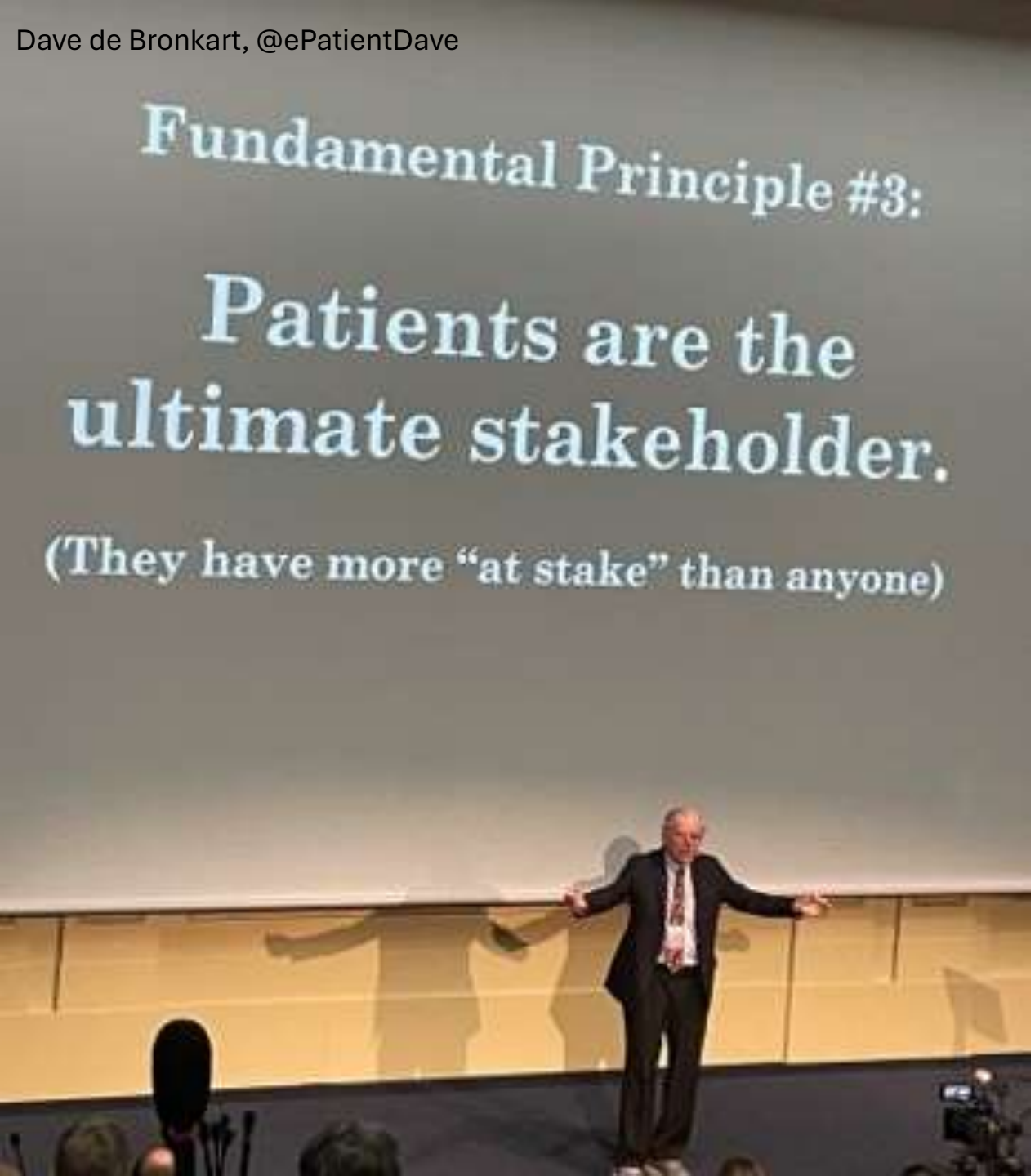
ESC Patient Forum

A patient's perspective on accelerated approval pathways

Inga Drossart, ESC Patient Forum

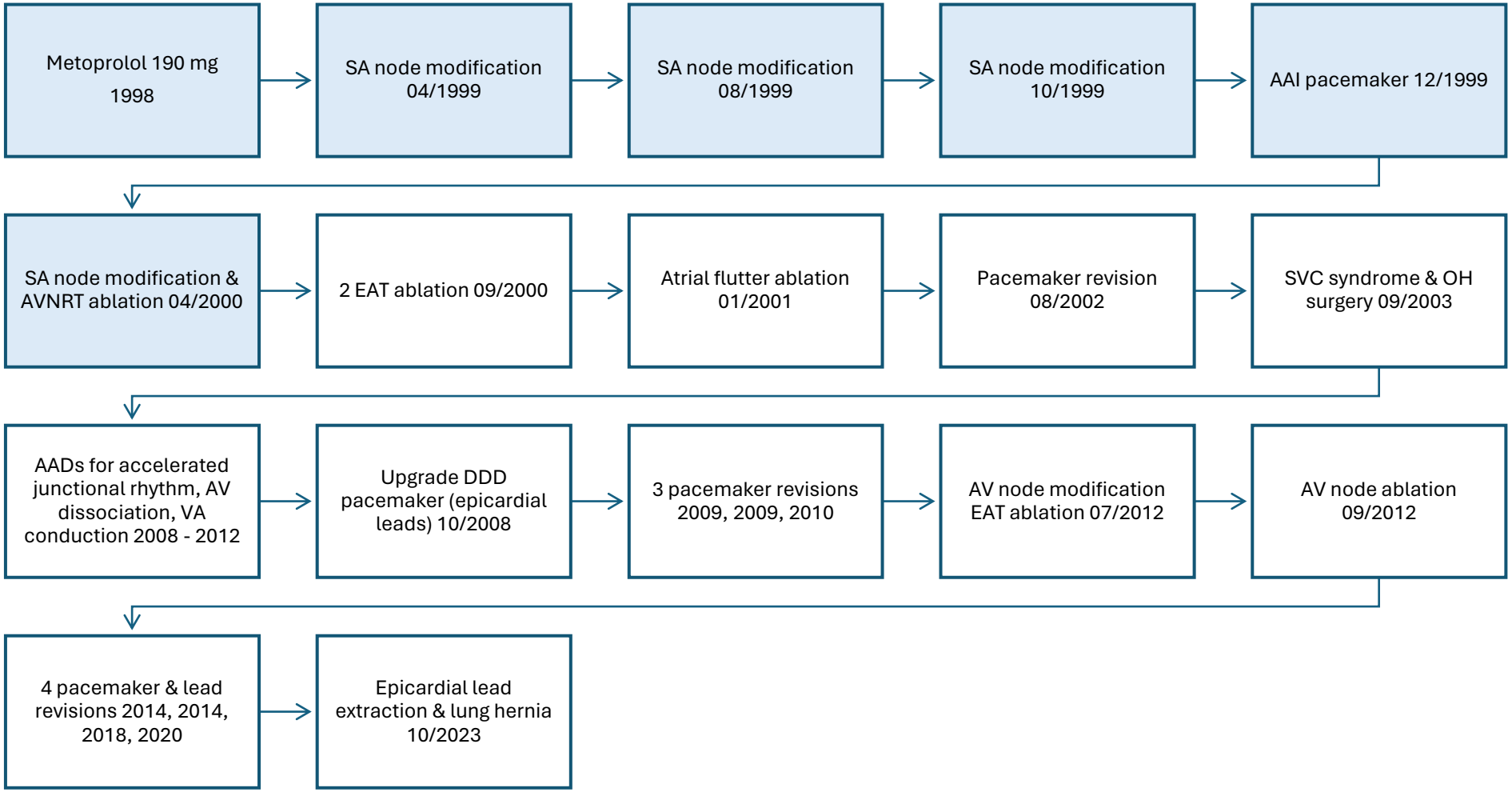
CRT Plenary meeting "Priorities for the evolution of medical device regulatory approval systems", Brussels, April 17-18, 2024

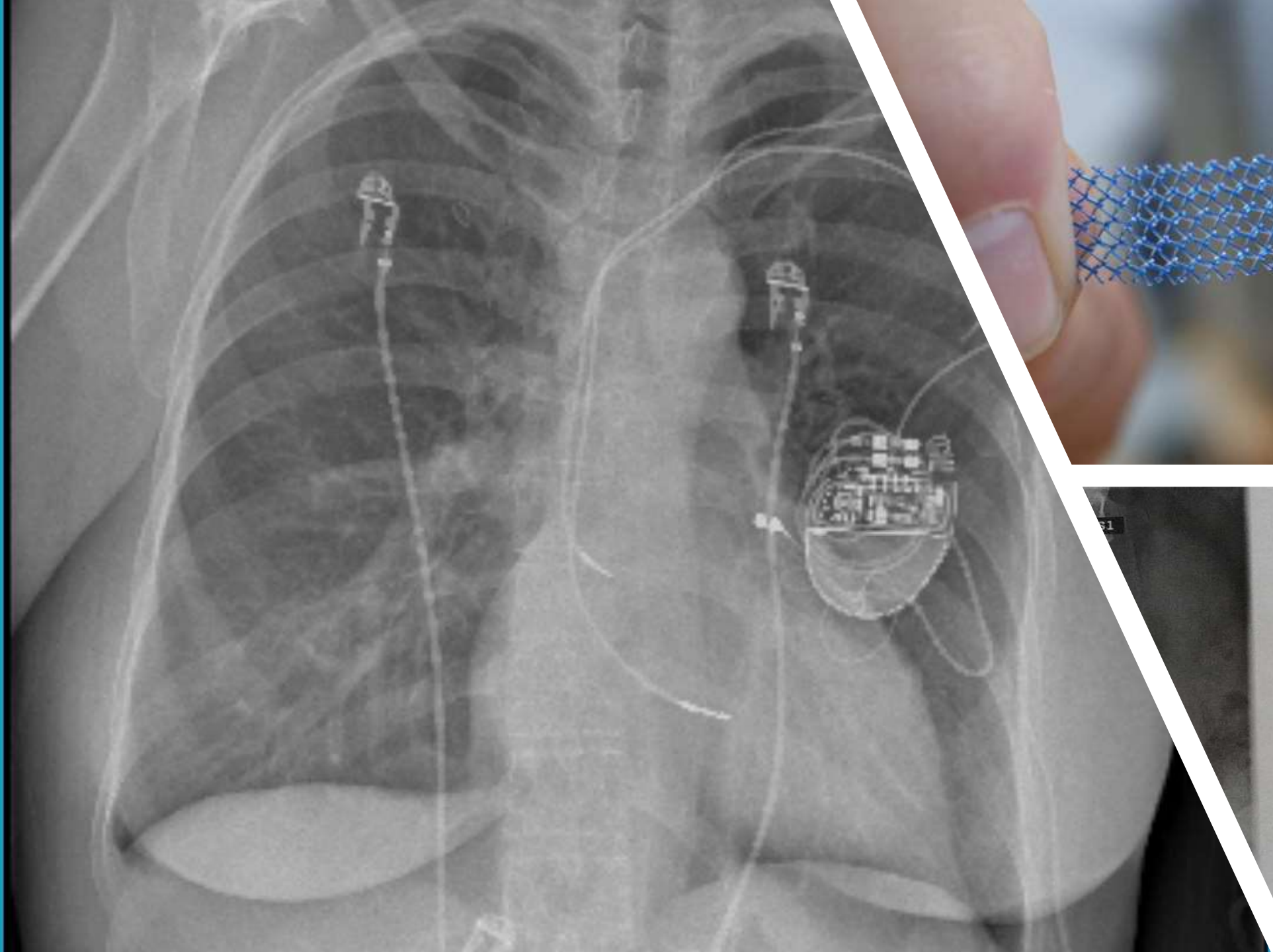
Alan G Fraser and others, Imp nsibilities for evidence-based practice: a report from the Regulatory Affairs Committee of the European Society of Cardiology, European Heart Journal, Volume 41, Issue 27, 14 July 2020, Pages 2589–2596, https://doi.org/10.1093/eurheartj/ehaa382

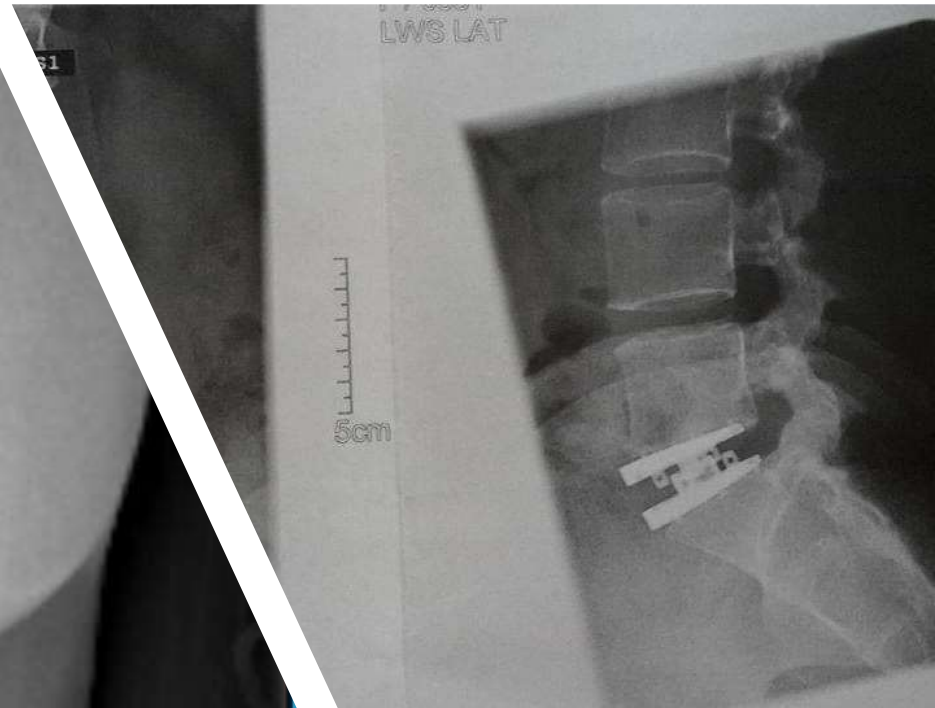


Therefore, I must engage - and you with me!

Inappropriate sinus tachycardia – an unmet medical need






LWS LAT
5cm

UK firm sold spinal implants that disintegrated

Plastic discs that also moved in some patients were only tested on 30 people in six months

Many patients who
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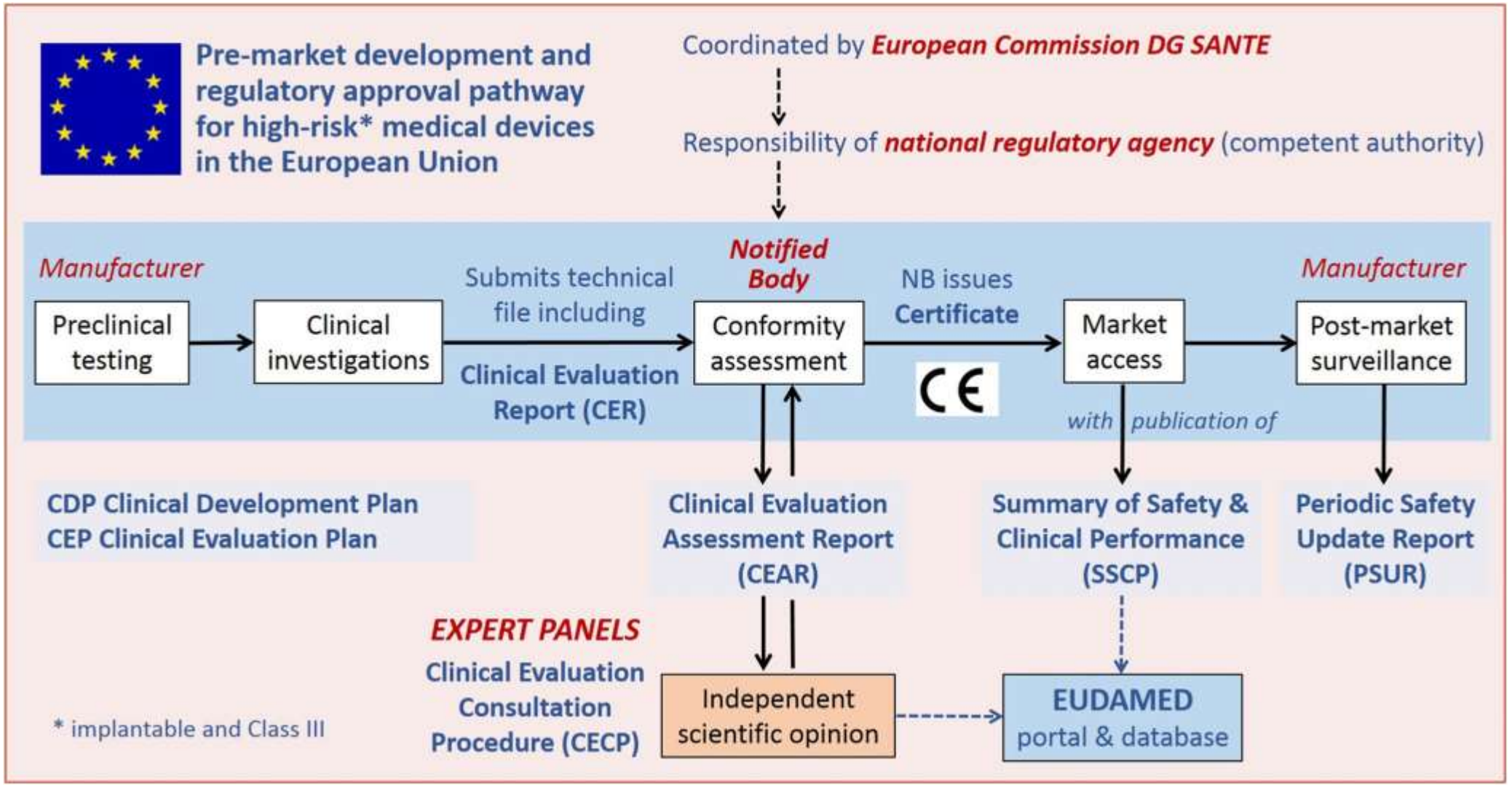


Alan G Fraser et al., Implementing the new European Regulations on medical devices—clinical responsibilities for evidence-based practice: a report from the Regulatory Affairs Committee of the European Society of Cardiology, European Heart Journal, Volume 41, Issue 27, 14 July 2020, Pages 2589–2596, https://doi.org/10.1093/eurheartj/ehaa382

→ REASSURANCE

Safety is important.

Efficacy matters, I want to get better!

What about **reimbursement**?

Trials or **off-label use** are also an option for patients.

I want to benefit from **innovation**.

Fast access to new technology when I need it.

It's not well tested, but **maybe I want to take the risk**? Depends on my situation …

Definitions?

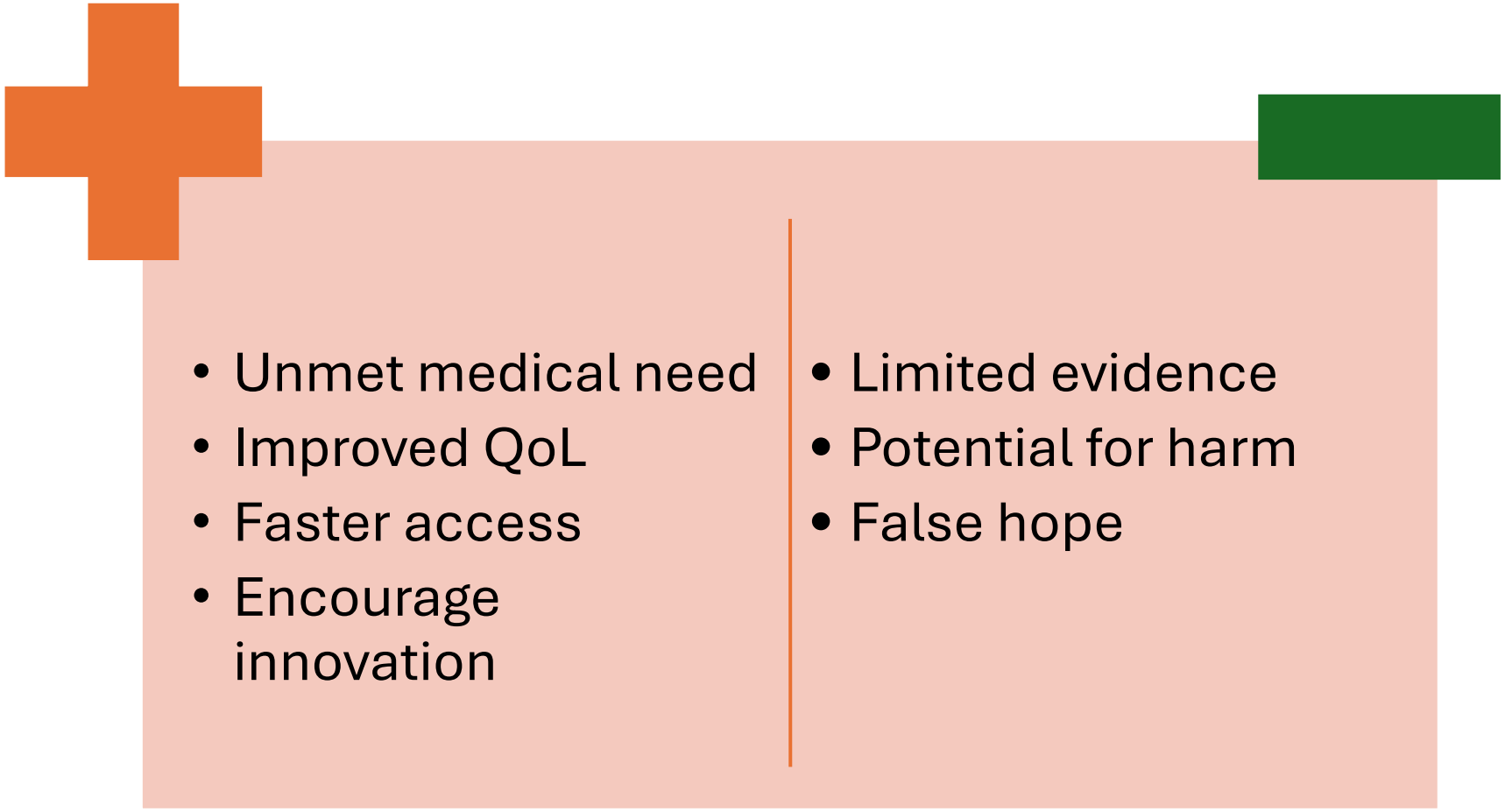
Safety & performance standards?

Who is involved in review & approval?

Criteria	Description	Refer to Guidance
First Criterion	The device provides for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human disease or conditions	Section III.B.1
Second Criterion		
	a. Represents Breakthrough Technology	Section III.B.2.a
	b. No Approved or Cleared Alternatives Exist	Section III.B.2.b
	c. Offers Significant Advantages over Existing Approved or Cleared Alternatives	Section III.B.2.c
	d. Device Availability is in the Best Interest of Patients	Section III.B.2.d

FDA criteria for breakthrough devices.

Accelerated approval pathways - summary



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Thank you very much!

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