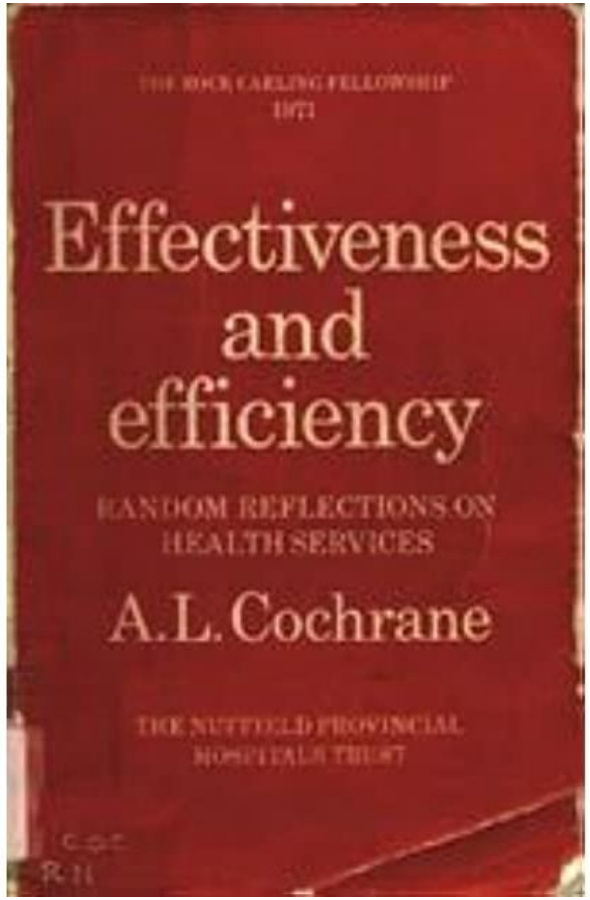
Pubmed search for "regulatory science"

Regulatory science – where science and politics collide

Policymaking is the process of setting goals for the public good and implementing strategies to attain them. Every public policy is the outcome of an **institutional** decision. Public institutions, such as regulatory agencies or state courts, are themselves **creatures of the political process**.

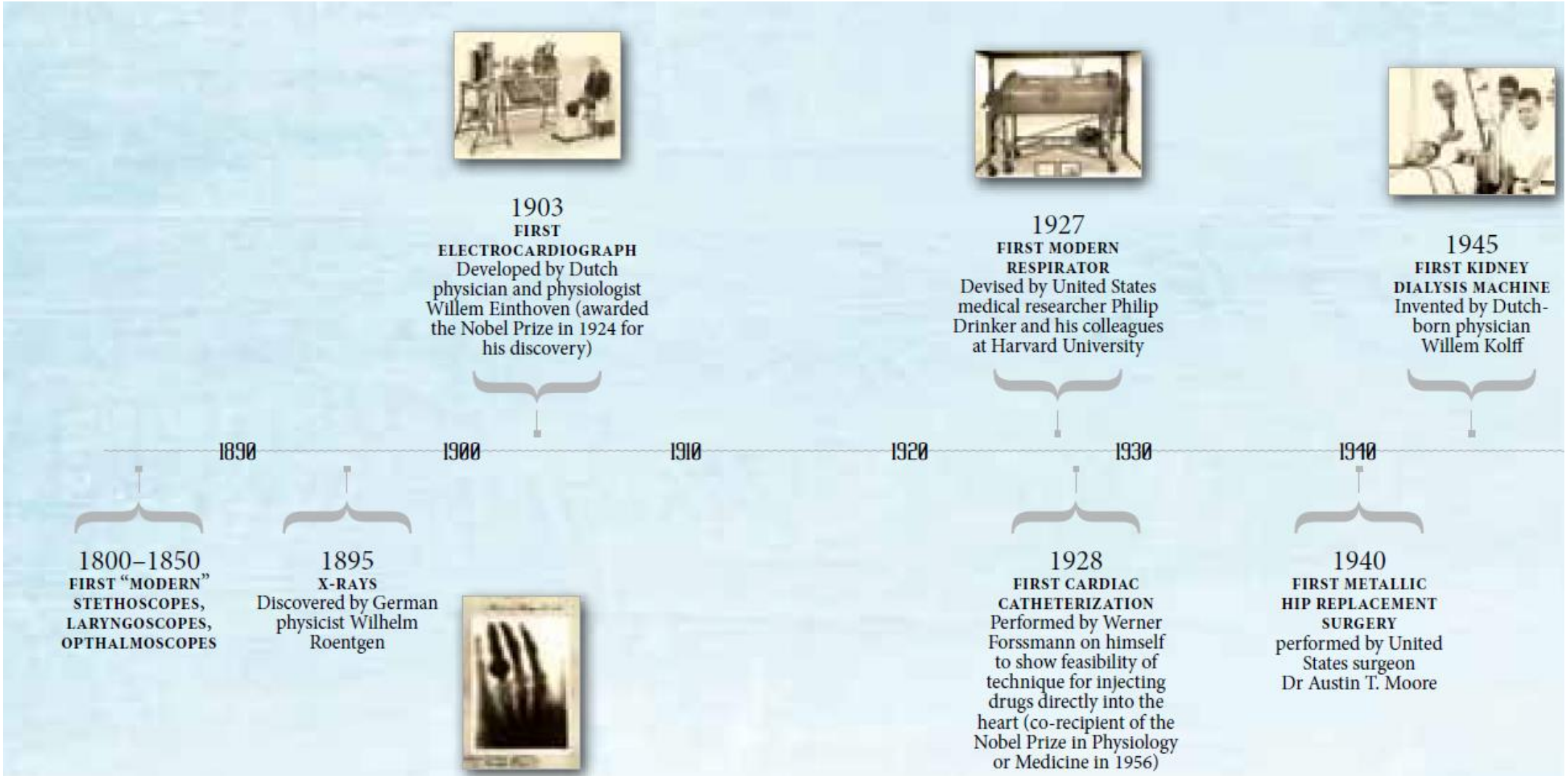
Managing the Medical Arms Race. Public Policy and Medical Device Innovation. Susan Bartlett Foote

The ‘crisis’ model of regulatory development

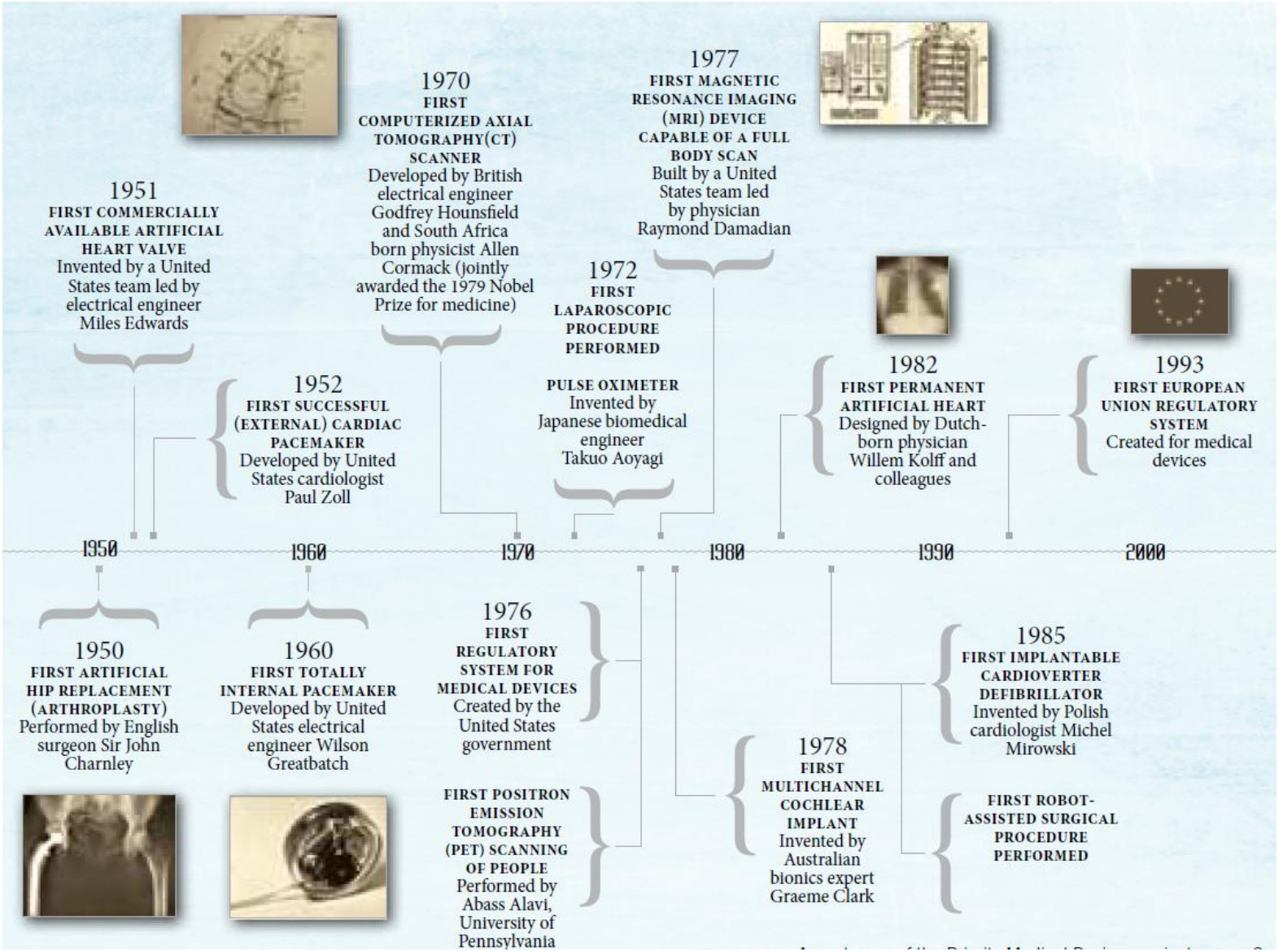


"One should … be delightfully surprised when any treatment at all is effective, and always assume that a treatment is ineffective unless there is evidence to the contrary."

Regulatory science and medical devices



World Health Organisation, MEDICAL DEVICES: MANAGING THE Mismatch - An outcome of the Priority Medical Devices project, 2010



World Health Organisation, MEDICAL DEVICES: MANAGING THE Mismatch - An outcome of the Priority Medical Devices project, 2010

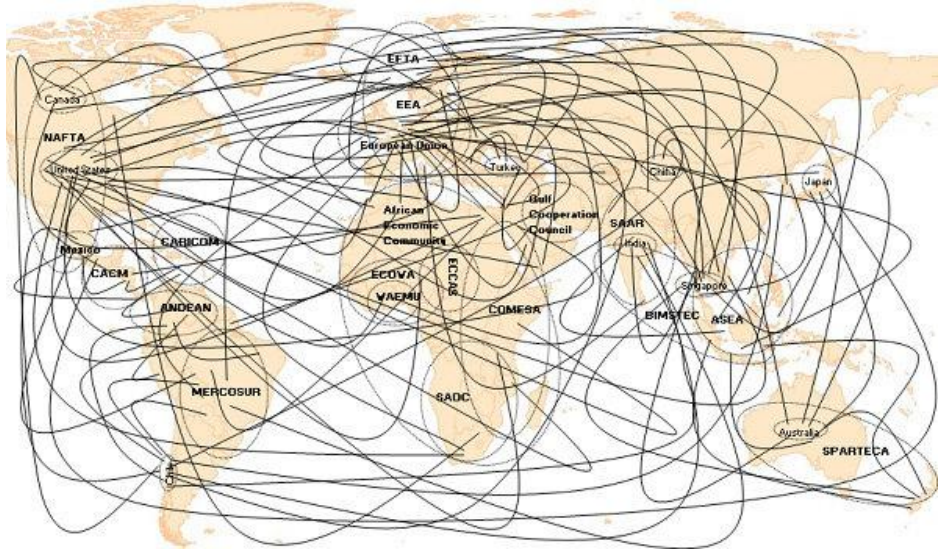
Technical barriers to trade and the Directives in Europe

The Commission then decided to re-constitute the Pacemaker Working Group as the '**Working Group on the Reduction of Technical Barriers to Trade in the Field of Electromedical Equipment**.' The IAPM modified its draft Directive as required by the Commission and presented it to the Working Group on 28 September 1987. The Commission then took over the work and circulated its own draft for the first time in January 1988.

Medical Device Safety, The Regulation of Medical Devices for Public Health and Safety, Gordon R Higson, Institute of Physics Publishing, 2001, page 27

Preamble to Active Implantable Medical Device Directive 90/385/EEC

Whereas national provisions ensuring that safety level should be harmonized in order to ***guarantee the free movement*** *of active implantable medical devices* ***without lowering existing and justified levels of safety*** *in the Member States;*

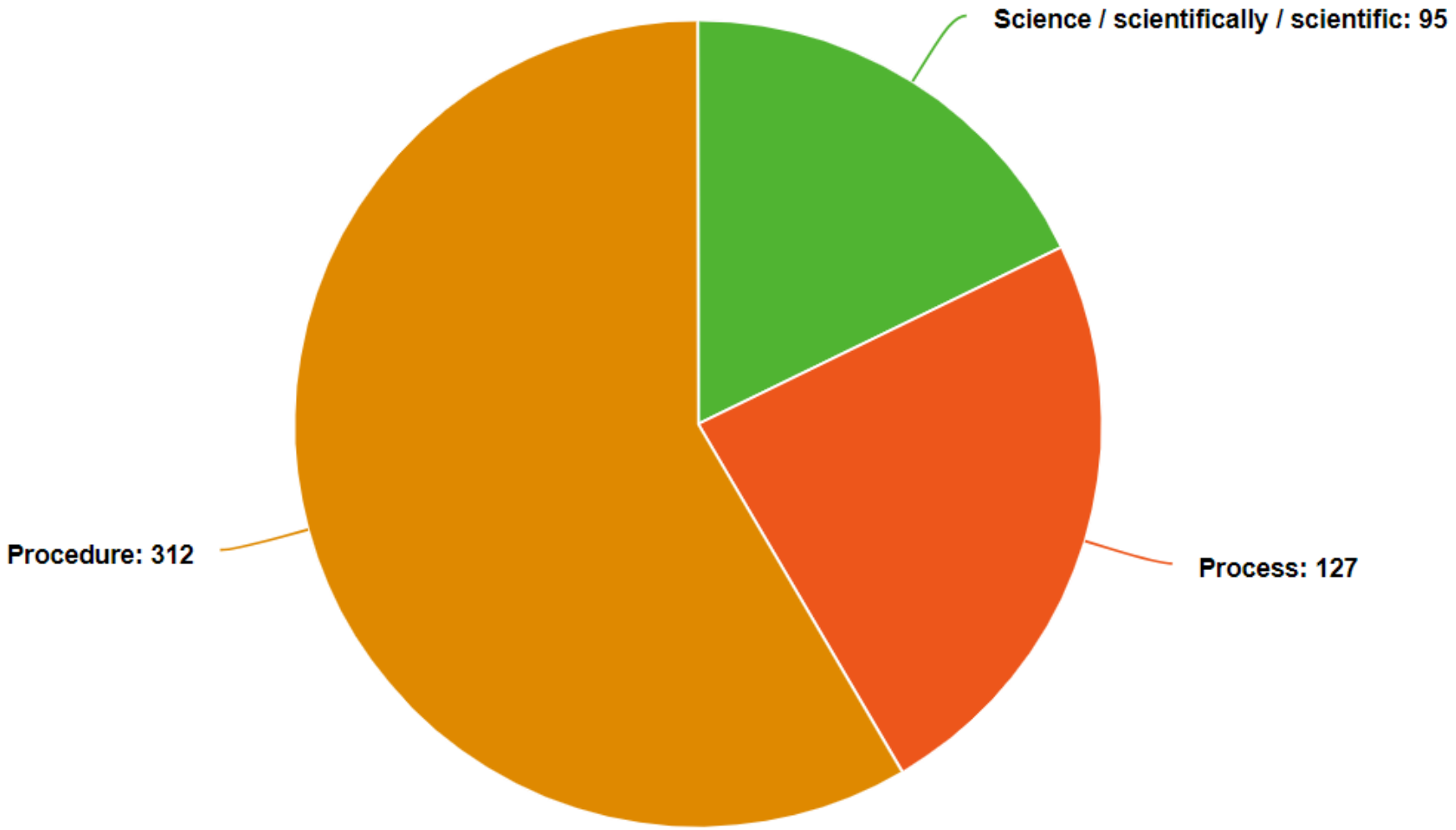


Lee, Sung & Park, Kun Soo & Seo, Yong. (2016). Multinational Firm's Production Decisions under Overlapping Free Trade Agreements: Rule of Origin Requirements and Environmental Regulation. Sustainability. 9. 42. 10.3390/su9010042.

Directive to Regulation

Same basic structure – still ‘new legislative framework’

Number of new processes / procedures


Science / scientifically / scientific: 95
Process: 127
Procedure: 312

Public health challenges and crises continue

Ongoing examples of significant safety issues which medical devices can present:

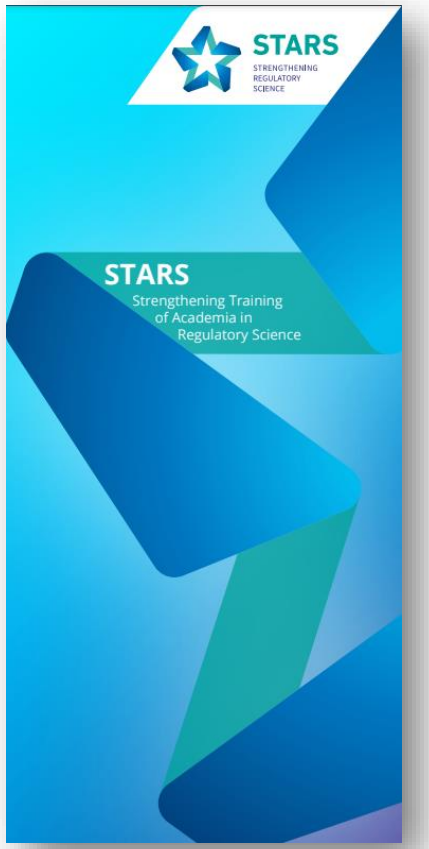
- Safety issues such as transvaginal mesh, BIA-ALCL etc. etc.
- The ‘implant file’ investigation of ICIJ

Regulation and the free market are a difficult fit

Furthermore, efforts to fix flailing competition-based policies have required armies of health regulators, reams of regulation, and seemingly endless evaluation and adjustment by technocratic experts—to no avail. Behavioural economics-inspired attempts **to educate and nudge** participants to better results fall short, despite significant investments of time and money into these efforts. The result is a **market-lubricating regulatory scaffold**—a **bureaucracy as vulnerable to capture and at least as large** as what more direct regulatory approaches would likely produce.

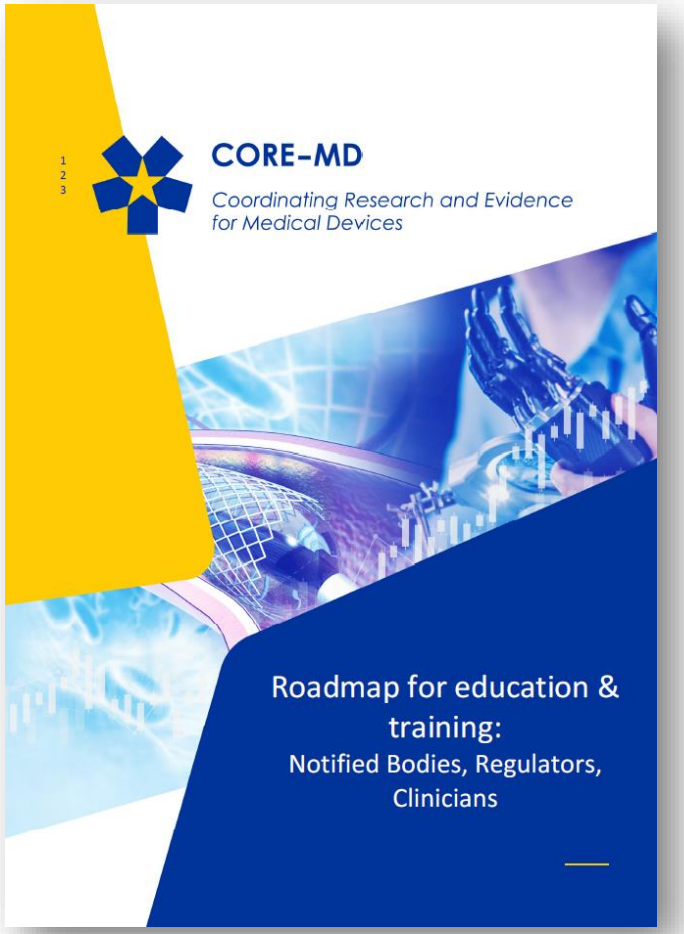
U.C.L.A. Law Review Health Care's Market Bureaucracy Allison K. Hoffman 66 UCLA L. Rev. 1926 (2019)

Future directions



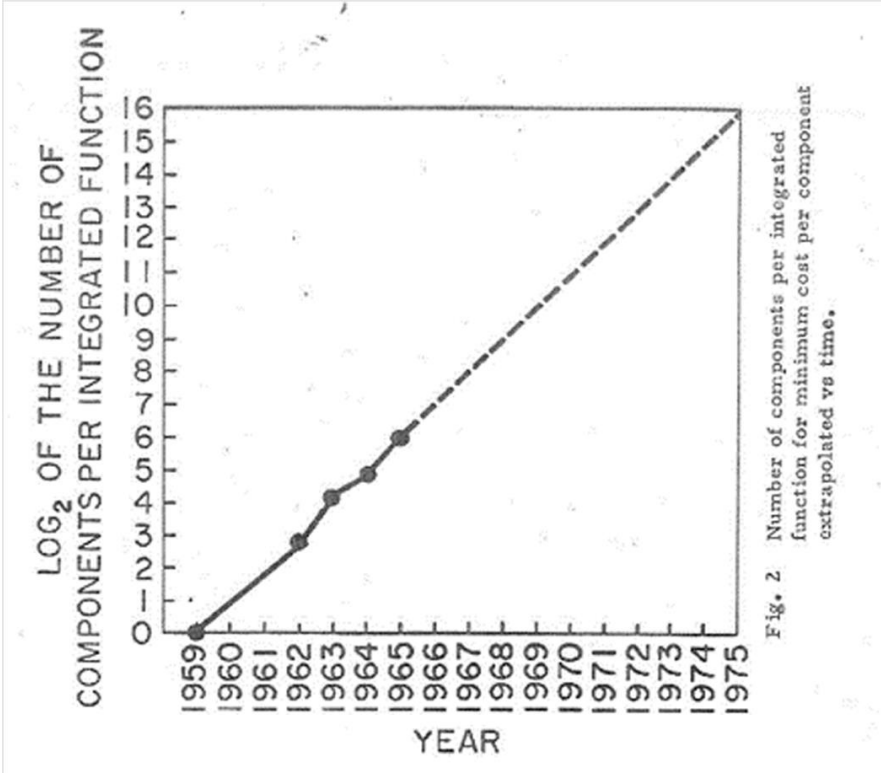
STARS is a coordination and support action (CSA) that has been granted for funding through the EU Framework Program for Research and Innovation ‘Horizon 2020’ under grant agreement no [825881].

CORE-MD project to support curriculum development

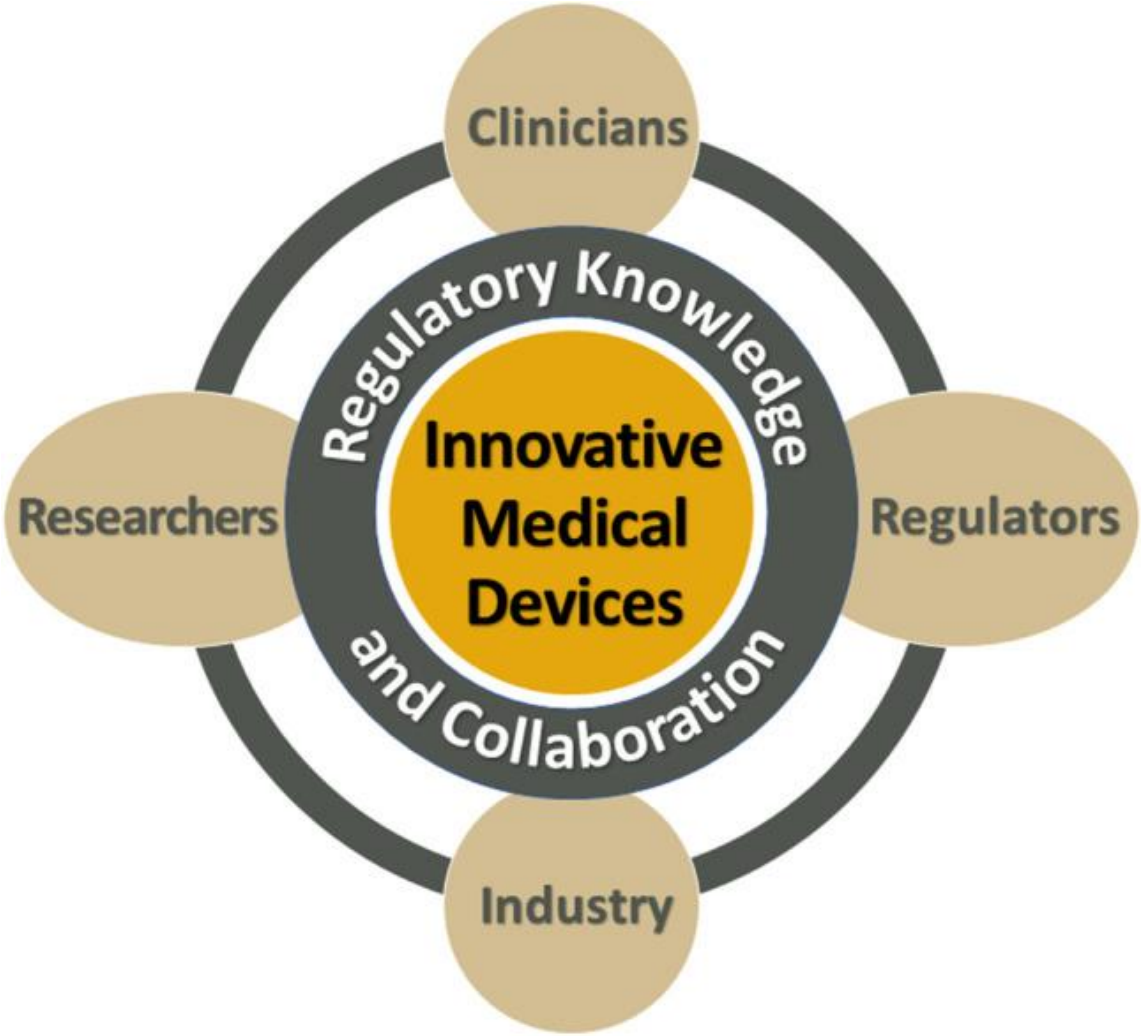


To identify the training needs of all stakeholders to enhance their expertise in methodologies for the assessment of high-risk medical devices, and develop appropriate educational objectives

Innovation and the pace of technological advancement



Ref. G.E. Moore, "Cramming more components onto integrated circuits, Reprinted from Electronics, volume 38, number 8, April 19, 1965, pp.114 ff.," in IEEE Solid-State Circuits Society Newsletter, vol. 11, no. 3, pp. 33-35



Lottes AE, Cavanaugh KJ, Chan YY, Devlin VJ, Goergen CJ, Jean R, Linnes JC, Malone M, Peat R, Reuter DG, Taylor K, Wodicka GR. Navigating the Regulatory Pathway for Medical Devices-a Conversation with the FDA, Clinicians, Researchers, and Industry Experts. J Cardiovasc Transl Res. 2022 Oct;15(5):927-943.

How might we foster regulatory science in Europe?

Better rule preparation

People who need to comply with rules part of development

Stronger institutions who work transparently

We look for medicine to be an orderly field of knowledge and procedure. But it is not. It is an imperfect science, an enterprise of constantly changing knowledge, uncertain information, fallible individuals, and at the same time lives on the line.

Atul Gawande (2002), Complications: A Surgeon's Notes on an Imperfect Science

Life is short, the art long, opportunity fleeting, experience treacherous and judgement difficult

Hippocrates

Thank you