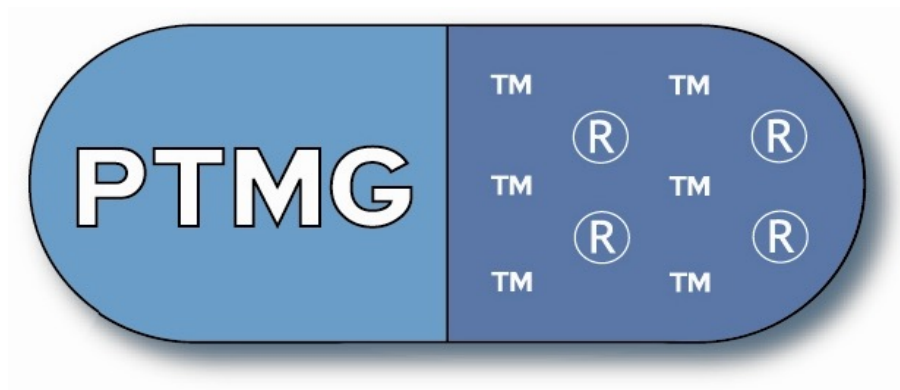




John Wilkinson
OBE

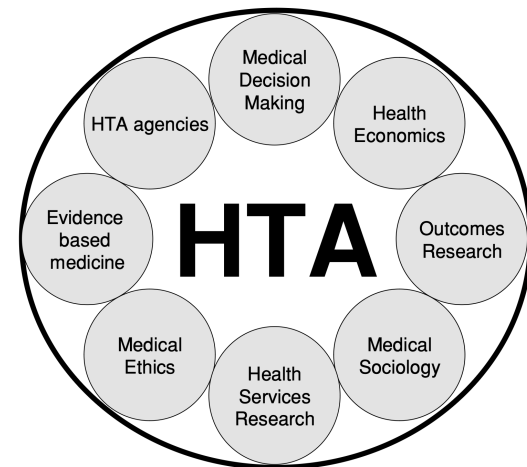
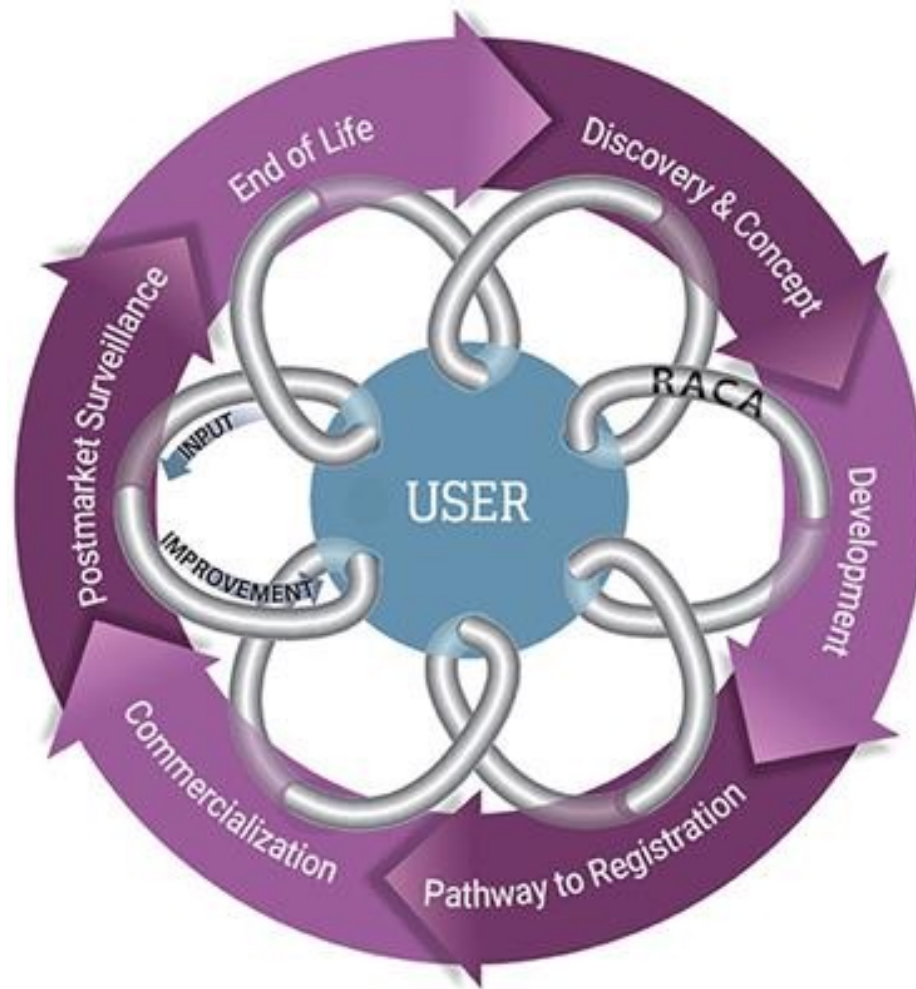
Technological convergence and data-science challenge traditional regulatory thinking

John Wilkinson
PTMG – October 2026

- Some observations on the evolving role of regulatory affairs
- Medicines and devices culture gulf
- Combination products and combinations of products and a changing risk management environment
- Structural and cultural change







PRESCRIPTION ONLY MEDICINE
KEEP OUT OF REACH OF CHILDREN

SafeSystem™

Zoladex® 10.8mg

goserelin

Equivalent to 10.8 mg goserelin (as the acetate)
Contains one sustained release implant in
a prefilled injection applicator.
For subcutaneous injection. 3-month.

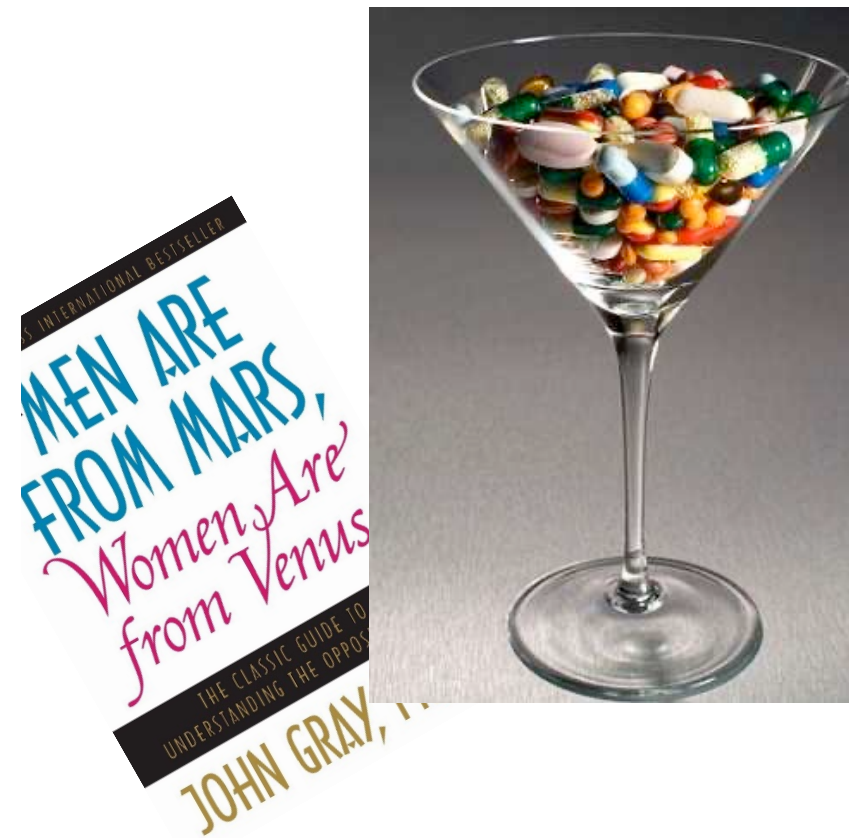
The SafeSystem™ incorporates a protective needle
sleeve that automatically locks in place following
administration of the implant to aid in the prevention
of needle stick injury.

AUST R 55242
Reorder 02376

AstraZeneca 



MEDICINES ARE FROM MARS



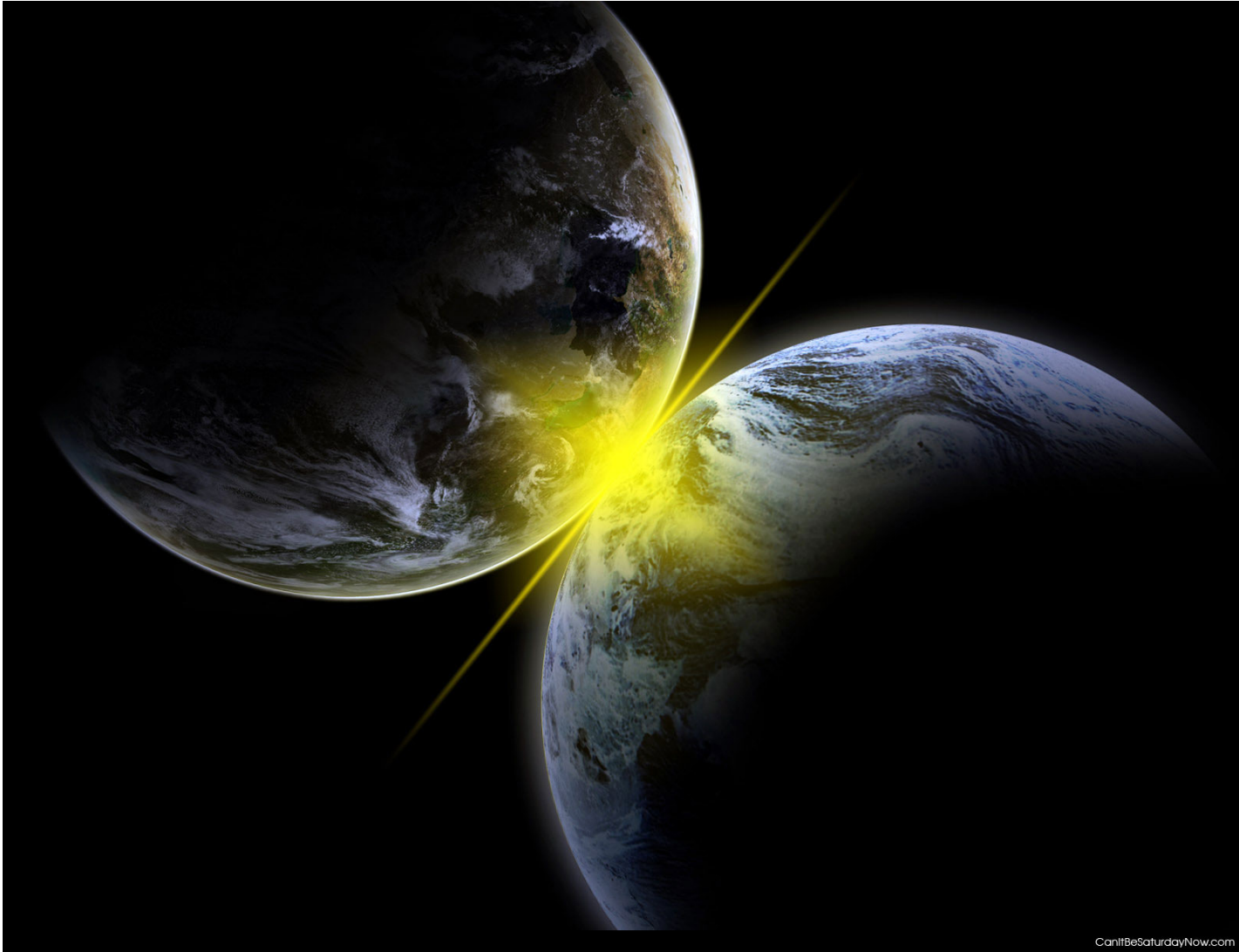
Devices Are from Venus





- 2008 re-cast of Medical Device Directives
- 2012 PIP
- 2014 Metal-on-metal
- 2016 Mesh
- 2017 Medical Device Regulation
- 2026 Review (before implementation complete)

- Most devices cannot be evaluated with randomised clinical trials as it is hard to blind and randomise devices due to strong ethical and practical issues in the choice of the 'comparator' (e.g. what would have been a comparator for an implantable cardiac defibrillator? How would one implant a placebo hip?).
- Device impact depends heavily on clinician training and experience, patient selection and the care delivery setting. This varies per doctor, hospital and country and is thus nearly impossible to predict with any precision. We therefore believe that 'real world' data from observational studies performed under routine conditions are equally important (structured post market surveillance).



Pharmacologists
and pharmacists

Mechanical and
electrical
engineers

Clinical
specialists

Materials
scientists

Toxicologists

Epidemiologists

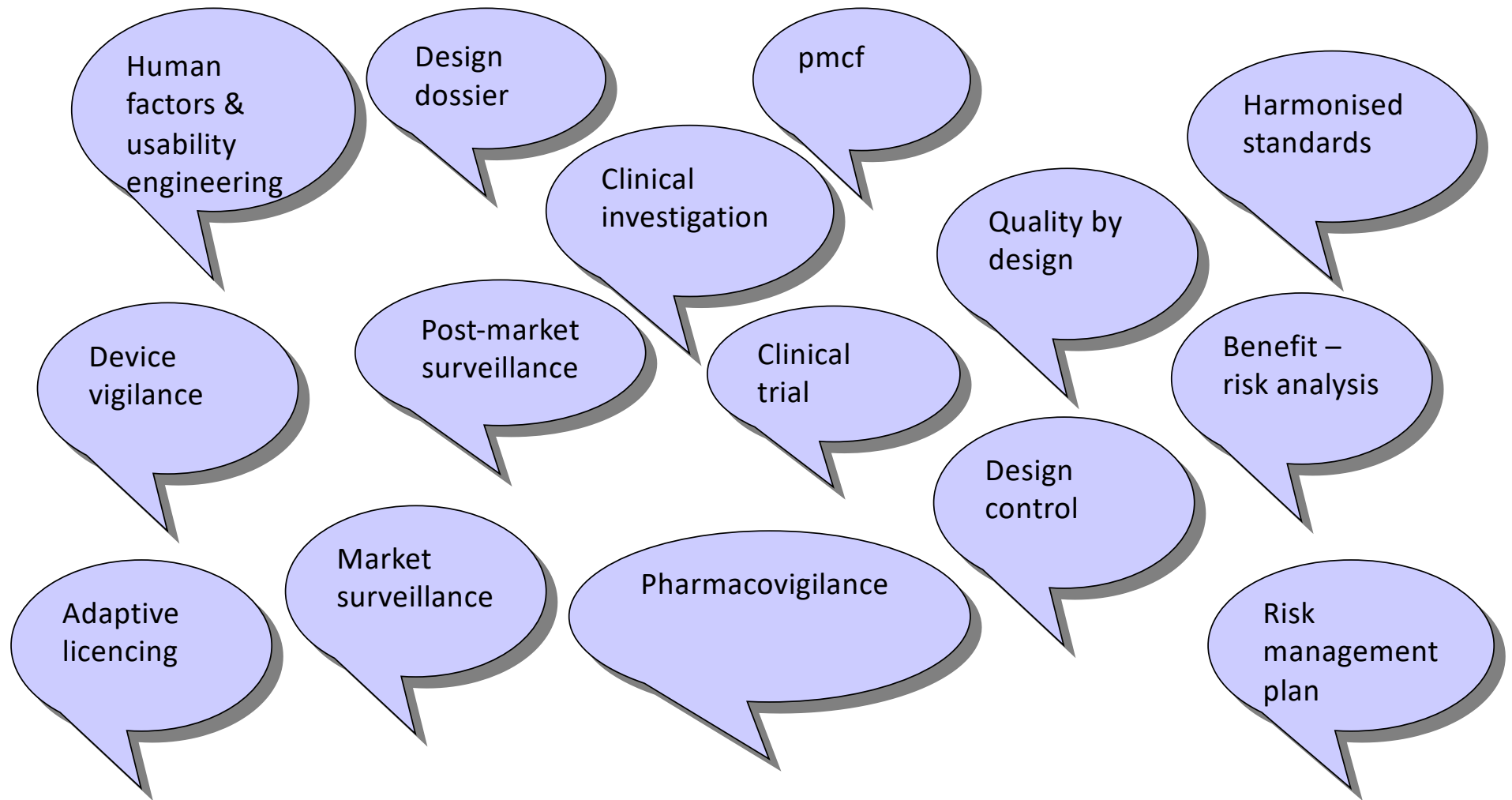
Statisticians

Data scientists

Software
engineers

Biological
safety experts

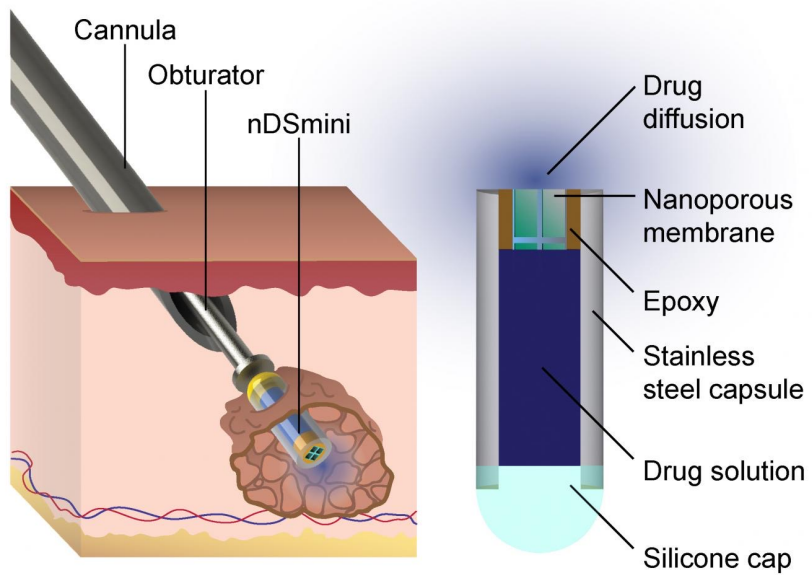
Laboratory
scientists



	Pharma	Devices	Software
Global Market estimate 2025	\$1,738bn*	\$580bn**	\$70bn***
Potential failure modes	Few	Many	Very many
User variability	Some	Lots	?



- * Includes 250bn+ of drug-device combination products
- ** Includes 5-10bn of software as a medical device
- *** Some regulated, much may be 'medical device'



Core challenges

- Combination products are the ‘canary in the mine’ for future challenges
- Complex combination products and combinations of products can only be managed by multidisciplinary teams
- Devices, medicines and software people need to come together as equals to develop innovative ways to risk-manage products that are here and will be more prevalent in the future
- For this to happen culture, structure and process all need to change

When things go wrong?



When things go wrong?

- Device, drug or software?
- Or clinician?
- Or patient selection?
- Or information provided by clinical software?
- Or software implementation failure?
- Or drug interactions?
- Or infrastructure failure?
- Or, or, or.....

When things go wrong?

- Multi-disciplinary approach
- Requires multi-disciplinary teams
- Parking binary solution mindset

These apply to clinical setting, industrial setting and regulators of all sorts.

Proactive role of data science

From:

- Adverse event reporting
- Disconnected data sets using different standards
- Extensive trails and evolution of understanding
- Use of established regulatory tools for software products

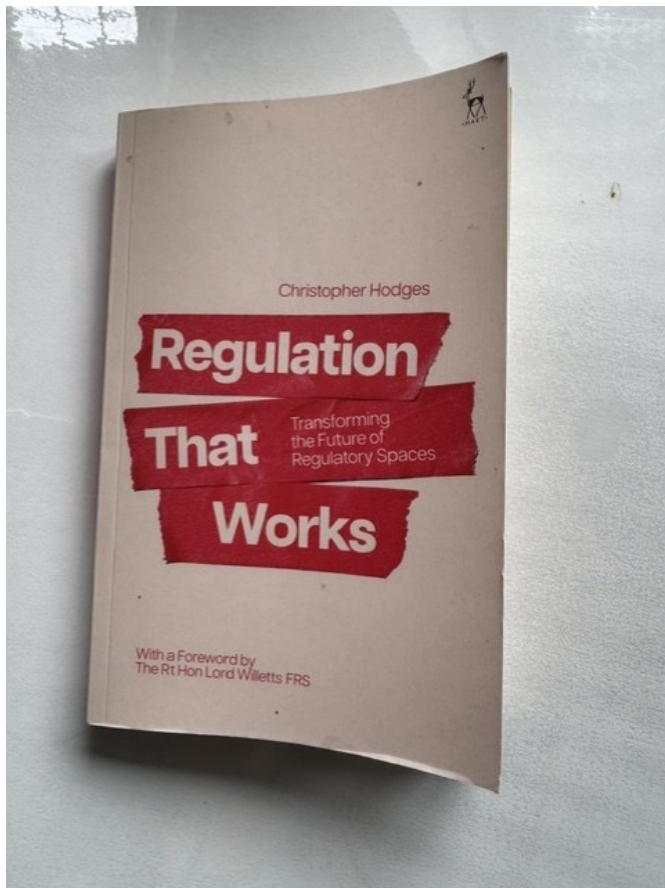
To:

- Outlier identification and analysis
- Comparable data sets using common standards
- In-silico modelling to reduce uncertainty and risk (both to patients and financially)
- Development of new suit of risk management tools for software

My vision for regulatory affairs of the future!

- Greater technological convergence and overlap, requiring integrated deployment of specialists
- Cross-specialist collaboration rather than silo working
- Transparency and shared goals with stakeholders (OBCR)
- Advanced data science capability and insight-driven decision making
- Collaboration and alignment between regulatory and health technology assessment (HTA) data
- Regulatory leadership equipped to drive partnerships, agility and trust

Outcome-based Collaborative Regulation



Christopher Hodges

Emeritus Professor of Justice Systems,
University of Oxford and Chair of HM
Government's Regulatory Horizons
Council

Demanding of new leadership





**THANKS
FOR
LISTENING**

Discussion & Questions



Recent articles:

[The future of regulatory affairs: Collaboration, data science and integrated expertise | Regulatory Rapporteur](#)

[Medical Device Regulation 2.0: Why stakeholder disagreement is bad for all | Regulatory Rapporteur](#)

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