Beyond Compliance

Nicole Small

element

“What do regulators want - how and when to communicate and engage?”

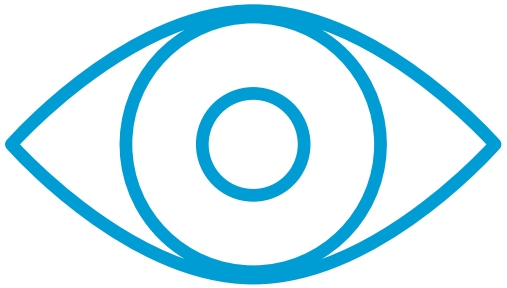
“What pathways are available to seek advice?”

Slido (Word Cloud)

element

Q: What stops you from seeking pre-submission advice/feedback from regulator(s)?

1. Didn’t know I could
2. Didn’t know costs involved
3. Go elsewhere - such as a consultant



- “Watchdog”
- “The police”
- “The enforcers”

Sharing the same common goal

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U.S. FOOD & DRUG ADMINISTRATION	Medicines & Healthcare products Regulatory Agency	HPRA	Australian Government Department of Health and Aged Care Therapeutic Goods Administration
Responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices	Ensure medicines, medical devices and blood components for transfusion meet applicable standards of safety, quality and efficacy (effectiveness)	We are committed to excellence in health product regulation through science, collaboration and innovation	Safeguards and enhances the health of the Australian community through effective and timely regulation of therapeutic goods

PRE-MARKET PHASE

Lessons learned

element

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MHRA - 2021
Common reason for the MHRA objecting to a clinical investigation is the failure of the manufacturer to supply the **necessary data within the statutory assessment time** period.

Year	Completed review	Withdrawn by applicants	Grounds for objection raised	Common reasons for objection
2019	58	6	15	Insufficient evidence provided to demonstrate the appropriate biological safety, clinical or technical effectiveness of the device or poor study design
2020	49	6	9	Insufficient evidence of biological safety, sterilisation and software testing
2021	71	8	12	Insufficient devices validation and sterilisation process qualifications, unclear CE marking status, missing evidence demonstrating the appropriate biological safety, clinical or technical effectiveness of the device or poor study design

40

FDA - 2021

- ❑ Pre-Notices of Noncompliance to encourage voluntary compliance with the ClinicalTrials.gov requirements:

- Failing to submit required clinical trial information
- Submitting false or misleading clinical trial information

30%

- ❑ 30% 510k submissions not accepted for initial review

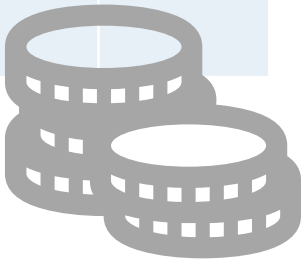
Source:
FDA Takes Action ClinicalTrials.Gov | FDA (MPs and MDs)
IDE Application | FDA
MHRA CI numbers (MD)

PRE-MARKET PHASE

Costs

Source:
MHRA Fees from April 2023 - Consultation Response (2022-2023)
Notify the MHRA about a clinical investigation for a medical device - GOV.UK (www.gov.uk)
HPRA fee application form for human products
BfArM fees

	MHRA*	HPRA	BfArM
Class IIb implantable or long-term invasive, Class III, and active implantable devices: **Notification**	£15,627	£4,300	Up to €6,130
Class IIb implantable or long-term invasive, Class III, and active implantable devices: Notification - **re-notification in the event of an objection**	£11,069	£1,900	-



Public wanting better health outcomes

£ priceless

PRE-MARKET PHASE

Pathways to engagement..

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FDA feedback and meetings – The Pre-submission Program

No fees

EMA – pilot expert panels' scientific advice (MDR) - prior to its clinical evaluation and/or investigation (MDR Article 61).

No fee (during pilot)

MHRA innovation office regulatory advice if you are developing a product which uses new or novel technology, materials, methods or approaches or manufacturing processes

No fee

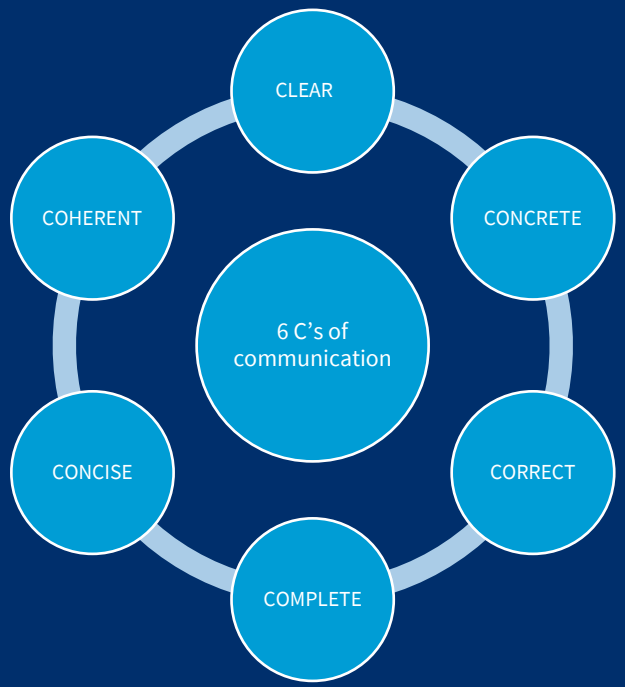
MHRA Consultation fees (new/optional): CI Regulatory advice: £906 / Statistical review: £782

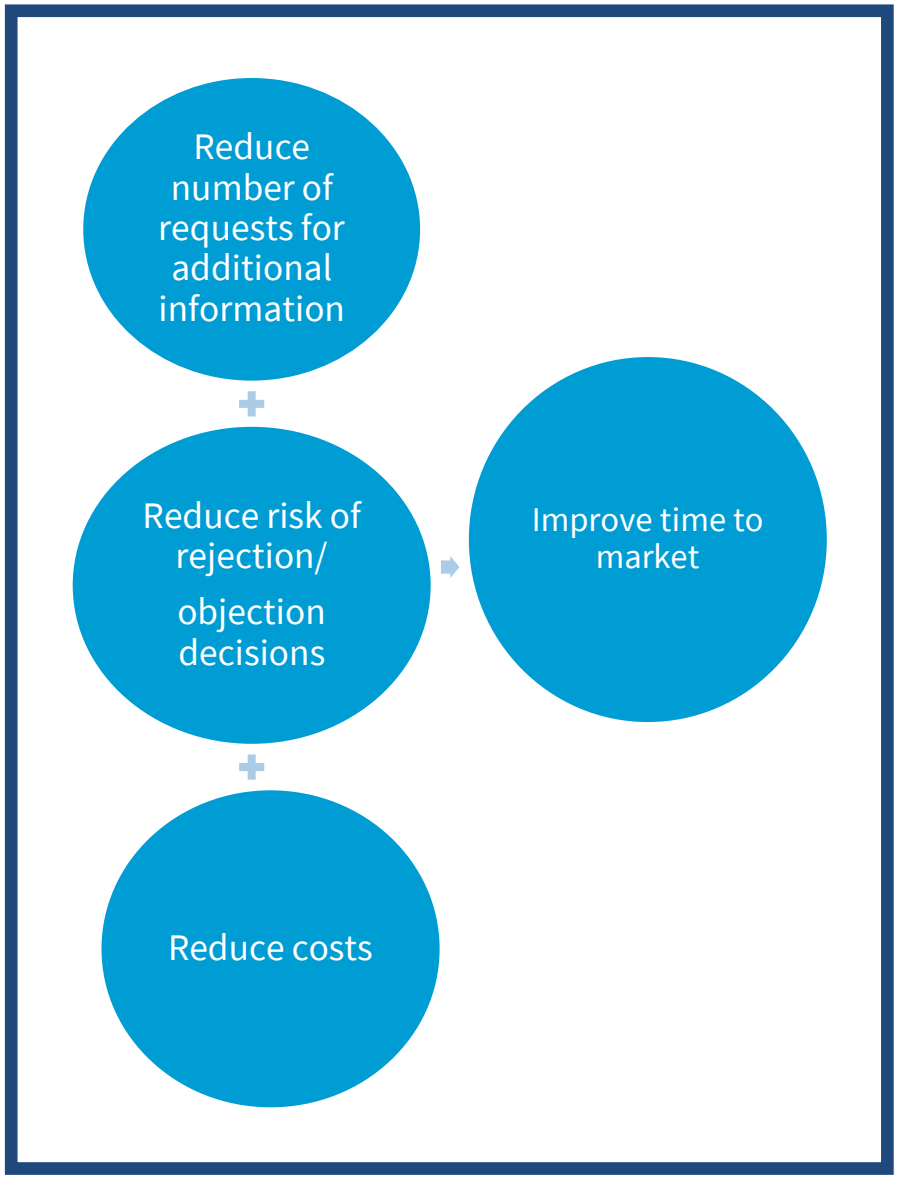
- ❑ **No cost**

Extensive guidance documents

- Notification
- Compiling submission
- Guidance for clinical investigators
- Statistical considerations
- Biological safety assessments

Effective communication and engagement





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- Review submission guidance – prepare,
- Hold structured dialogue expect lots of questions
- Challenge with credibility
- Submit documentation within statutory deadlines

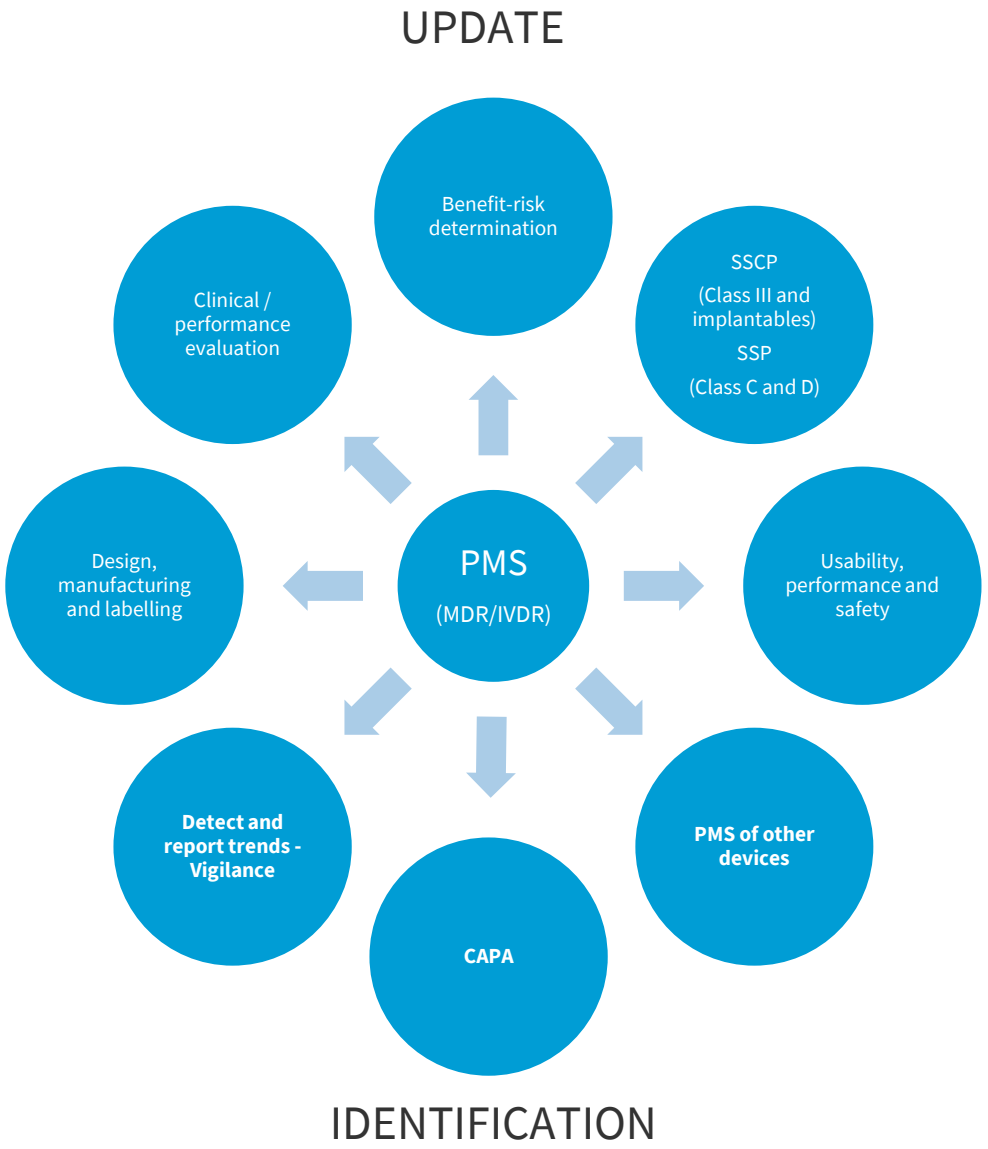
POST MARKET PHASE

Post-market surveillance

"

Is the device …

- produced as intended?
- performing as intended?
- compatible with state of the art?



POST MARKET PHASE

Field Safety Notices (UK)

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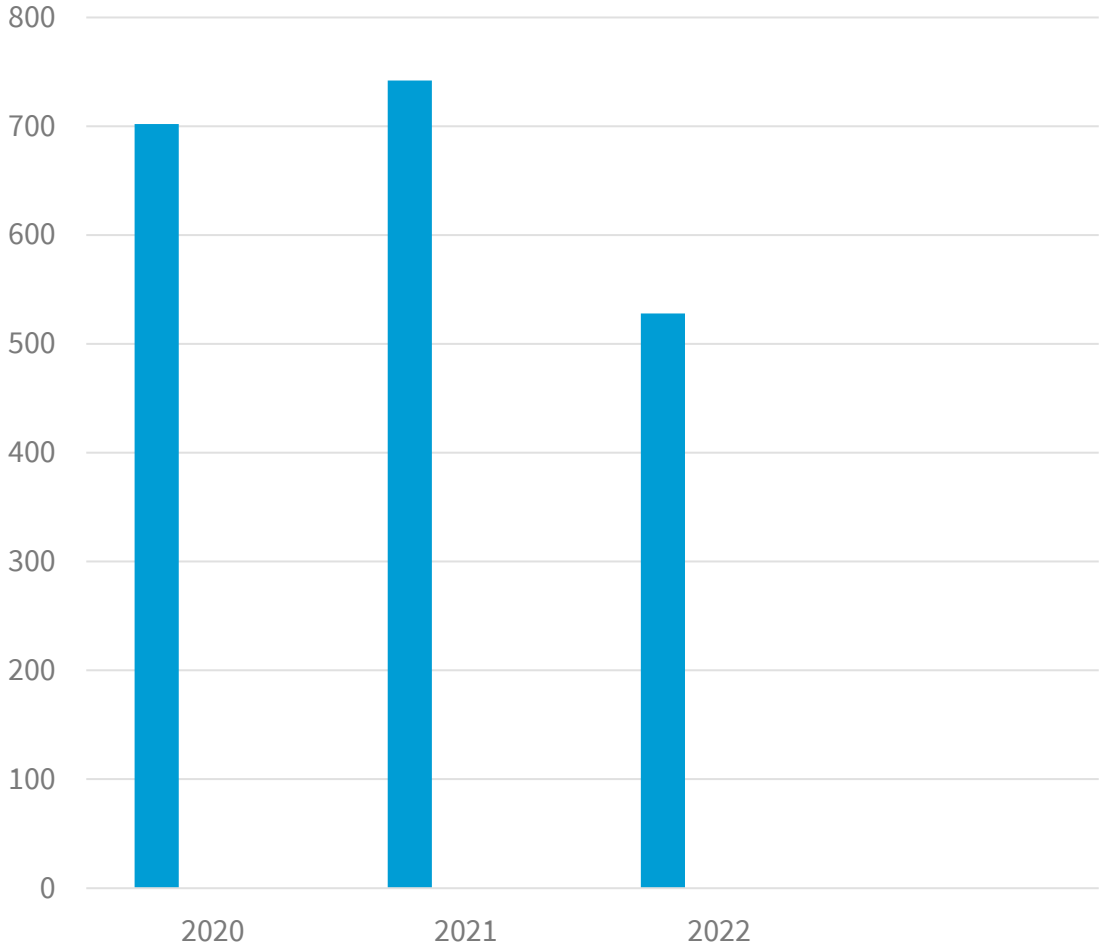

Common issues:

- Risk and actions not clear
- Targeting / traceability
- Poor response rates

Solution

- Effective FSCA strategy
- Discuss draft FSN / communication
- Follow guidance by regulatory body
- Seek local knowledge

Source: Medicines and Healthcare products Regulatory Agency (filecamp.com)

POST MARKET PHASE

When non-compliant …

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Government of Canada

As part of its regulatory responsibilities, Health Canada is responsible for compliance monitoring and enforcement activities related to health products **in order to verify that regulatory requirements are being applied** appropriately.

Medicines & Healthcare products Regulatory Agency

In the majority of circumstances, we intend to **provide high level guidance on how you can comply with the regulations** and what you need to do to ensure that you are not putting members of public at risk unnecessarily.

FDA U.S. FOOD & DRUG ADMINISTRATION

The FDA works with manufacturers to **help them achieve regulatory compliance,** and takes enforcement action as appropriate.

Specific enforcement activities include actions **to correct and prevent violations**

Key take aways

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Ecosystem of regulatory support

Develop meaningful multi-level relationships

Utilise pathways to feedback/advice – **as early as possible**

Keep abreast of best practice guidance on submissions, notifications etc

Positive impact on public health outcomes

Q&A

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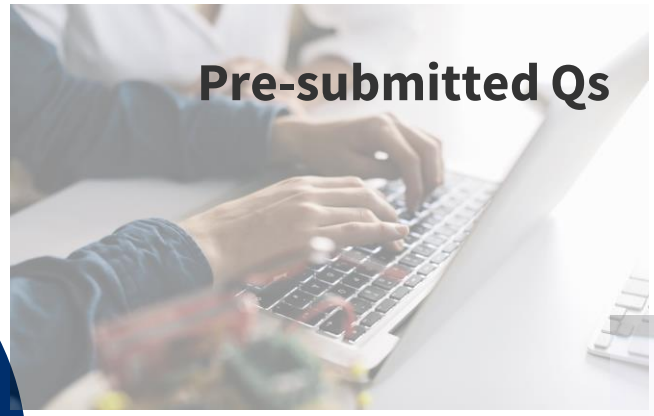

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