

Health Innovation Manchester

SME'S AND CONFIDENTLY TACKLING THE MEDICAL DEVICES REGULATIONS

Wednesday 13th February 2019

Agenda - AM

SME'S AND CONFIDENTLY TACKLING THE MEDICAL DEVICES REGULATIONS

Time	Session Details
09:00 – 10:00	Networking Breakfast & Registration
10:00 – 10:15	Welcome & Introductions
10:15 – 10:45	Medical device regulation overview
10:45 – 11:15	Notified body role & technical data expectations
11:15 – 11:30	Refreshments
11:35 – 12:15	Translating the above into a 'project plan'
12:15 – 12:30	Morning wrap-up & surgeries overview
12:30 – 13:45	Lunch

We are Health Innovation Manchester

We work with innovators to **discover, develop & deploy** new solutions that improve the health and wellbeing of Greater Manchester's citizens.

Health Innovation Manchester



Strategic aims

Health Innovation Manchester

Our vision is to become a recognised international leader in accelerating innovation that transforms the health and wellbeing of our citizens.



Ensure a constant innovation pipeline into health and social care.



Prioritise and monitor innovation activities that meet the needs of GM.



Accelerate delivery of innovation into health, care and wellness delivery.



Amplify existing academic and industry value propositions.



Influence national and international policy.

HEALTH & CARE CATALYSTS

DIGITAL DISRUPTORS

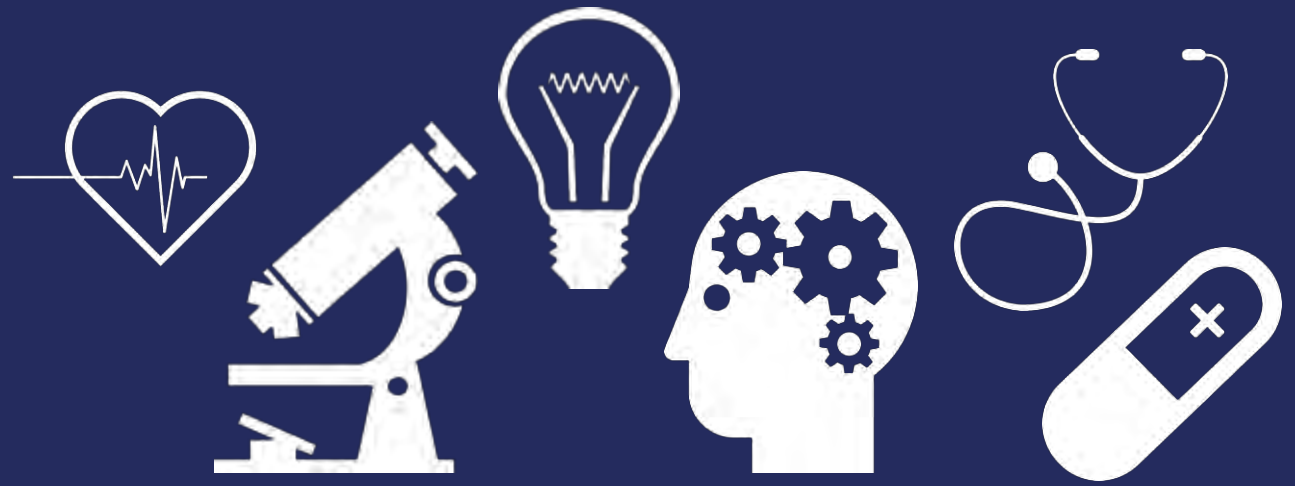
GROUNDBREAKING RESEARCHERS

INDUSTRY PARTNERS

ACCLAIMED ACADEMICS

Health Innovation Manchester

We have an active portfolio of more than 90 innovation projects covering tech, pharma, digital, academia and research themes.



GM's pulling power

Brokering partnerships with industry from SMEs to global players is a key part of our strategy.



Health Innovation Manchester











Oxford Road Corridor







The Growth Company

Digital transformation opportunity

Health Innovation Manchester

Industry and academic engagement to develop, deliver, and evaluate products and services supported by real world data and evidence

Clinical and data science expertise to develop and deploy advanced approaches to provide enhanced actionable insights from comprehensive data

Computer science evolution to transform our ability to tackle healthcare problems at scale and at pace

To drive better clinical and business outcomes



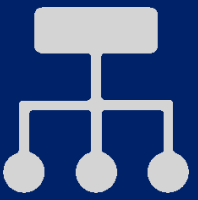
Understand our population



Define population needs

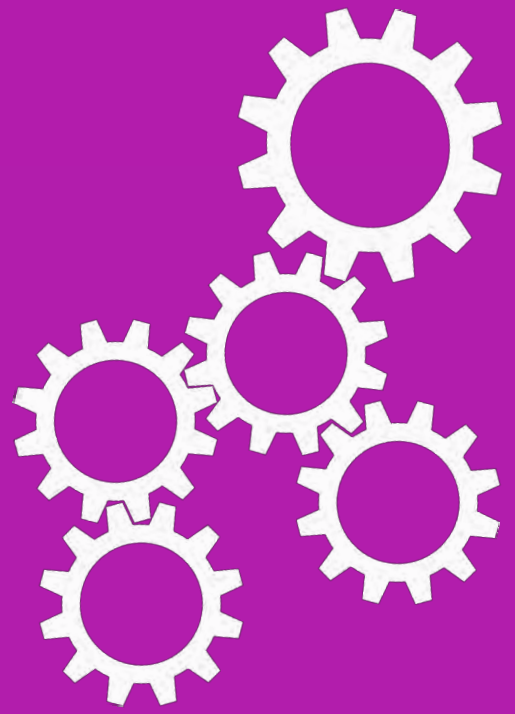


Business model transformation



Operating model transformation

Vision for the future



- Power will come from collaboration
- Leverage strengths and go with the grain
- Always start with WHY
- Don't just chase the money

Health Innovation Manchester

Health
Innovation
Manchester

WE ARE HEALTH INNOVATION MANCHESTER

wearehinm.co.uk #weareHInM

ABHI

Regulatory Briefing

Health Innovation Manchester

13th February 2019

Agenda

- **Introductions**
- **The Rules;** Medical Device Regulation overview (to include elements of classification, Risk, Quality Management, MHRA expectations etc.)
- **Expectations;** Notified Body role and Technical Data expectations
- **Practical solutions;** How to plan your transition
- **Wrap-ups, Q&A**

WHO WE ARE

The leading health technology industry association in the UK

- A community of over 280 Members
- **We support the HealthTech community to provide products and services that help people live healthier lives**



We are the voice of the industry

We show the value of health technology and overcome barriers to people benefitting from it now and in the future.

We are recognised as building trust and cooperation between industry and our partners.



We are the support that powers industry

We provide insight and expert assistance.

We outline industry's strategic vision, contributing to the development of policy in areas such as regulation, procurement and technology adoption.



We facilitate collaboration and help businesses to grow

Member-led groups address a wide variety of topical issues.

We run international trade missions and provide support for UK companies in overseas markets.

All our work is underpinned by a robust Code of Business Practice, mandatory for Member organisations, so that healthcare professionals and the public can have confidence in the integrity of our industry.

HealthTech for Life

We support the HealthTech community to provide products and services that help people live healthier lives.

Shaping the Future

We shape how data and technology will transform healthcare and the lives of patients in the future.

Our work in this area:

- Digital health
- Life Sciences Industrial Strategy
- AAR
- Health data and informatics

Leading Access to HealthTech

We work with industry and the healthcare system to show the value of health technology, improve patient outcomes and overcome barriers to people benefiting from HealthTech.

Our work in this area:

- Market access strategies
- AAR
- Procurement
- Commissioning
- Value of health tech

Influencing Regulation

We are experts in regulation and help companies to understand them so patients can access HealthTech safely and quickly.

Our work in this area:

- Interpretation of legislation
- Medical device legislation
- UDI
- Standards
- Environmental responsibilities

Supporting Growth

We create a positive environment that encourages growth and helps HealthTech companies to connect with new customers around the world.

Our work in this area:

- Industrial strategy
- Brexit representation
- ABHI International
- Trade Fairs (Arab Health)
- Missions
- Dell Med School Hub
- Small Business Community

Building Trust

We insist on the highest professional standards and ethical behaviour so that the HealthTech industry is recognised as a trusted partner in healthcare.

Our work in this area:

- Code of Conduct
- Credentialing
- Human Rights

2019 PRIORITIES

Through 2019 we will place strong emphasis on the following elements



Procurement

Why

- The single issue common to all Members
- Situational context (NHS finances) means strong policy focus
- New structures, systems, and processes being rolled-out.

What

- Strategic focus on value-based procurement
- Address operational issues.



Regulation

Why

- Of concern to the whole HealthTech sector
- Effective compliance with device regulation is key to successful business
- Transition to MDR runs until 2022 for most companies.

What

- Monitor and manage changes in the regulatory environment
- Provide updates and guidance
- Deliver the key UK HealthTech regulatory conference.



Brexit

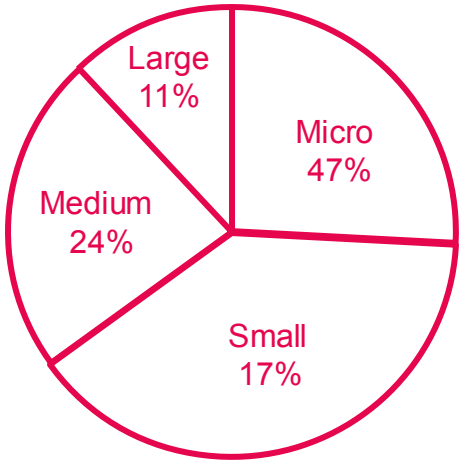
Why

- Potential disruption to all aspects of business
- MDR implementation and transition
- Sector prioritisation, and Day 1 company preparedness.

What

- Key sector messages distributed across government
- Play full and active role in broader life sciences collaborative approach
- Bilateral approach to EU27 countries
- Member preparedness activity.

OUR MEMBERS



280 Members

Implants | Single Use | Capital | Instruments | Digital

The Medical Device Regulation

The New Approach and CE-Marking

- The principles of the ‘New Approach’, as it relates to Medical Technologies;
  - Liabilities and differences with Pharmaceutical legislation
  - Essential Requirements
  - Classification and Risk
  - Conformity Assessment
  - Standards
  - The ‘Technical File’
  - Notified Bodies and Competent Authorities
  - The ‘Declaration of Conformity’
- The Medical Device Directive (MDD) vs. the Medical Device Regulation (MDR)

The Medical Device Regulation

The New Approach and CE-Marking – MDD vs. MDR

- Regulation moving towards a more ‘business related’ approach rather than product related requirement
- Holistic approach to CE Marking
- Pre- and Post- marketing requirements
- BUT – similar structure to MDD, based on risk and conformity assessment
- Satisfaction of ERs/GSPRs for all products
- Technical Files for all products

The Medical Device Regulation

The New Approach and CE-Marking – MDD vs. MDR

- Regulation still has both MHRA and Notified Body interactions
- MDR provides significant increase in requirements over MDD, particularly with regards to clinical performance
- Some classification changes and wider scope
- Brexit impact?

The Medical Device Regulation

Competent Authorities

- One per Member State!
- Deals with registration onto national market
- Deals with approval of clinical investigations
- Deals with Vigilance issues

Notified Bodies

- Commercial organisations
- 58 in EU at present
- Manufacturer can choose their Notified Body, depending on 'Scope'
- Deals with Conformity Assessment
- Deals with Technical reviews

http://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=directive.pdf&refe_cd=93%2F42%2FEEC&requesttimeout=900

The Medical Device Regulation

Liabilities and Differences between Pharmaceutical Regulation

- The Declaration of Conformity vs. the Product License
- Pharma rules aimed at approval by EMA or National Authorities
- Device manufacturer interactions with Competent Authorities and the Notified Bodies
- Completion of a Technical File, demonstrating compliance with GSPRs (or ERs in old money)
- Demonstration of Quality Management
- Product liability lies solely with the Legal Manufacturer

The Medical Device Regulation

So, what do I have to do to apply the CE Mark to my product?

- Essential Requirements / General Safety and Performance Requirements
  - Annex I of the MDD and Annex I of the MDR
  - 23 GSPRs as opposed to 13 ERs
  - Chapter I; **General Requirements** covering risk mitigation
  - Chapter II; **Design and Manufacture** covering chemical, physical and biological properties of the given product
  - Chapter III; **Information Supplied by the Manufacturer** covering labelling and instructions for use

Medical Device Regulation

So, what do I have to do to apply the CE Mark to my product?

- Classification and Risk
  - Application of Harmonized Standard, EN ISO 14971:2012
  - https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/medical-devices_en
  - Classification rules, Annex VIII
    - 22 Rules, covering non-invasive, invasive, active and special rules.
    - Provides a classification based on risk presented to the patient
    - Determined by the manufacturer, but can be challenged by the Notified Body
    - Classes I/I(s)/I(r)/I(m)/IIa/IIb/III

Medical Device Regulation

So, what do I have to do to apply the CE Mark to my product

- Classification and Risk
  - Risk is constantly challenged and updated as a result of increased product knowledge and patient exposure
  - Links with product design and development
  - Evaluation of Risk v Benefit dynamic
  - Potential changes to ‘Classification’, e.g. total joint replacements, surgical instruments and surgical meshes
  - Driver for product lifecycle analysis
- MDD vs MDR

Medical Device Regulation

So, what do I have to do to apply the CE Mark to my product

- Conformity Assessment
  - Application of Quality Management Systems (predominantly EN ISO 13485:2016)
  - Options depending on product and it's manufacture
    - Based on QMS and assessment of Technical Documentation
    - Based on Type Examination
    - Based on Product Conformity Verification
- Certification issued by Notified Body
  - Related to Quality Management System
  - Conformity Assessment

Medical Device Regulation

So, what do I have to do to apply the CE Mark to my product

- Class I products;
  - Self Declared
  - Notified Body input depending on Sterile, Measuring or Re-useable functions
  - Quality Systems not confined to EN ISO 13485:2016
  - Manufacturer draws up Declaration of Conformity based on satisfaction of GSPRs

Medical Device Regulation

So, what do I have to do to apply the CE Mark to my product

- Class I(s), Class I(r), Class I(m) products
- Class IIa/IIb/III products
  - Notified Body input into Technical Files and Conformity Assessment
  - Increasing risk demands increasing sophistication in clinical performance satisfaction
  - Technical File content described in Annex II
  - Potential for the 'Scrutiny Procedure' to the invoked in the case of novel Class III's (initially)

Medical Device Regulation

What does a Technical File look like?

- Annex II;
  - Device Descriptions and specifications
  - Information supplied by the manufacturer
  - Design and manufacturing information
  - GSPR
  - Risk/Benefits and risk management information
  - Product verification and validation
  - Pre-clinical and clinical data
  - Additional information as necessary

Medical Device Regulation

Why do you consider this a business regulation – all product so far?

- Signing the Declaration of Conformity is just the start!
  - Continuous updating of Quality, Clinical and Risk Assessments
  - Vigilance
  - Planned and actual Post-Marketing Surveillance activities
  - Public availability of safety and clinical data
  - Regulation contains elements of all the above, making them 'legal requirements'
  - Never letting the ink dry – ensuring 'state-of-the-art'…

ABHI
HealthTech for Life

THANK YOU

E: enquiries@abhi.org.uk

T: +44 (0)20 7960 4360

@UK_ABHI

107 Gray's Inn Road, London, WC1X 8TZ

Notified Body role and Technical Data expectations

	Session 10.45 - 11.45	**Health Innovation Manchester**	
Date	13/02/2019	Version	0.0
Name	**Martin Penver**		
Role	Technical Regulatory Manager		

Key Learning Points :-

1. Just because a Clients device has a MDD certification CE does not guarantee a MDR certificate.



2. Pro-active Post Market Surveillance – is important

Articles 120: Transition and next steps

- **After 25 May 2020 :** A device with a valid MDD certificate may only be remain on the market or in service provided it continues to comply with the MDD Directive and provided there are no significant changes in the design and intended purpose.

- There can be no certificate extensions or significant changes.
- By the end of the transition period, any new products need to conform to the MDR.

Key Stages for Transition

- Clients determine their :
  - Portfolio Planning – are you going to keep all current CE market products ?
  - Assessment Phase (MDD to MDR) – when will you be ready ?
  - Any scope changes ? Or classification changes?
- Clients to submit:-
  - Transition plan of products from MDD to MDR
  - Application against MDR - (Annex IX page 146)
  - Supply list of possible Significant changes (after May 2020)

Note Manufacturers can have MDD & MDR certificates for the same device – at the same time.

Certification Process MDR by - N.B.

2 reports are required before a certificate can be issued for **CE**

QMS Visit report MDR

Product / Device report MDR



Technical Managers CE (MDR) Certificate decision – needs visibility of both reports

CE cert includes **QMS** (Annex) & **Product**

Article 10(9) & Annex IX Chapter I : QMS

- **Article 10(9) (WHAT)** states that manufacturers **shall**… establish, document, implement, maintain, keep up to date and continually improve a **quality management system.** **(starts on page 24 MDR – have a look)**

  The quality management system **shall** cover all parts and elements of a manufacturer's organisation dealing with the quality of processes, procedures and devices **– it lists 13 requirements**

- **Annex IX Chapter I: (HOW)** Conformity assessment based on a quality management system and technical documentation lays down the criteria for the manufacturer to ensure that their QMS is compliant with the regulation.

  starts on page 146 MDR – have a look, read from section 2.1

  have a look, read from section 2.2c procedures

  It states that the manufacturer **shall** establish, document and implement a quality management system and maintain its effectiveness throughout the life cycle of the devices concerned as described in **Article 10(9)**

Annex IX Chapter I – QMS section 2.1

Annex XI (product QuALity Assurance) 6.1 – ALL ELEMENTS IN SECTION 2.1 Annex IX

The manufacturer **shall**:

- Lodge an **application for assessment** of the quality management system with a notified body
  - as specified in Section 2.1
  - Section 2.2 ~ Moreover, the documentation to be submitted for the assessment of the quality management system shall include an adequate description of, in particular: ……(read)
- be subject to **audit**, as laid down in Sections 2.3 and 2.4
- to **surveillance** as specified in Section 3

Annex IX Chapter I – QMS Application

The application **shall** include the following: Section 2.1 (read)

- a draft of an EU declaration of conformity in accordance with Article 19 and Annex IV for the device model covered by the conformity assessment procedure,
- Document number / rev of quality manual covering MDR (EU) 2017/745
- Description of the procedures in place to fulfil the obligations arising from the quality management system and required under this Regulation
- Documentation on the manufacturer's post-market surveillance system and, where applicable, on the PMCF plan, and the procedures put in place to ensure compliance with the obligations resulting from the provisions on vigilance set out in Articles 87 to 92

Annex IX Chapter I – QMS Application

The application **shall** include the following: *continued*

- Description of the procedures in place to keep up to date the post-market surveillance system, and, where applicable, the PMCF plan, and the procedures ensuring compliance with the obligations resulting from the provisions on vigilance set out in Articles 87 to 92, as well as the undertaking by the manufacturer to apply those procedures,
- Documentation on the clinical evaluation plan
- Description of the procedures in place to keep up to date the clinical evaluation plan, taking into account the state of the art.
- Description of the procedures in place to identify if dual certification is held, which devices are manufactured against the MDD or MDR certificates

Annex IX Chapter I – QMS Application

The application **shall** include the following: *continued*

Section 2.2 ~ Moreover, the documentation to be submitted for the assessment of the quality management system shall include an adequate description of, in particular: whole page of text……(read)

- identification of applicable general safety and performance requirements and solutions to fulfil those requirements, taking applicable CS and, where opted for, harmonised standards or other adequate solutions into account,
- solutions for fulfilling the applicable specific requirements regarding design and construction, including appropriate pre-clinical evaluation, in particular the requirements of Chapter II of Annex I,
- In addition, the manufacturer shall grant the notified body access to the technical documentation referred to in Annexes II and III.

Key changes between ER's (mdd) and GRPR's (mdr) for a QMS Assessor to review

- A procedure is required according to Annex IX Chapter 1 sect 2.2 (c) for GS&PR
- If 6a remains in the checklist or requirements only go to 13 – not been updated from MDD
- NB will check each requirement is:-
  - The A or NA are relevant for the device in question
  - The correct standard, common spec etc has been correctly listed and the correct year / rev specified
- GS&PR's 10.4 – **substances** = requires warnings in the IFU for Invasive devices
- **Lay Person** requirement is 22.1 to 22.3 – therefore NB will check Usability is included within the design inputs and risk assessment documentation
- With 182 requirements covered within the 23.4 GS & P requirements an assessor can only **sample the checklist** / matrix, however :-
  - Focus on checking the matrix supplied covers the actual device being reviewed and this is not just a generic matrix
  - Focus on checking version control and date of the document

Stainless steel 316 (still used in Implants)

A Product Assessor would need to Check - Labelling in the IFU will require to include:- requirement GS&PR 10.4.5

- Stainless Steel 316 contains 16.4% weight of Chromium (VI) and risks may be posed for wear

Classification	Respiratory sensitisation Carcinogenic 1B	Skin Sensitization Category 1
GHS Pictogram		
Signal Word	Danger	Warning
Hazard Statement	H350i May cause cancer by inhalation	H317 Chromium May cause an allergic skin reaction

eg No

- Annex II – Technical documentation
- Annex III – Tech Doc on Post Market Surveillance
- Periodic Summary Update reports (PSUR's) Article 86
  - PSUR's are the results and analysis of PMS and required:-
    - **Every year** for **Class IIb & III** devices.
    - Every **two years** for for **Class IIa** devices
- Summary of Safety and Clinical Performance (sscp's) Article 32
  - SSCP's is the additional information for the users and required
  - **For ALL Class Implantable & Class III** devices.
  - Will be part of the Technical file review process completed by SGS

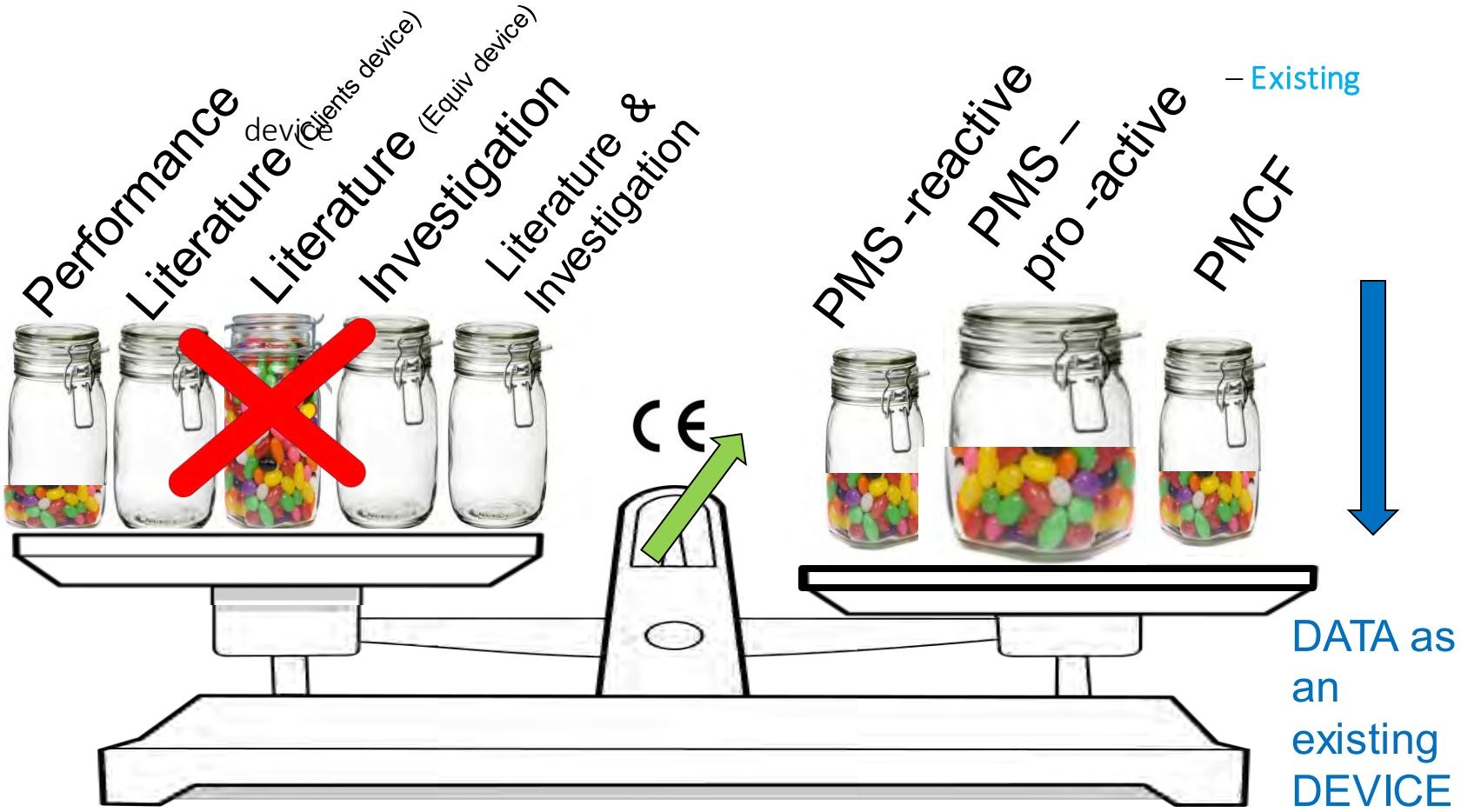
Differences MDD to MDR– Clinical Evaluation

- Consultation with the MDCG for class III devices and some IIb devices
- Literature on equivalence can only be used if a contract exists with the equivalent device manufacturer
- Investigations will be required in the majority of cases for NEW devices
- ***Performance evaluation may be most clients route to demonstrate compliance – based on "sufficient clinical evidence" from MDD device history***
- *MDR defines Notified bodies responsibilities to review clinical data in Annex VII*
- specific milestones need to be defined to allow the notified body to review updates
- Use of Harmonized Standards and Common Specifications

So how can we visualise

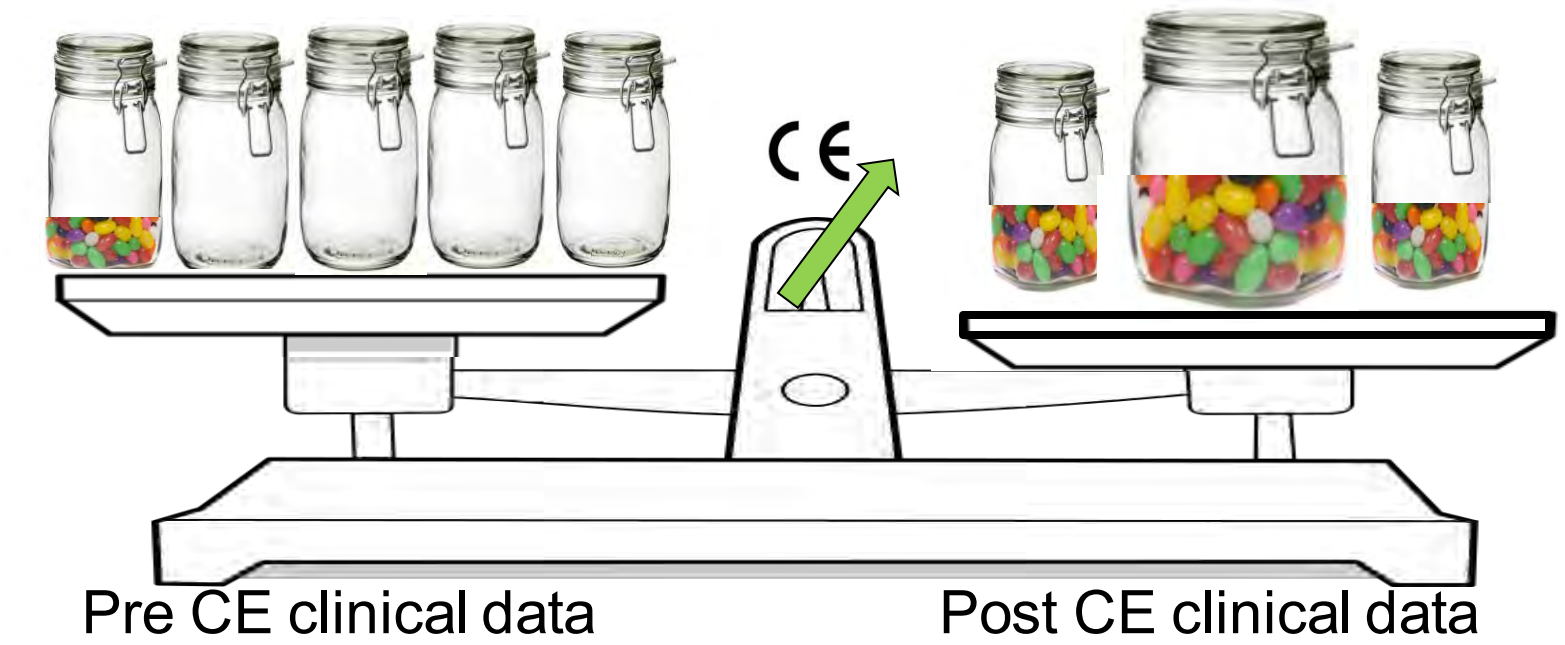
“sufficient Clinical evidence ?”

Weight of Sufficient Clinical DATA



Note ALL DATA here is GOOD,
its just that post CE data (right hand side of scales) is going to identify:- (as per MEDDEV 2.7.1 pg 17)

- new clinical data available for the device under evaluation; or new data for Comparable devices
- new knowledge about known and potential hazards, risks, performance, benefits and claims, including
- changes concerning current knowledge/ the state of the art, such as changes to applicable standards and guidance documents, new information relating to the medical condition managed with the device and its natural course, medical alternatives available to the target population;
- other aspects identified during PMS.



What are the main differences between MEDDEV 2.7.1 rev 4 & MDR

- MDR Annex XIV part A is 1 ½ pages of text (MEDDEV 65 pages) and therefore insufficient detail in MDR. (so 2.7.1 needs a re-write)
- Routes
  - Annex 1.1d = Article 61 – Paragraph 10 – Performance evaluation
  - Literature route = Article 61- Paragraph 3 (a) **on their device**
    = Article 61 – Paragraph 5 (with contract in place)
  - Clinical Investigation Route = Article 61 – Paragraph 3 (b)
  - Literature & CI Route = Annex XIV part A Paragraph 1 (e) "*analyse all relevant clinical data in order to reach conclusions about the safety and clinical performance of the device including its clinical benefits.*"
- the clinical evaluation report, must include a consideration of currently available alternative treatment options for that purpose, if any.
- For Class III devices and implantable devices, the PMCF & SSCP evaluation report shall be updated at least annually with such data.

MDR Article 61 – Paragraph 10 (1.1.d)

Therefore existing devices may needs to demonstrated sufficient clinical data based on:-

- performance evaluation,
- Bench testing
- and pre-clinical evaluation, to be adequate

Plus - Post market activities

- PMS Pro-active
- PMS Re-active
- Post Market Clinical Follow-up

Definition of Post Market Surveillance

(60) ‘post-market surveillance’ means all activities carried out by manufacturers in cooperation with other economic operators to institute and keep up to date a systematic procedure to **proactively collect** and review experience gained from devices they place on the market,

make available on the market or put into service for the purpose of identifying any need to immediately apply any necessary corrective or preventive actions; (page 19)

Lets look at your options

Post Market Surveillance

KEY
Re-active
Pro-active

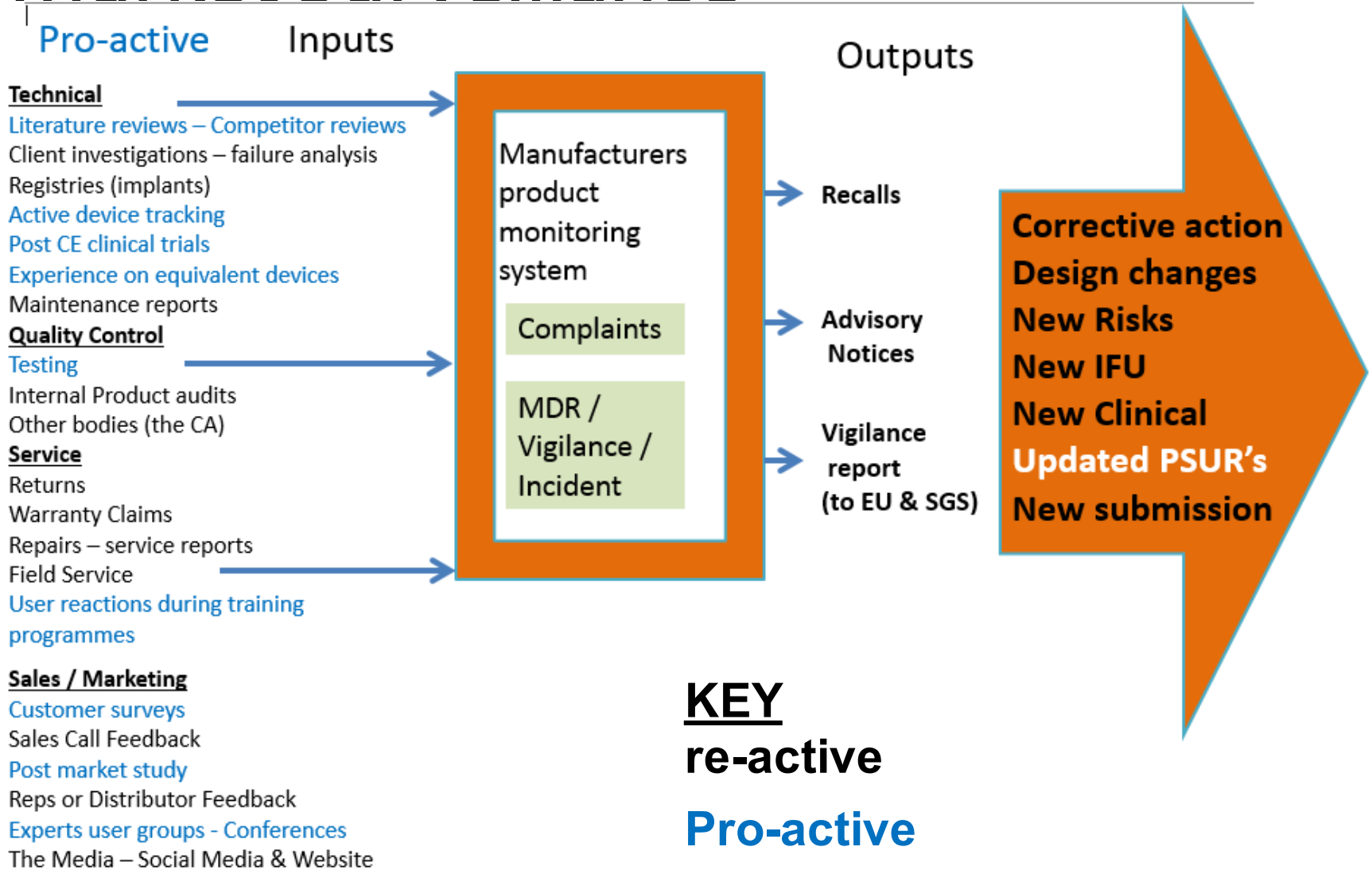
Technical
Literature reviews –
Competitor reviews
Client investigations
Registries (implants)
Active device tracking
Post CE clinical trials
Experience on equivalent devices
Maintenance reports

Quality Control
Testing
Internal Product audits
Other bodies (the CA)

Service
Returns
Warranty Claims
Repairs – service reports
Field Service
User reactions training programs

Sales / Marketing
Customer surveys
Sales Call Feedback
Post market study
Reps or Distributor Feedback
Experts user groups - Conferences
The Media – Social Media & Website

Post Market Surveillance



MDR Certification process by NB.

The notified body shall verify :-

- clinical evaluation is adequate
- Manufacture must have considered alternative treatments
- conformity with the relevant general safety and performance requirements.
- adequacy of the benefit-risk determination, the risk management,
- the instructions for use,
- the user training
- the manufacturer's post-market surveillance plan,
- adequacy of, the PMCF plan proposed, where applicable.

Thank you

SciMed Consultancy

Your partner in compliance



Wednesday 13th February 2019

Transitioning to the MDR: Practical Solutions

Alastair Selby BSc PhD
Managing Director, SciMed Consultancy Ltd

SciMed Consultancy

Introduction

WHO ARE SCIMED

WHERE TO START WITH YOU RA WORK

PRIMARY AREAS OF FOCUS

STRUCTURING TECHNICAL DOCUMENTATION

SciMed Consultancy

Who are SciMed?











Medical devices, Combination & Borderline Products and IVDs

Experienced with all Device Classes

In a Wide Range of Technology Areas

We are SME Specialists, Providing Bespoke RA Solutions

Practical Transition Tips

WHERE TO START

GAP ANALYSIS

GAP ANALYSIS

ANNEX I - GSPRs

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Practical Transition Tips

GAP ANALYSIS

ANNEX I - GSPRs

ANNEX II – TECHNICAL DOCUMENTATION

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Practical Transition Tips

GAP ANALYSIS

ANNEX I - GSPRs

ANNEX II – TECHNICAL DOCUMENTATION

ANNEX III – PMS TECHNICAL DOCUMENTATION

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Areas of focus

GSPRs

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Areas of focus

RISK MANAGEMENT

GSPRs

SciMed Consultancy

Areas of focus

RISK MANAGEMENT

CLINICAL EVIDENCE

GSPRs

SciMed Consultancy

Areas of focus

RISK MANAGEMENT

CLINICAL EVIDENCE

GSPRs

'LIFECYCLE APPROACH'

SciMed Consultancy

Areas of focus

RISK MANAGEMENT

CLINICAL EVIDENCE

GSPRs

'LIFECYCLE APPROACH'

USERS & USABILITY

SciMed Consultancy

Areas of focus

RISK MANAGEMENT

CLINICAL EVIDENCE

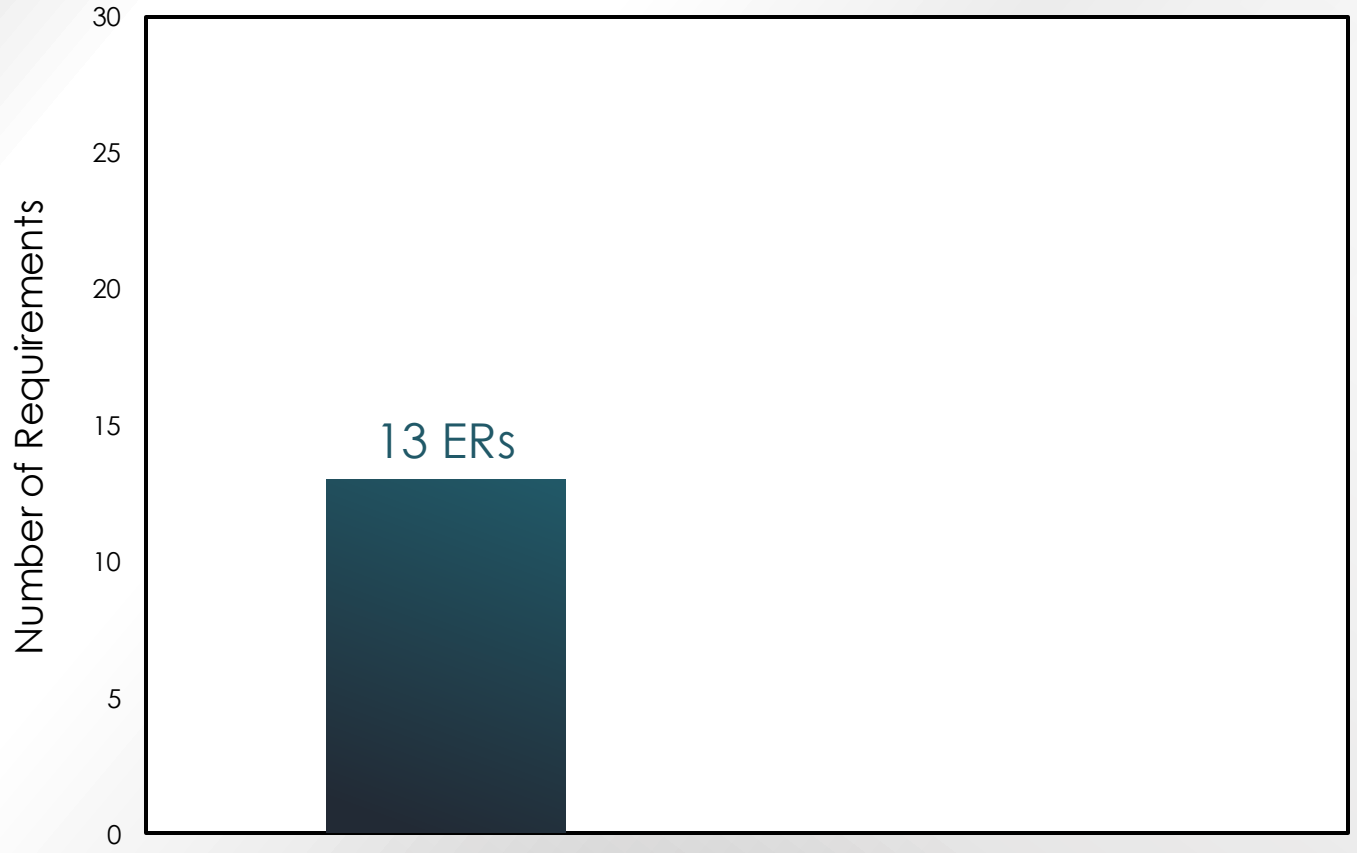
GSPRs

'LIFECYCLE APPROACH'

USERS & USABILITY

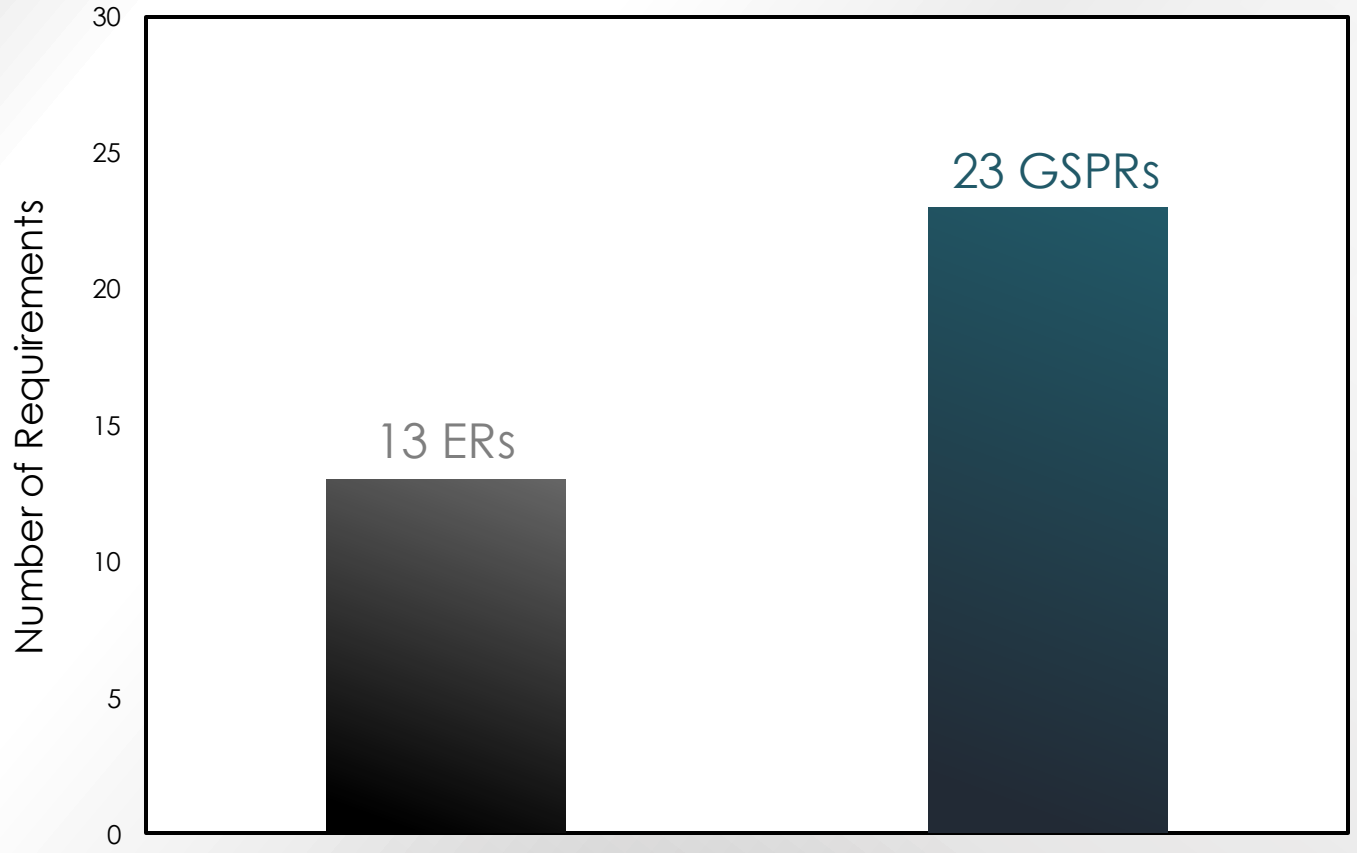
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MDDs ERs



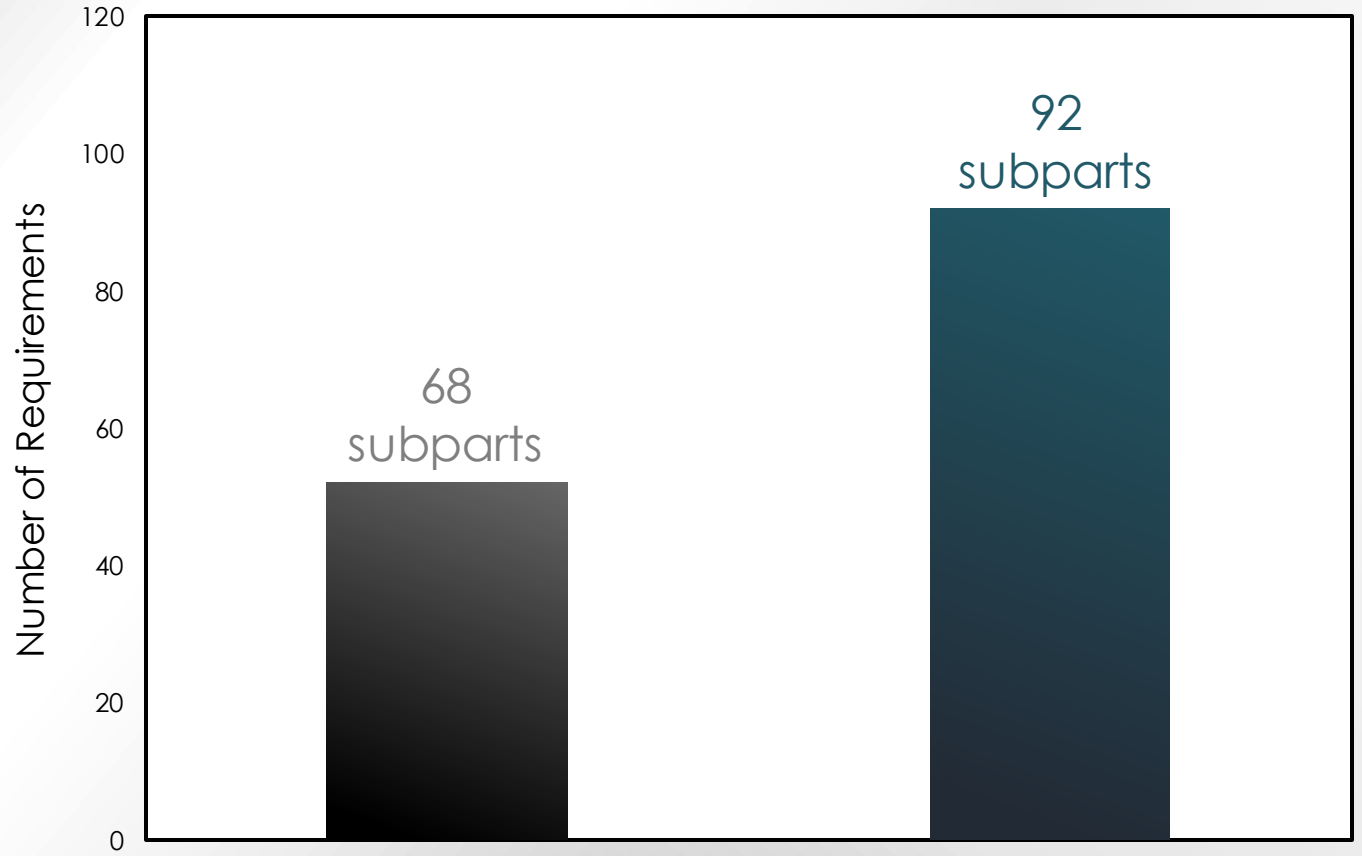
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MDRs GSPRs



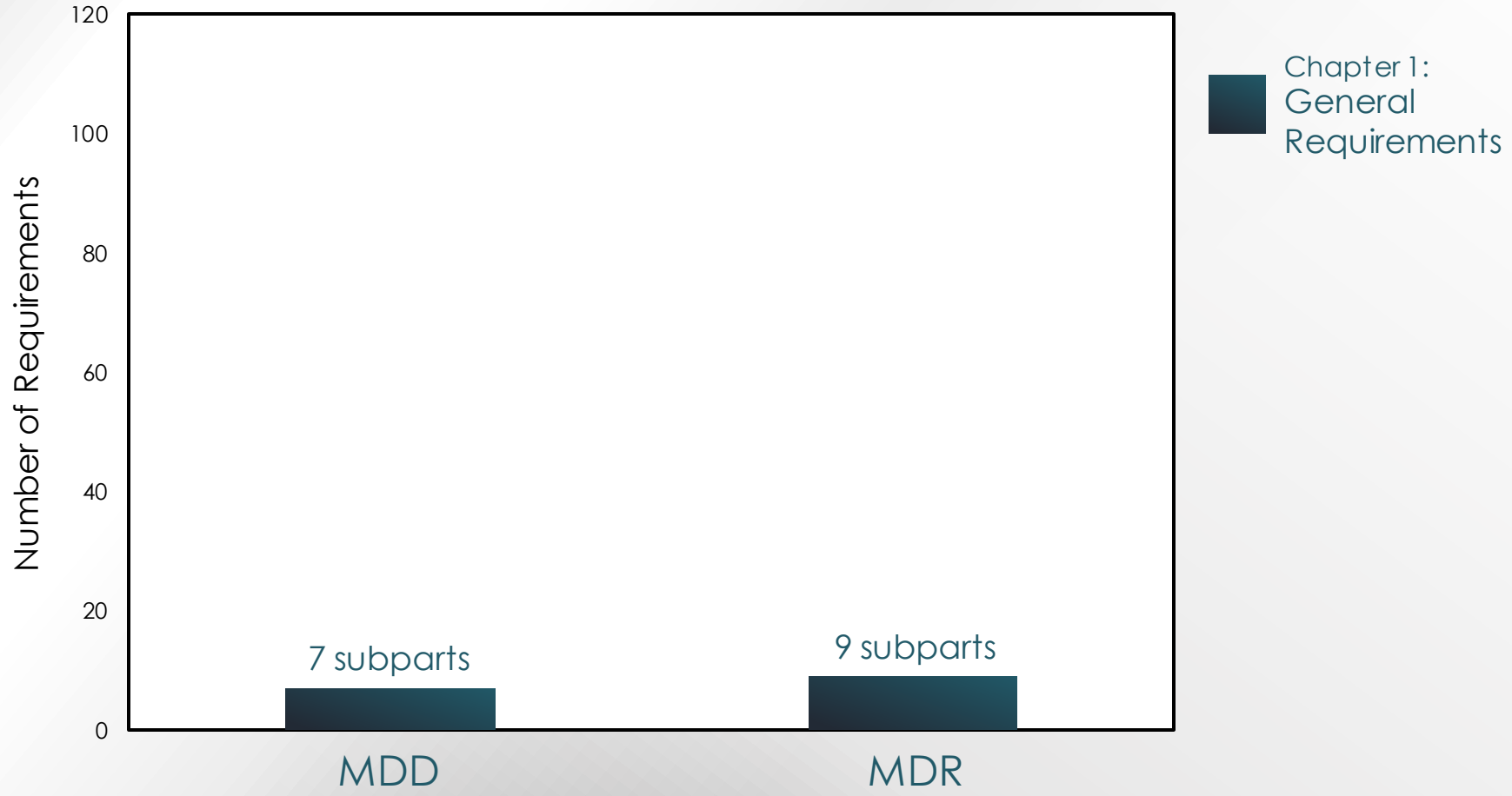
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MDD vs MDR



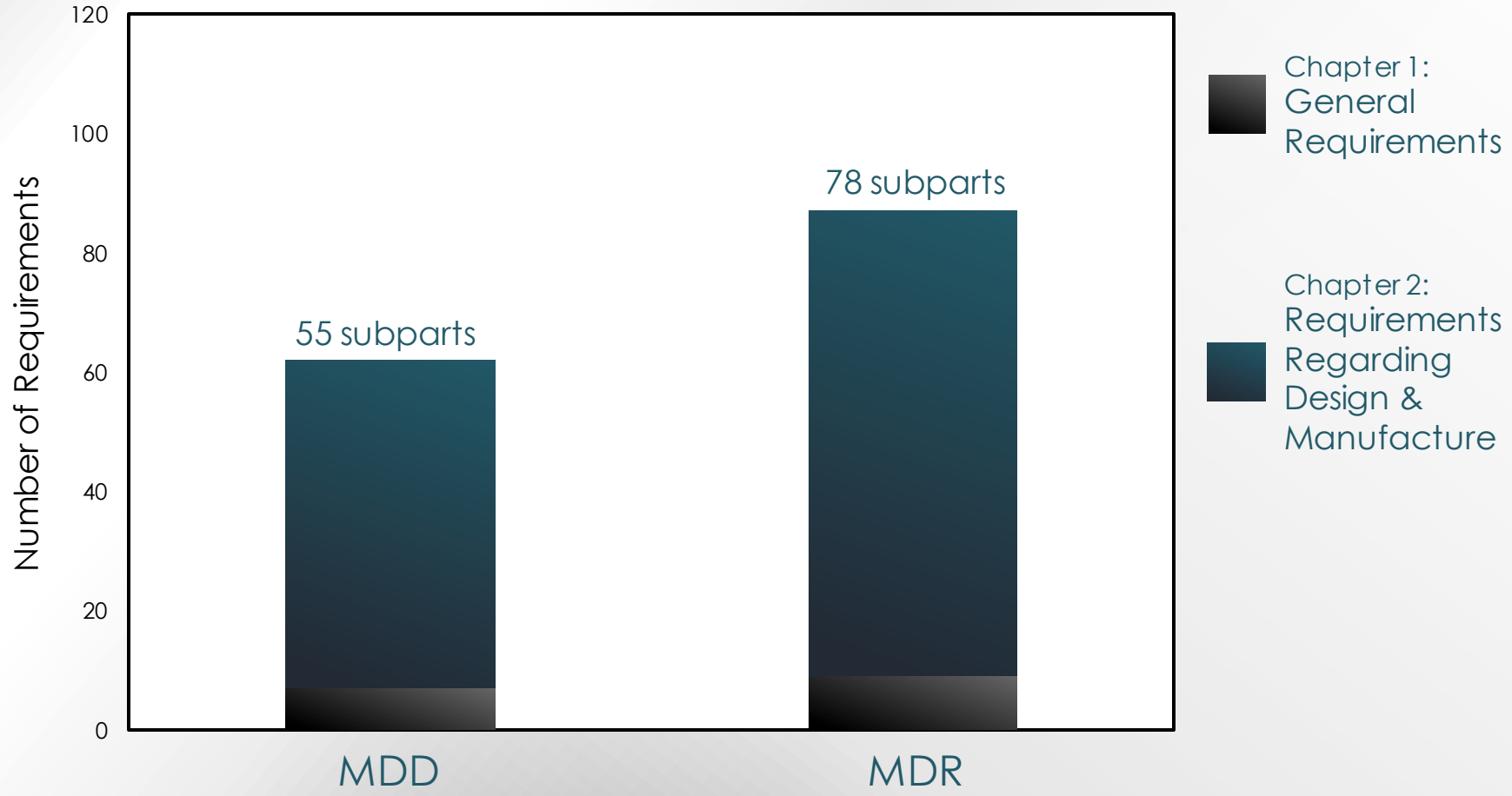
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MDD vs MDR



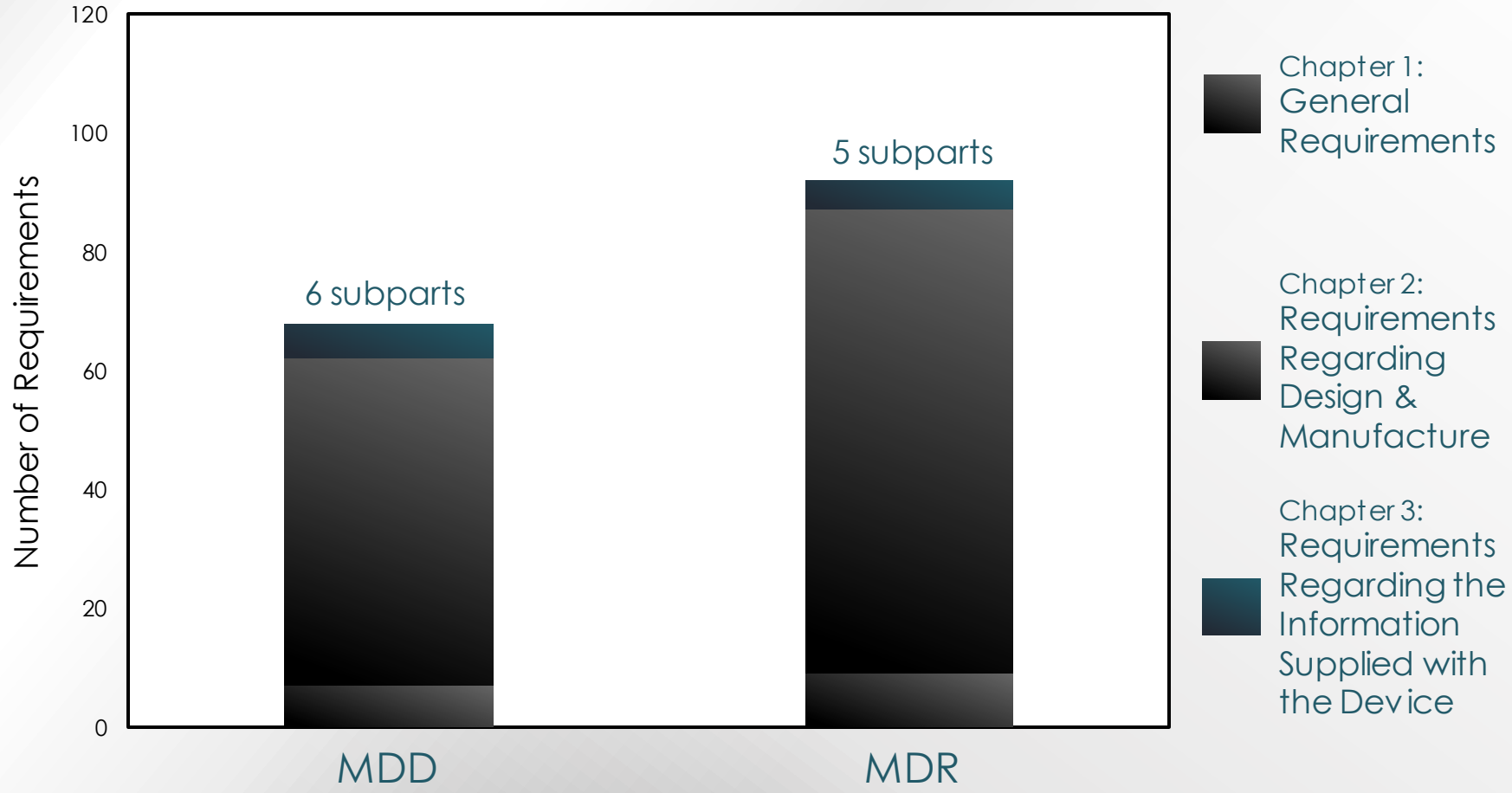
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MDD vs MDR



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MDD vs MDR



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Areas of focus

RISK MANAGEMENT

CLINICAL EVIDENCE

GSPRs

'LIFECYCLE APPROACH'

USERS & USABILITY

SciMed Consultancy

Areas of focus

RISK MANAGEMENT

CLINICAL EVIDENCE

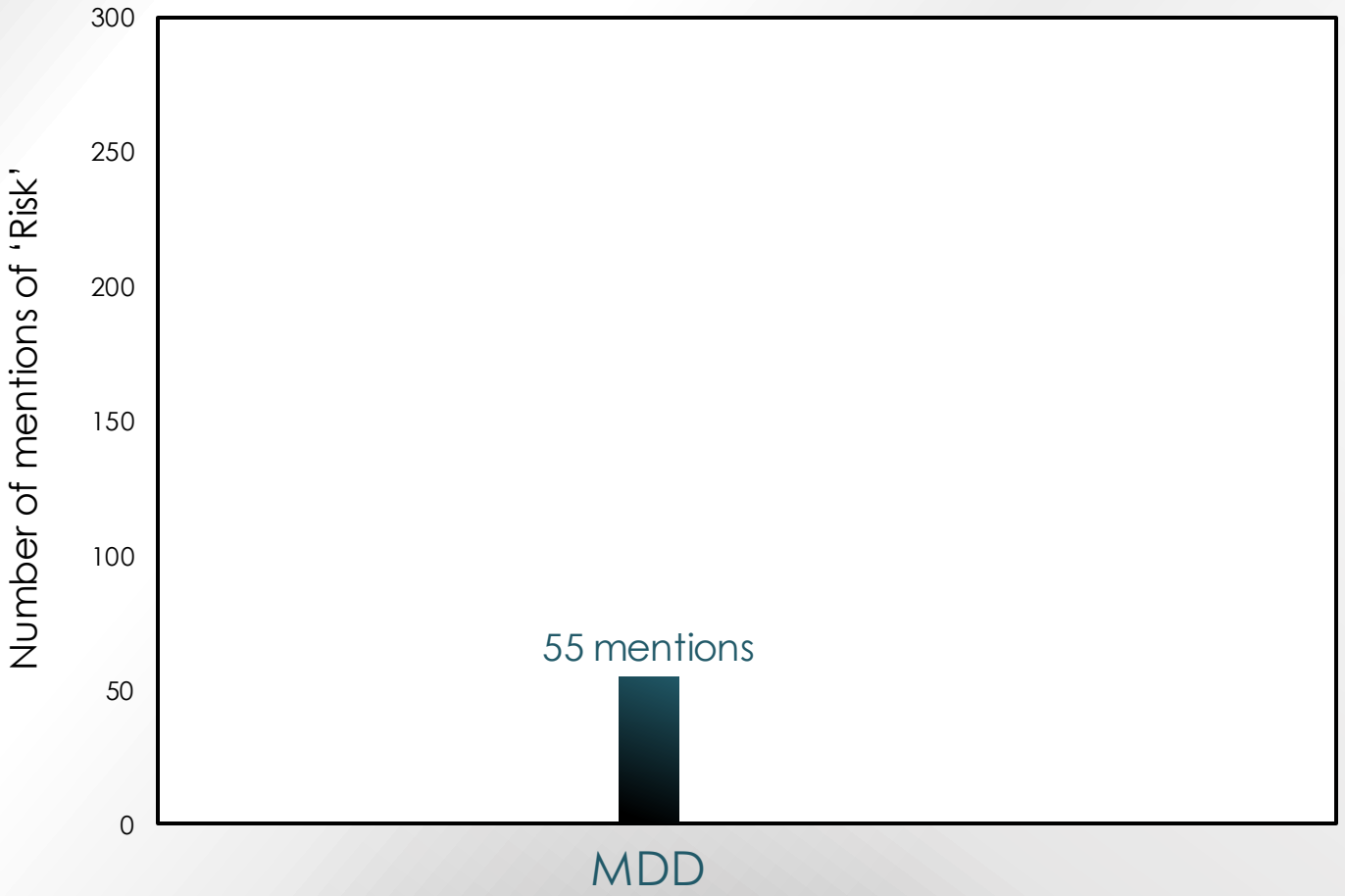
GSPRs

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USERS & USABILITY

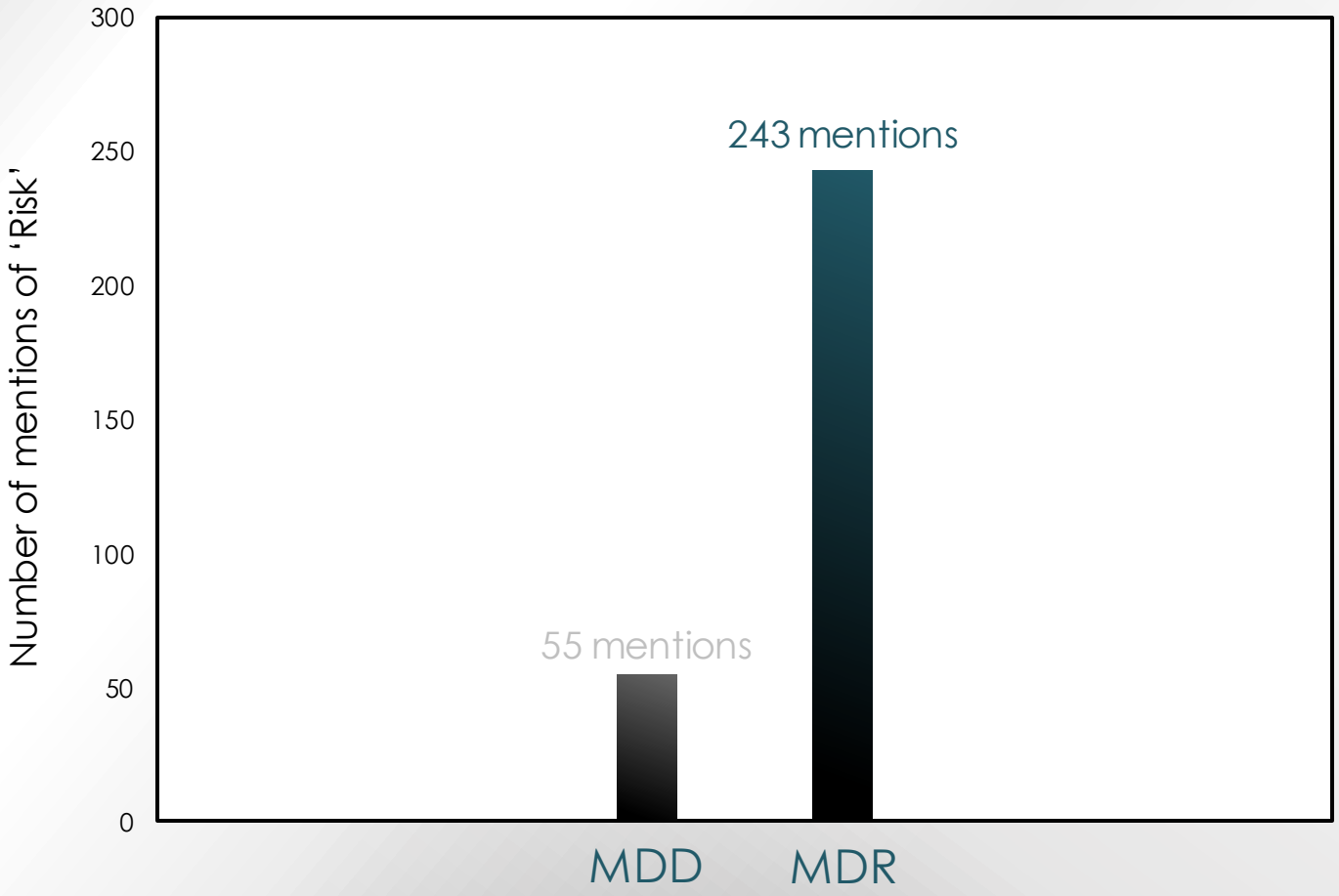
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Risk Management



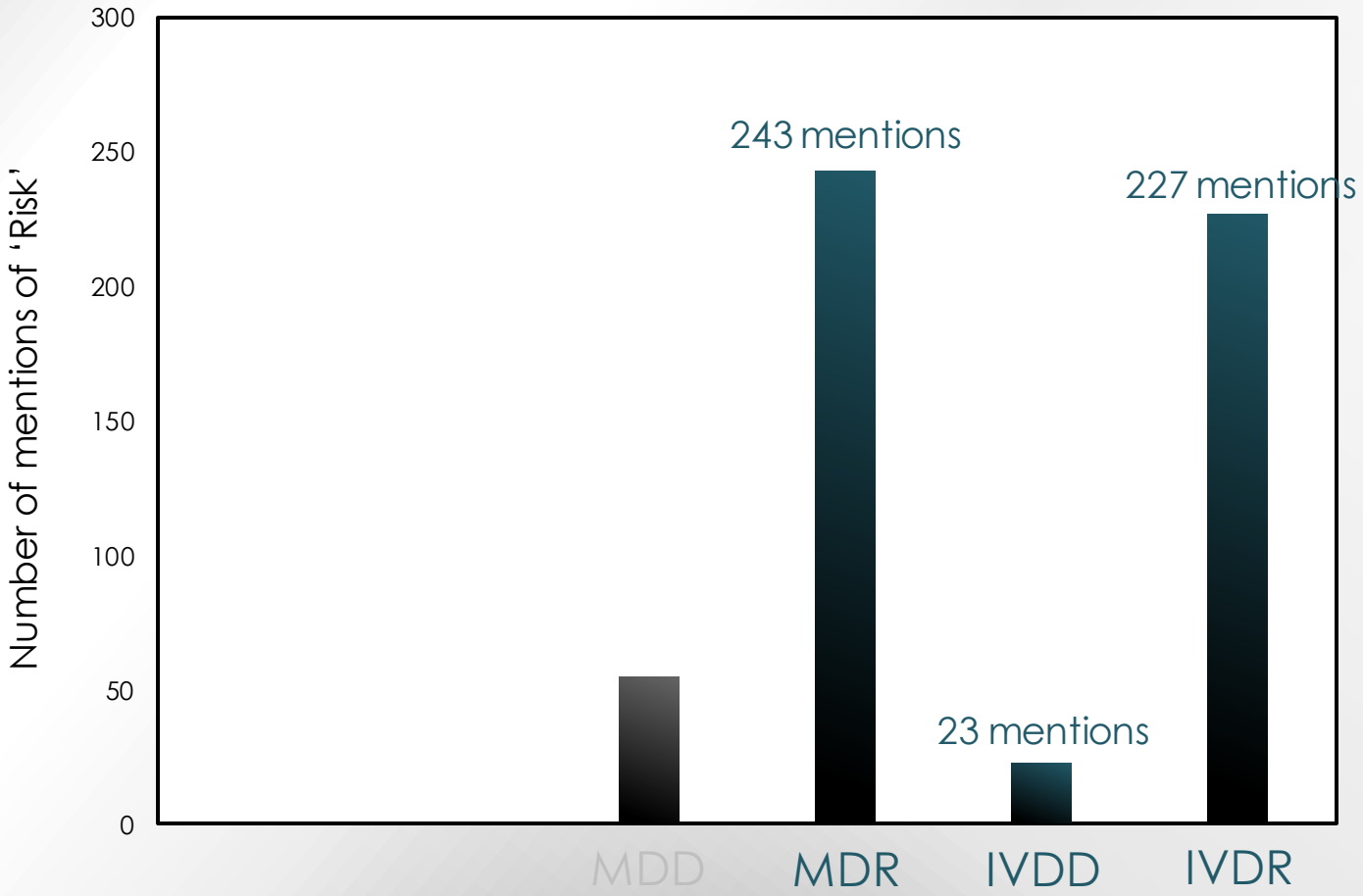
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Risk Management



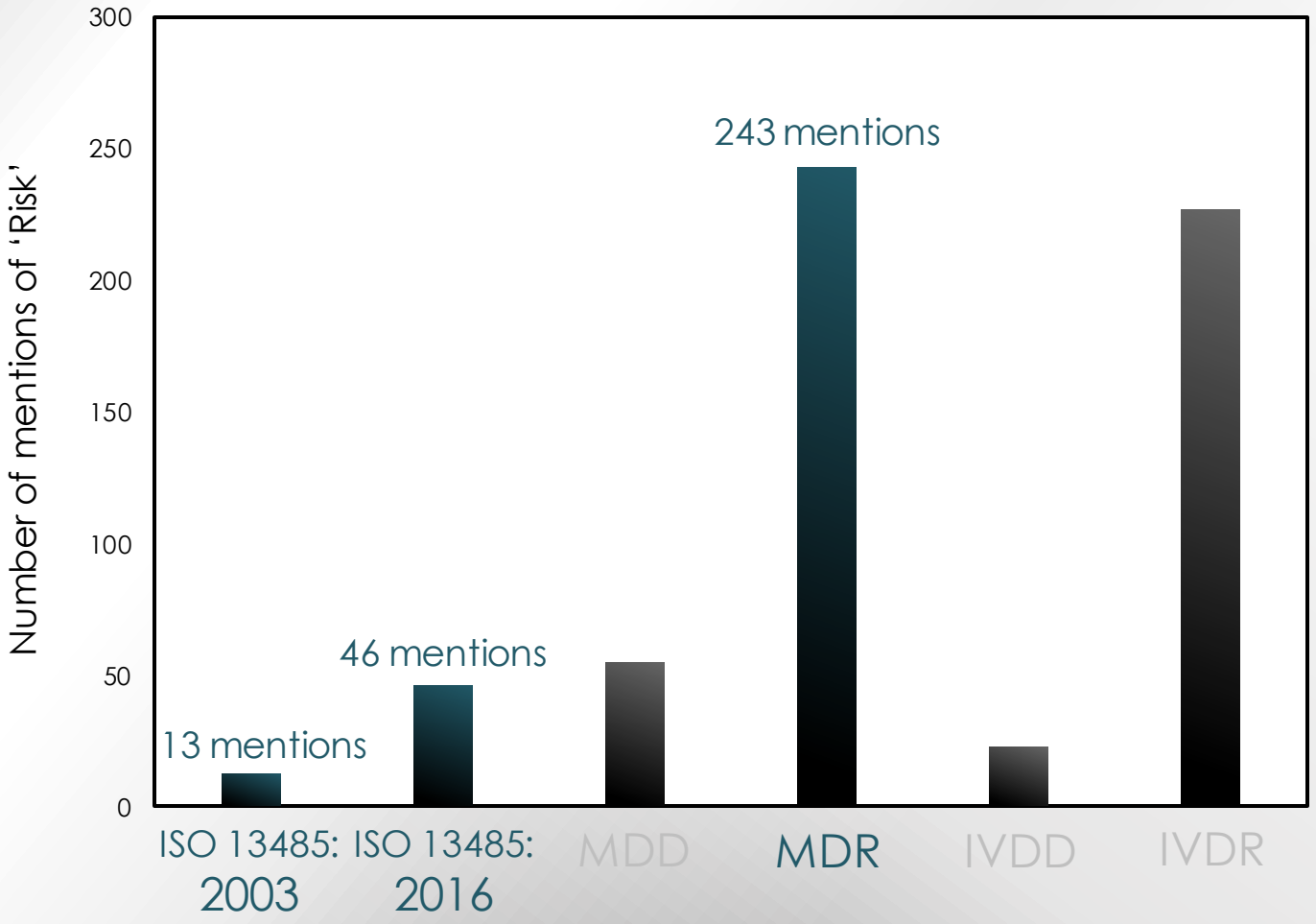
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Risk Management



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Risk Management



Risk Documents

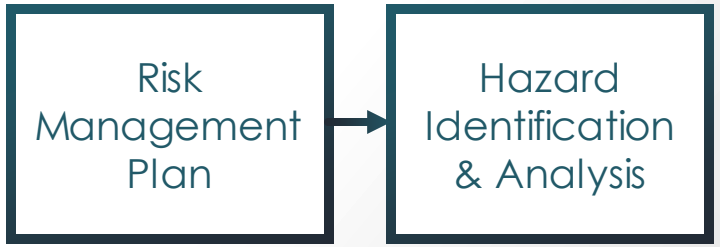
Risk Management

Risk Documents

Risk Management Plan

Risk Management

Risk Documents



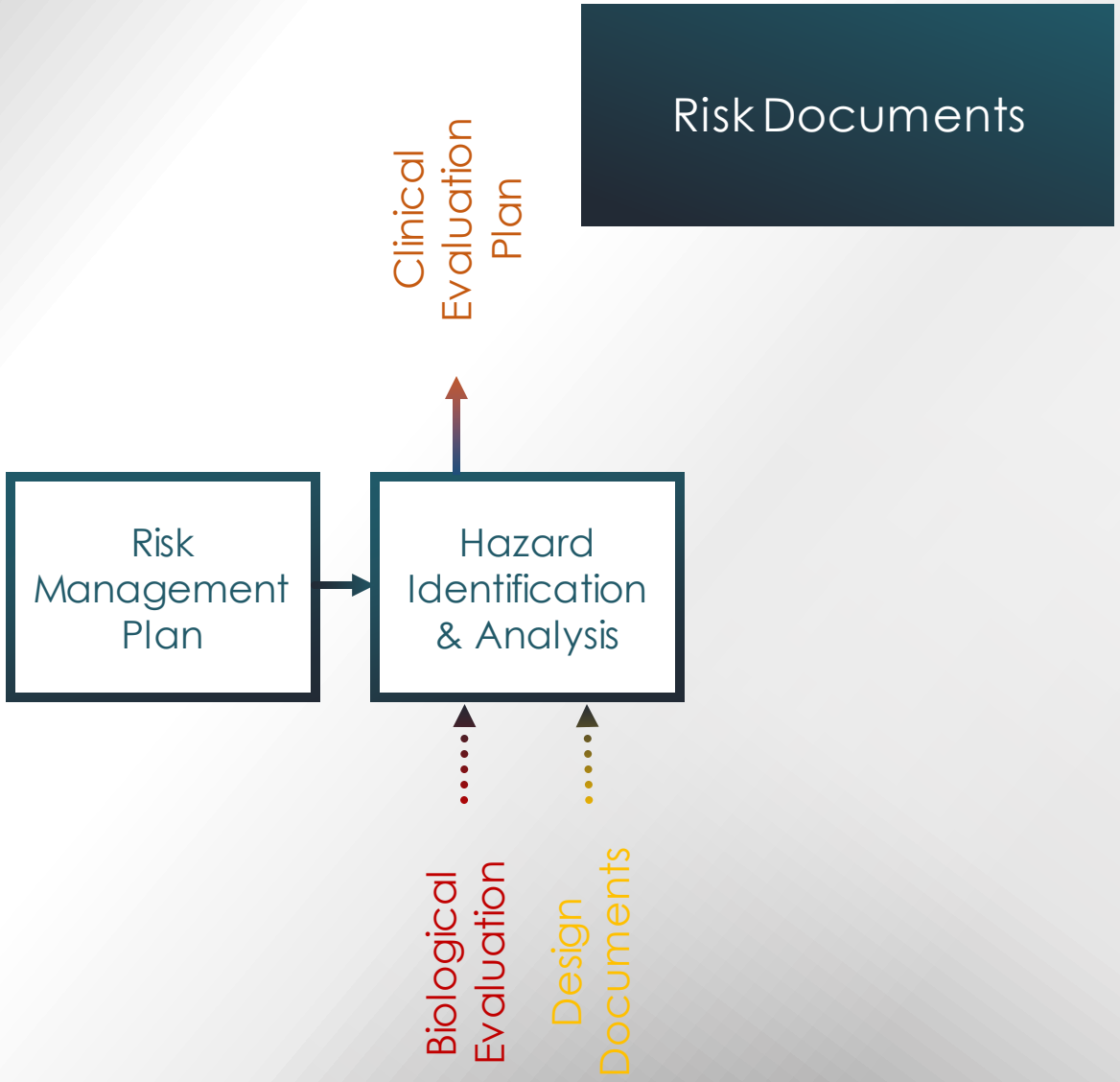
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Risk Documents



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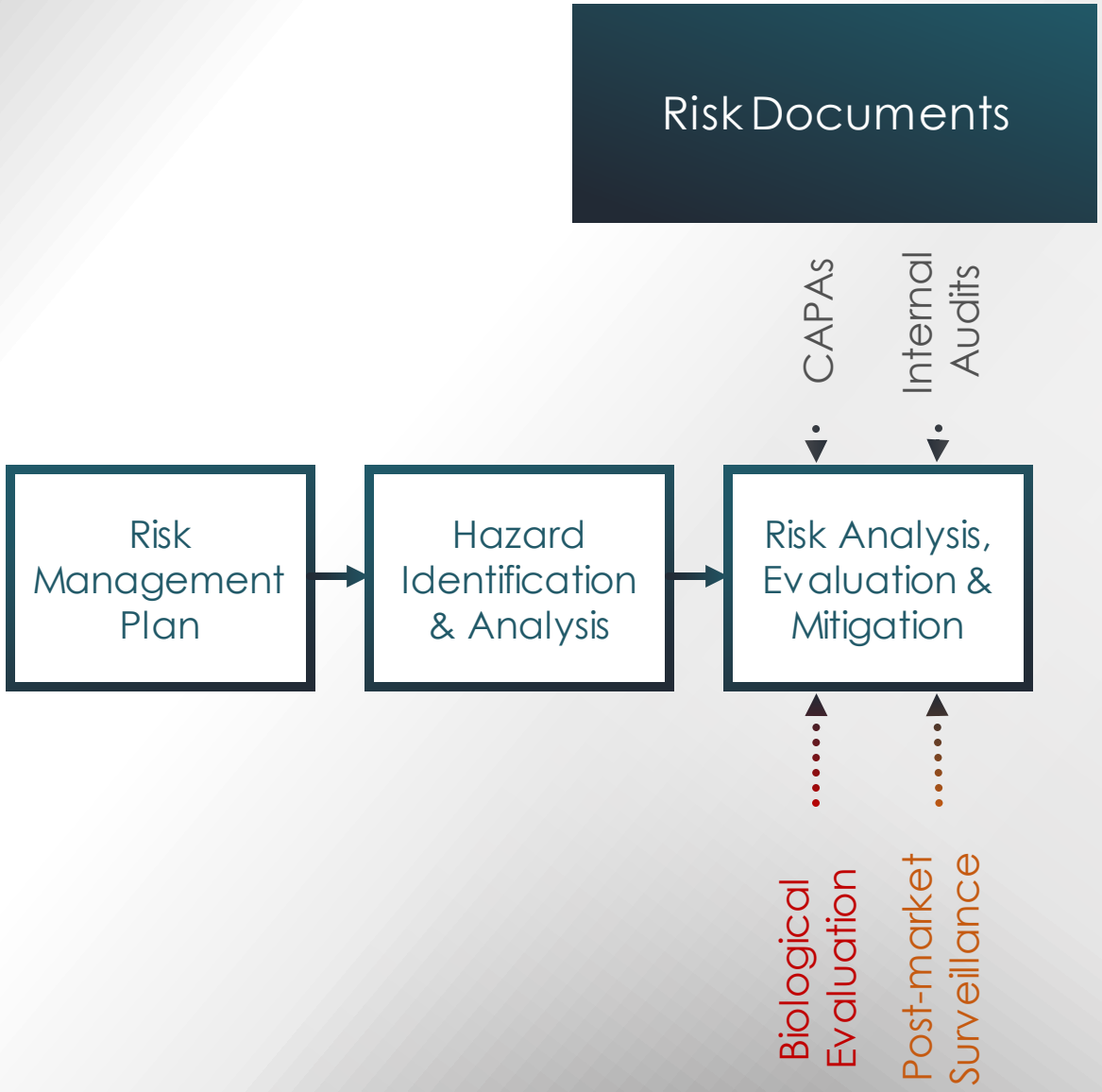
Risk Management

Risk Documents



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Risk Documents



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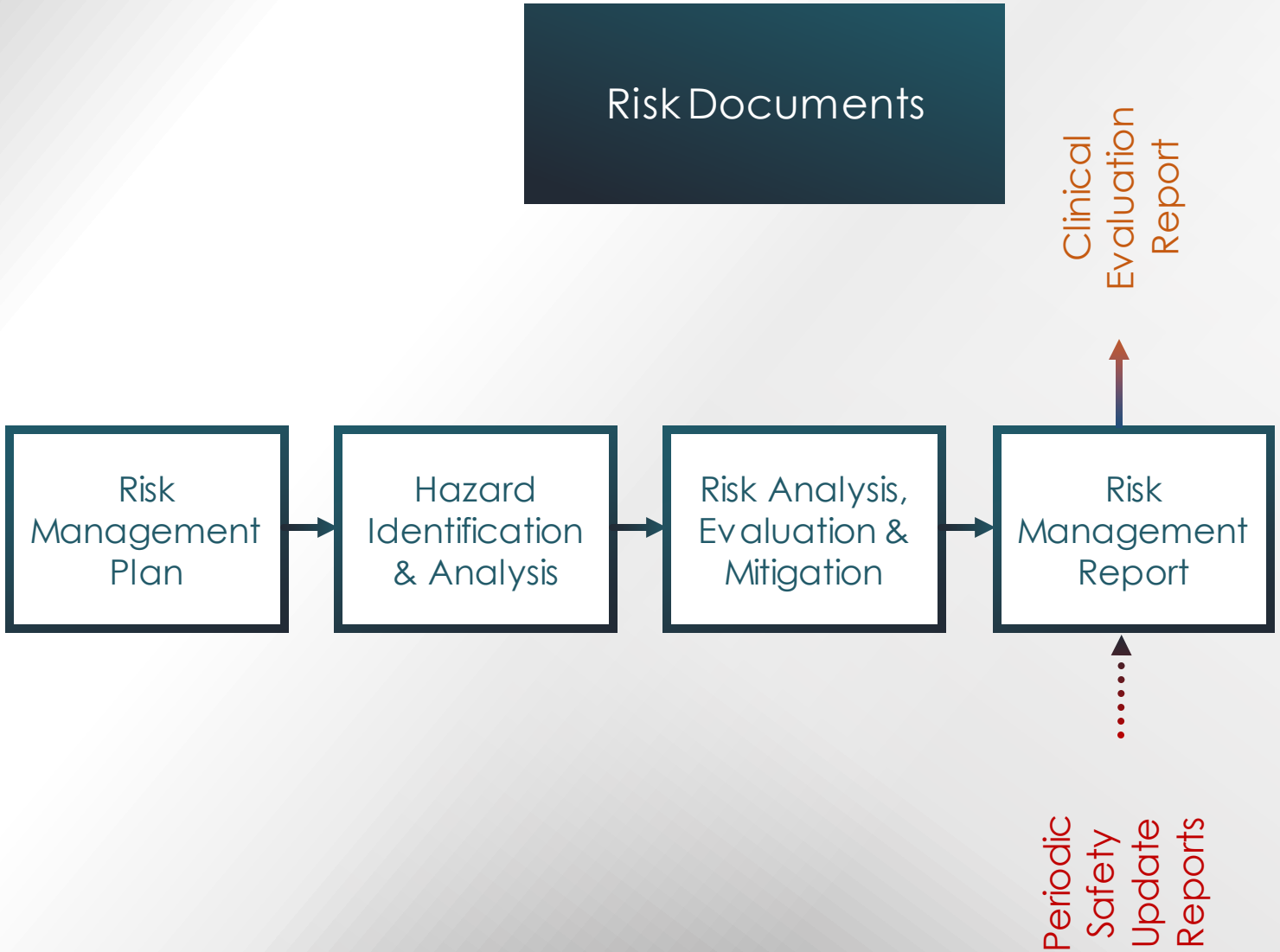
Risk Management

Risk Documents



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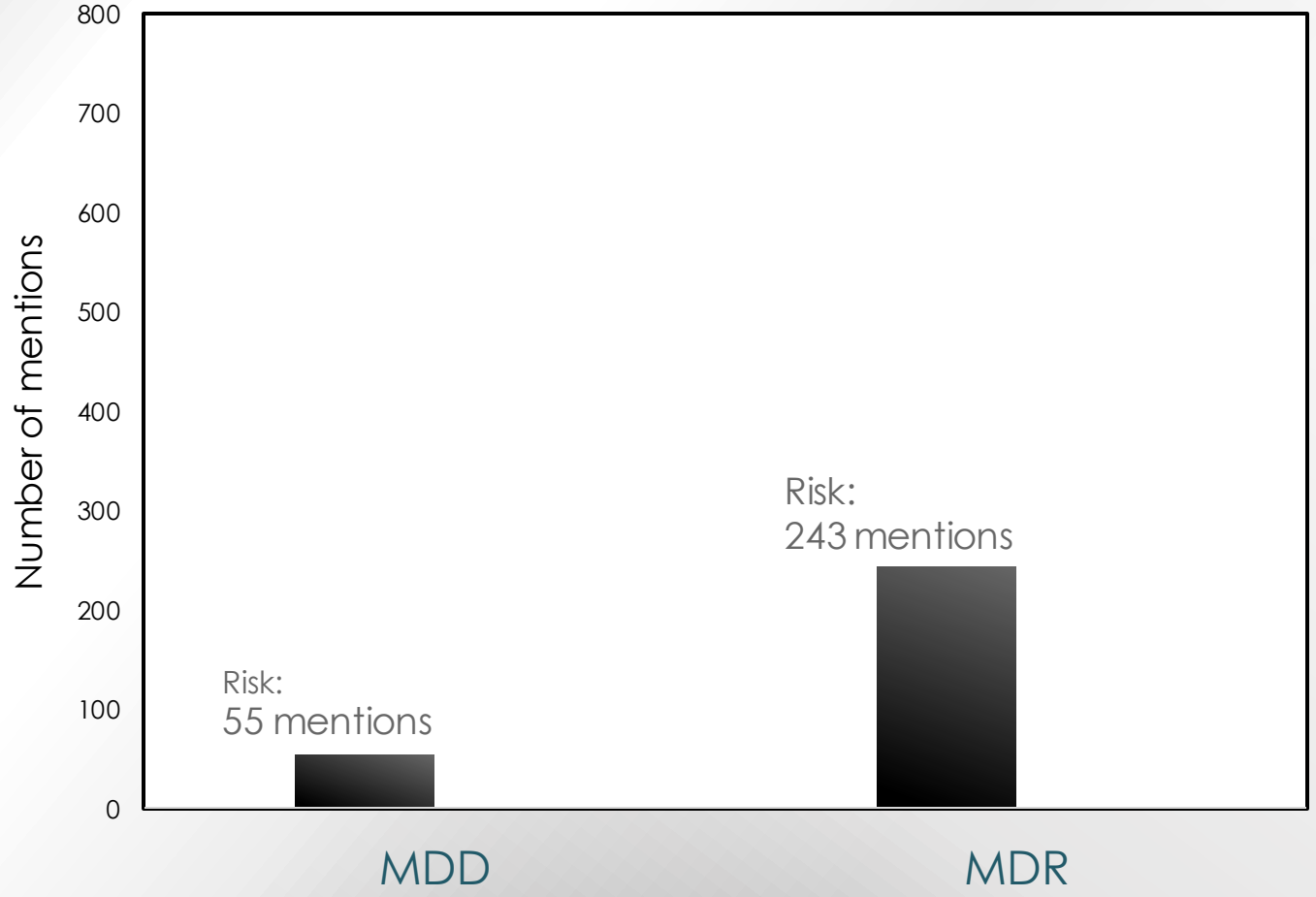
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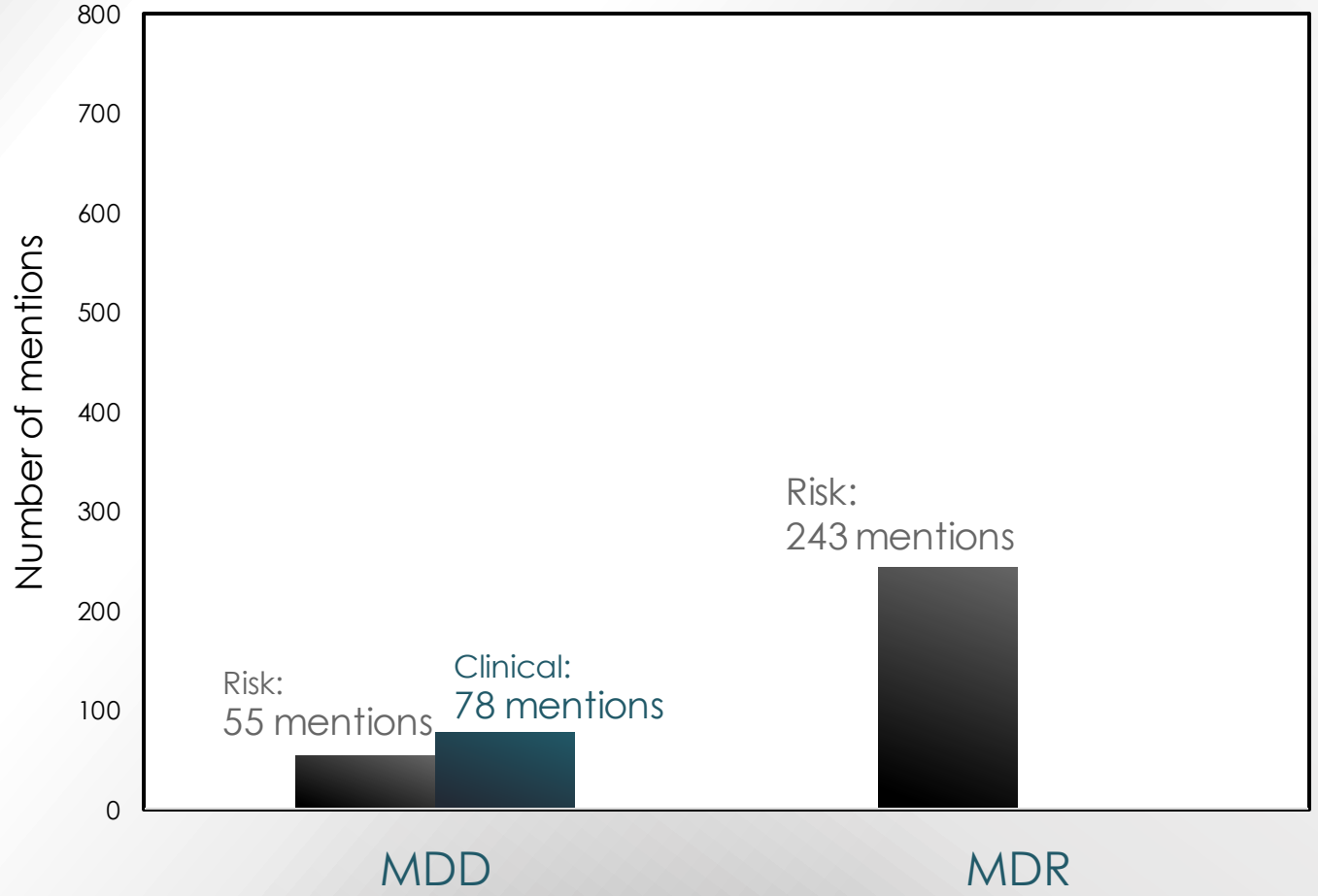
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Clinical Evidence



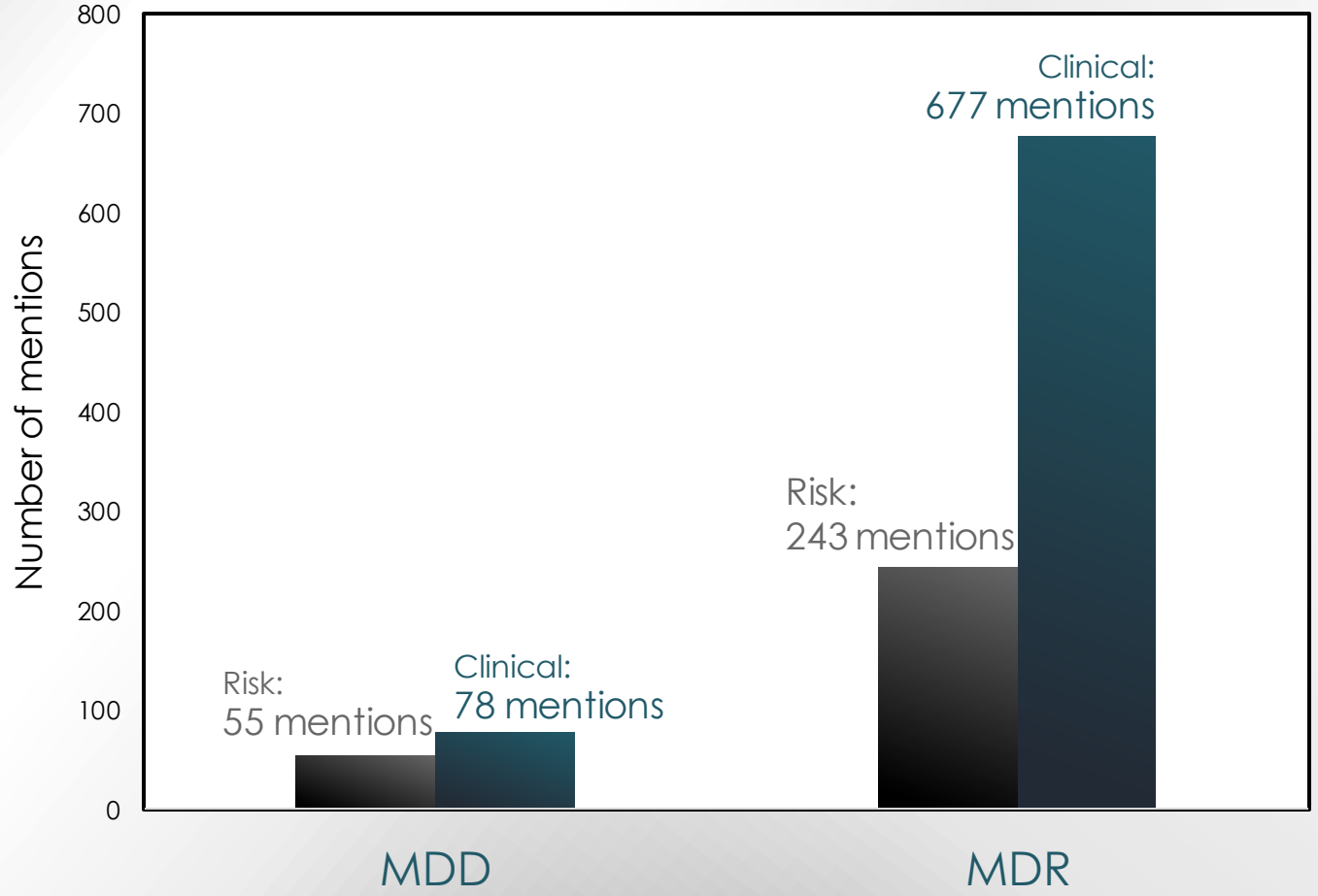
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Clinical Evidence



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Clinical Evidence



Clinical Documentation

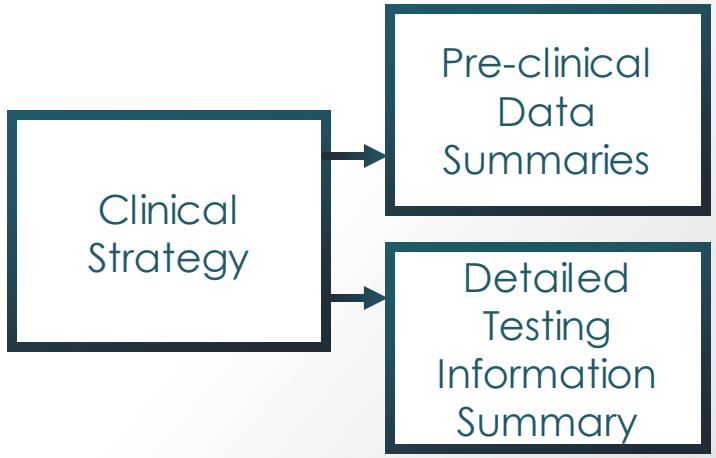
Clinical Evidence

Clinical Documentation

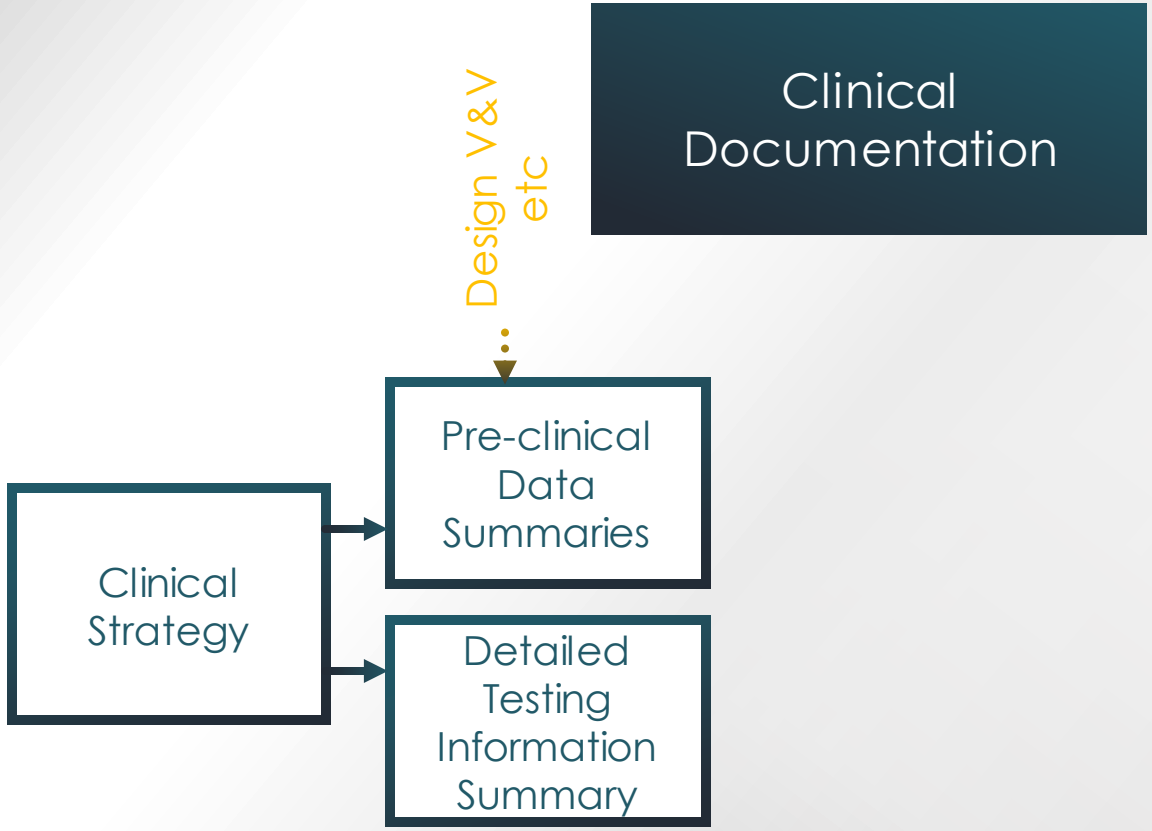
Clinical Strategy

Clinical Evidence

Clinical Documentation

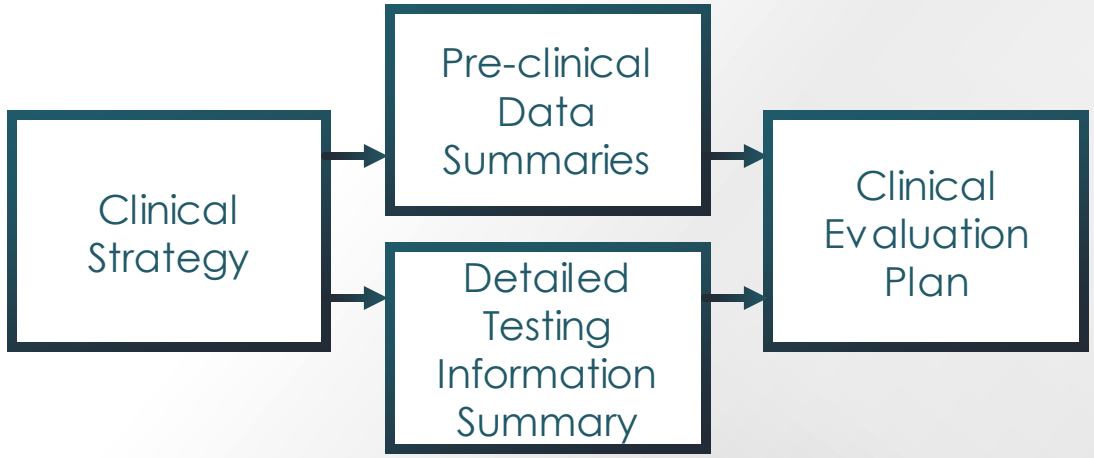


Clinical Evidence



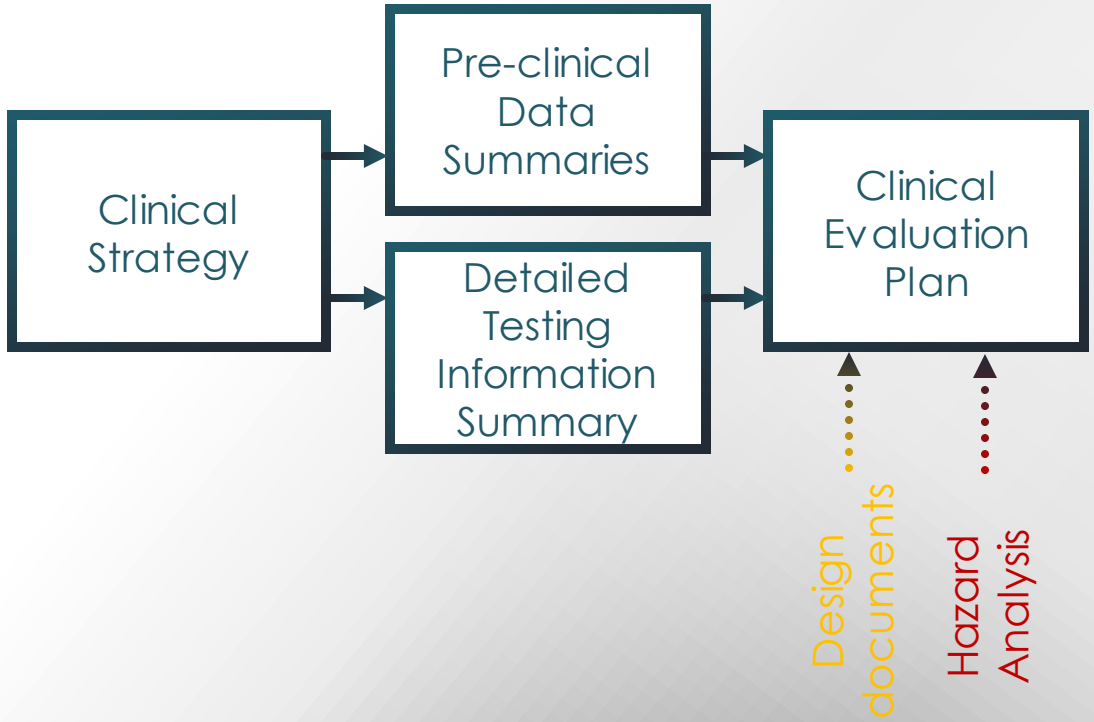
Clinical Evidence

Clinical Documentation



Clinical Evidence

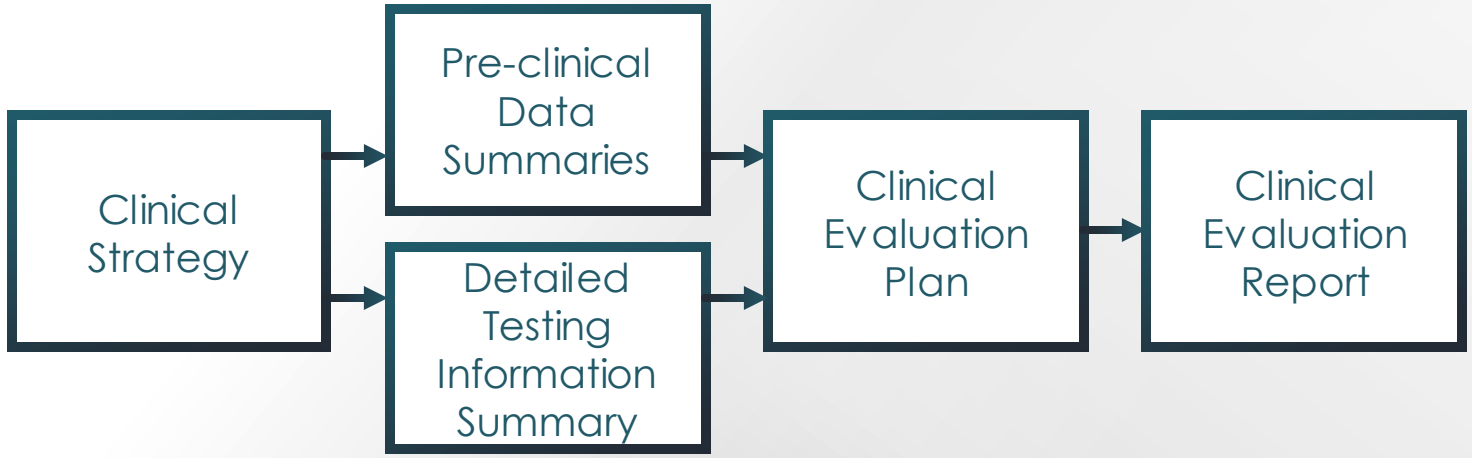
Clinical Documentation



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Clinical Evidence

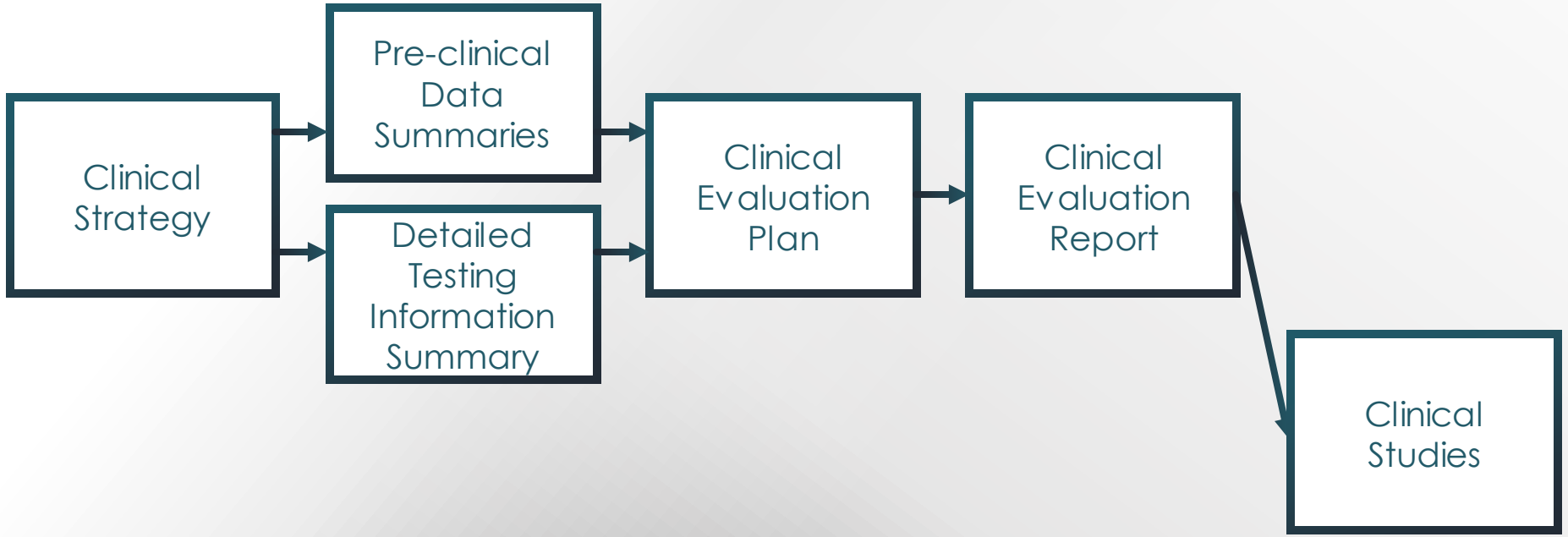
Clinical Documentation



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Clinical Evidence

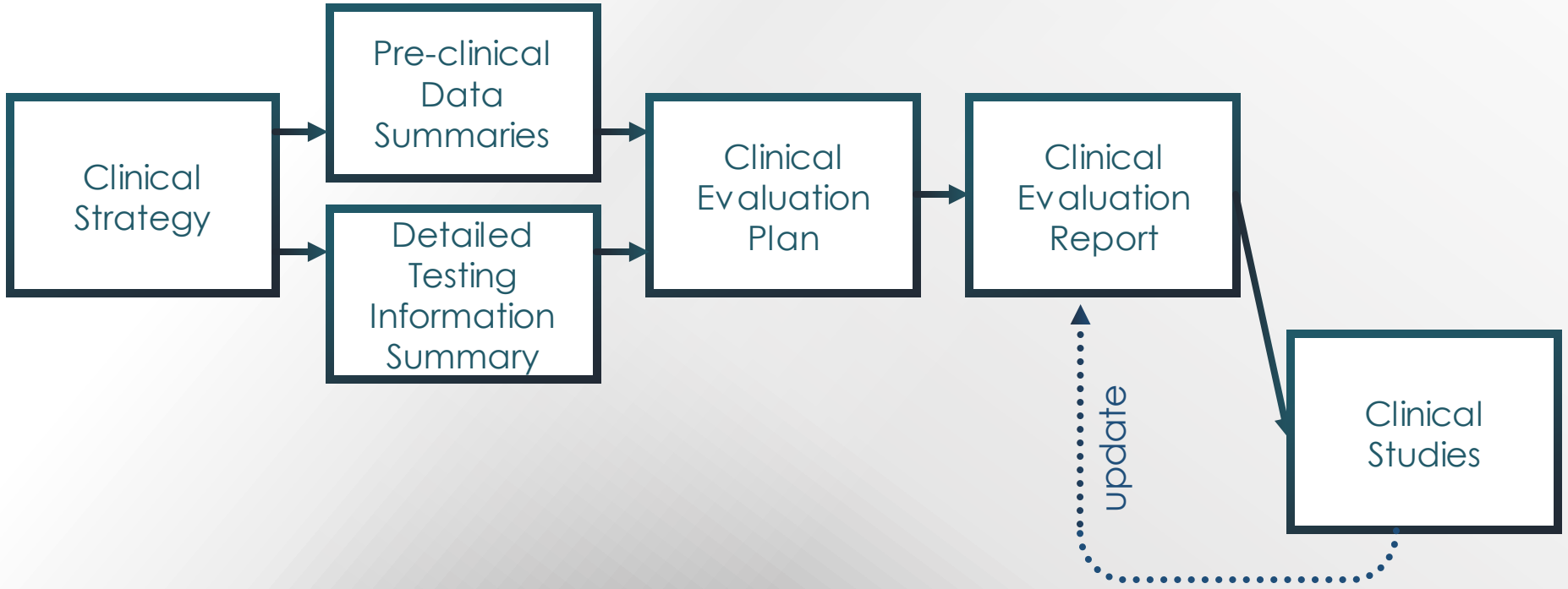
Clinical Documentation



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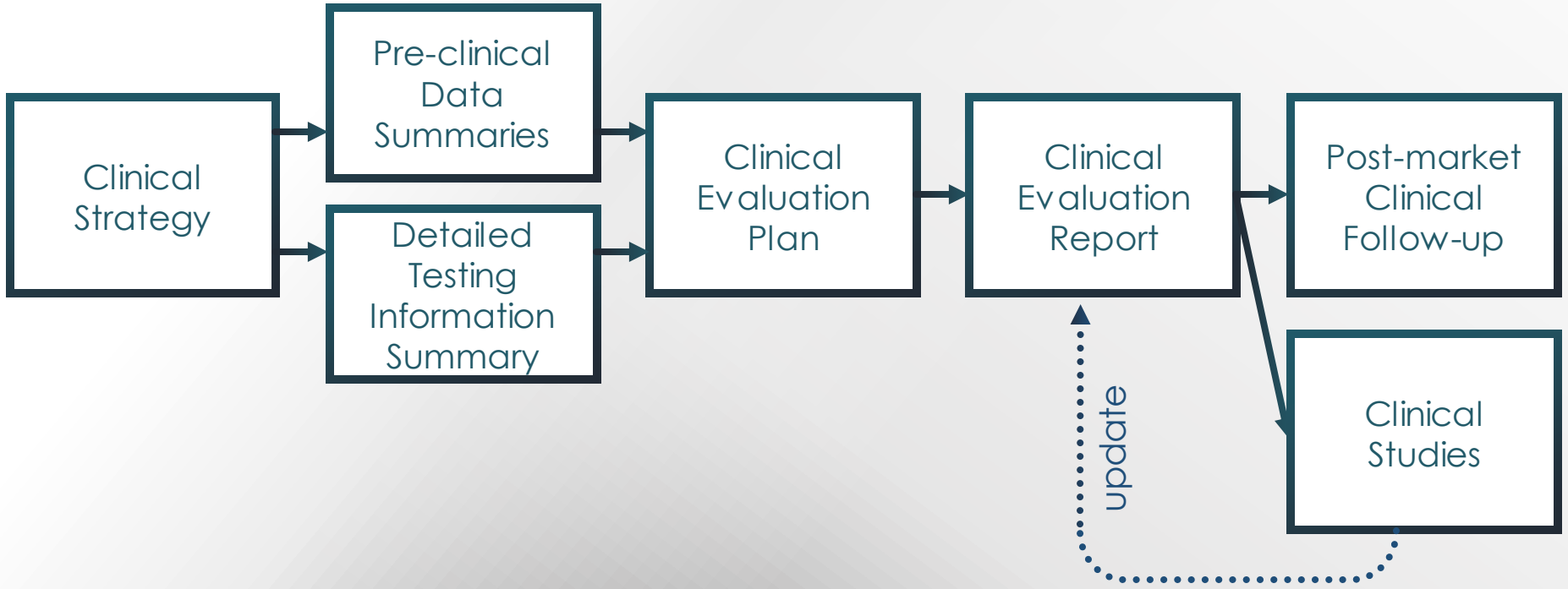
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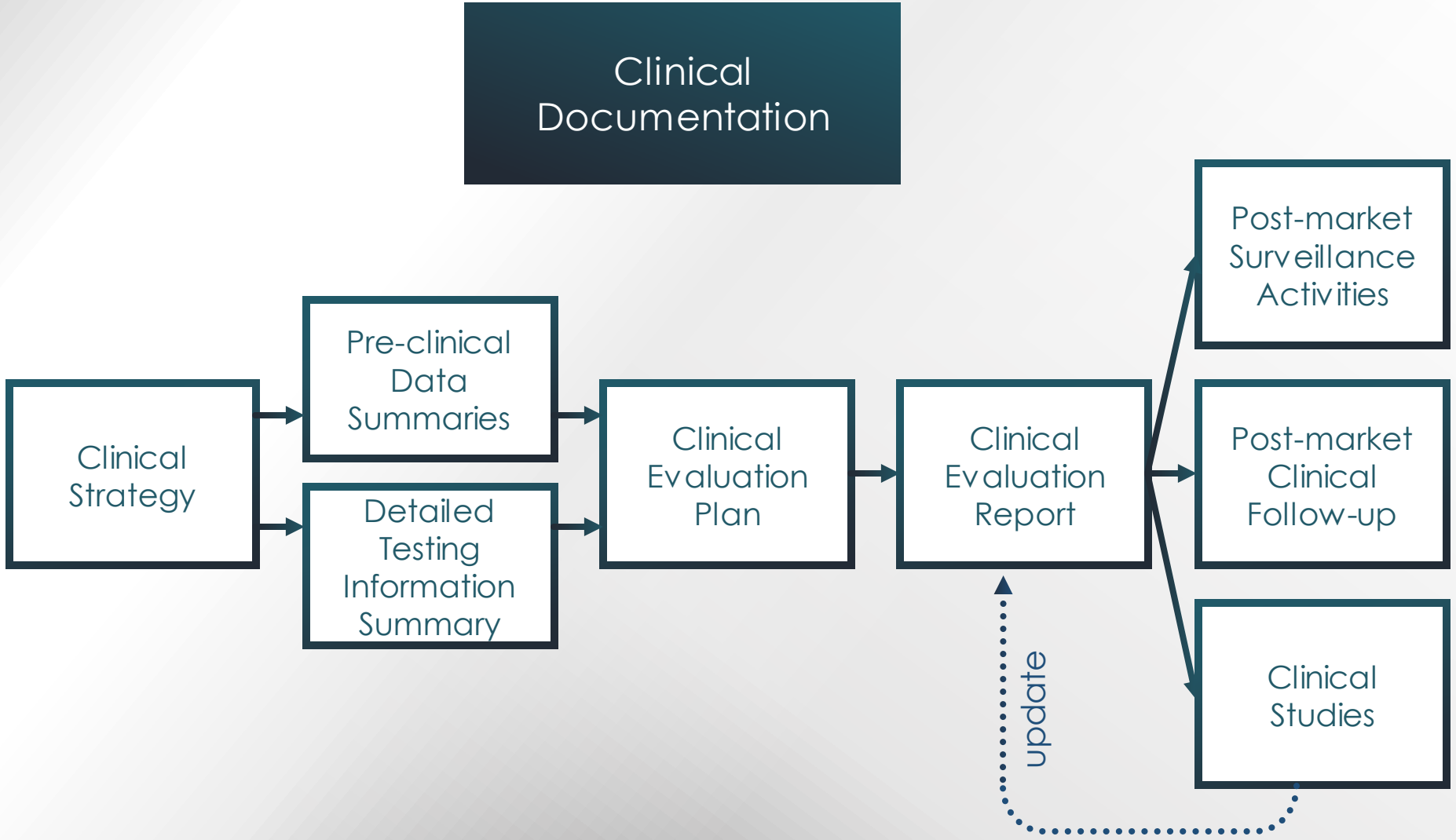
Clinical Evidence

Clinical Documentation



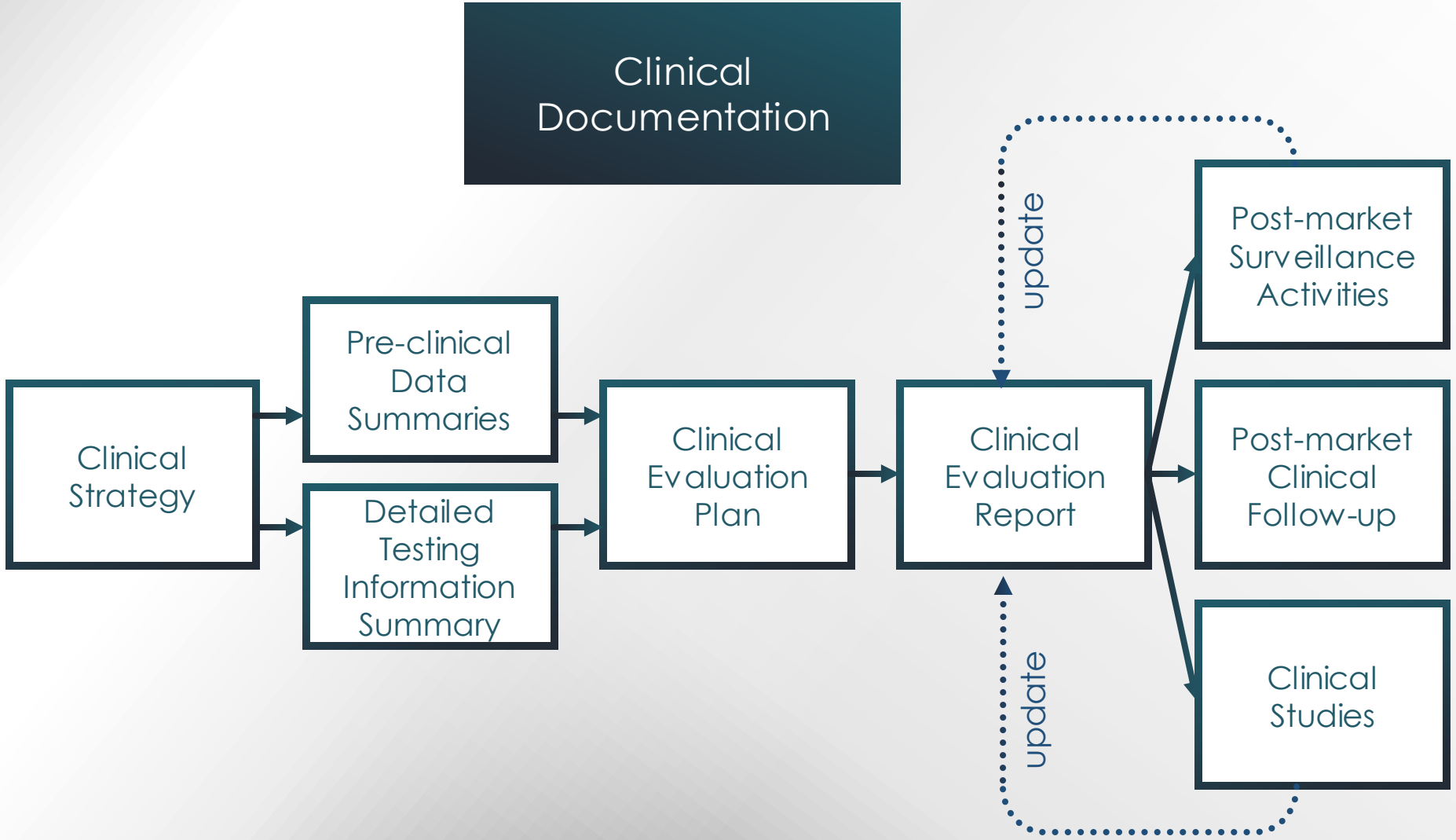
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Clinical Evidence



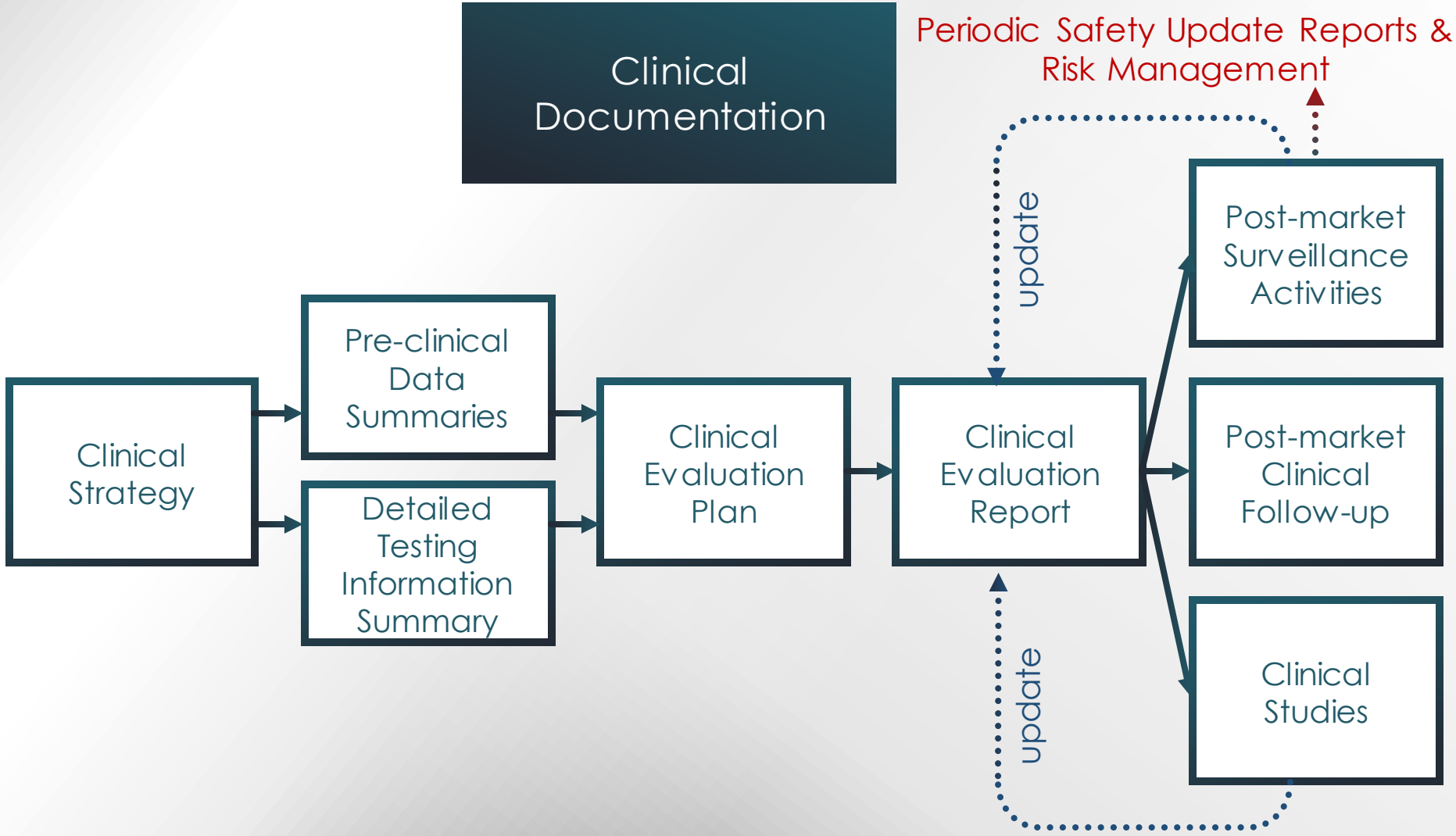
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Clinical Evidence



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Clinical Evidence



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Areas of focus

RISK MANAGEMENT

CLINICAL EVIDENCE

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'LIFECYCLE APPROACH'

USERS & USABILITY

DEVICE SUMMARY

DEVICE SUMMARY

CLINICAL DOCUMENTATION

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Users & Usability

DEVICE SUMMARY

CLINICAL DOCUMENTATION

USER NEEDS & SUBSEUQENT DESIGN DOCUMENTS

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Users & Usability

DEVICE SUMMARY

CLINICAL DOCUMENTATION

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RISK MANAGEMENT

USABILITY STUDIES

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Technical Documentation

Regulatory Documents

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Technical Documentation

Regulatory Documents

Design Documents

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Technical Documentation

Regulatory Documents

Design Documents

Risk Documents

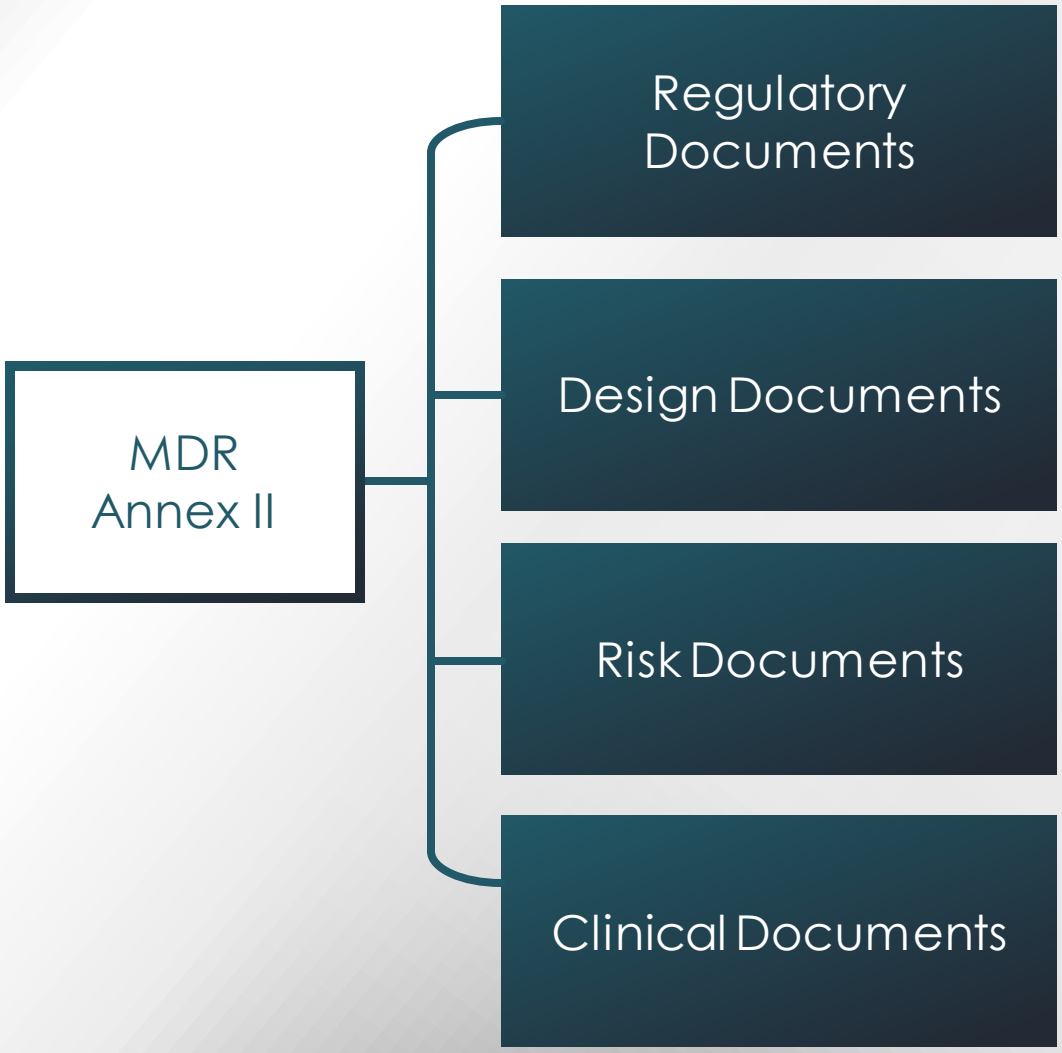
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Technical Documentation

- Regulatory Documents
- Design Documents
- Risk Documents
- Clinical Documents

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Technical Documentation



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Technical Documentation

Regulatory Documents

For example:

- GSPRs
- Qualification rationale
- Classification rationale
- Device Description
- IFUs & Device Literature
- UDI-DI information
- Regulatory Strategy
- Applicable Standards

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Technical Documentation

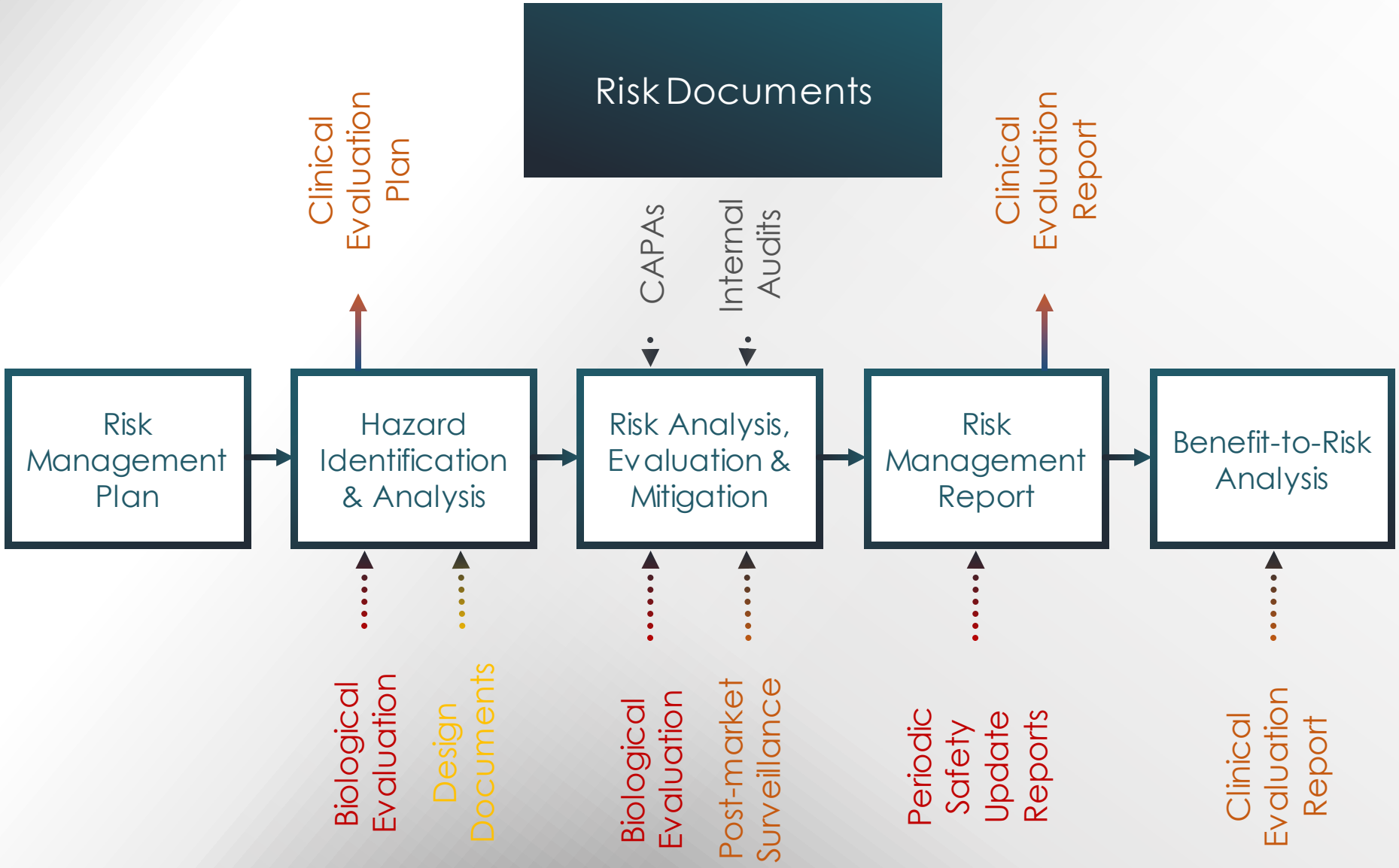
Design Documents

"Information to allow the design stages applied to the device to be understood."
For example:

- Design Plan
- Design Traceability Matrix
- Specs.
- Manufacturing information
- Manufacturing Validation
- Final Product Testing (inc. data)
- Design & Manufacturing sites
- Suppliers & sub-contractors

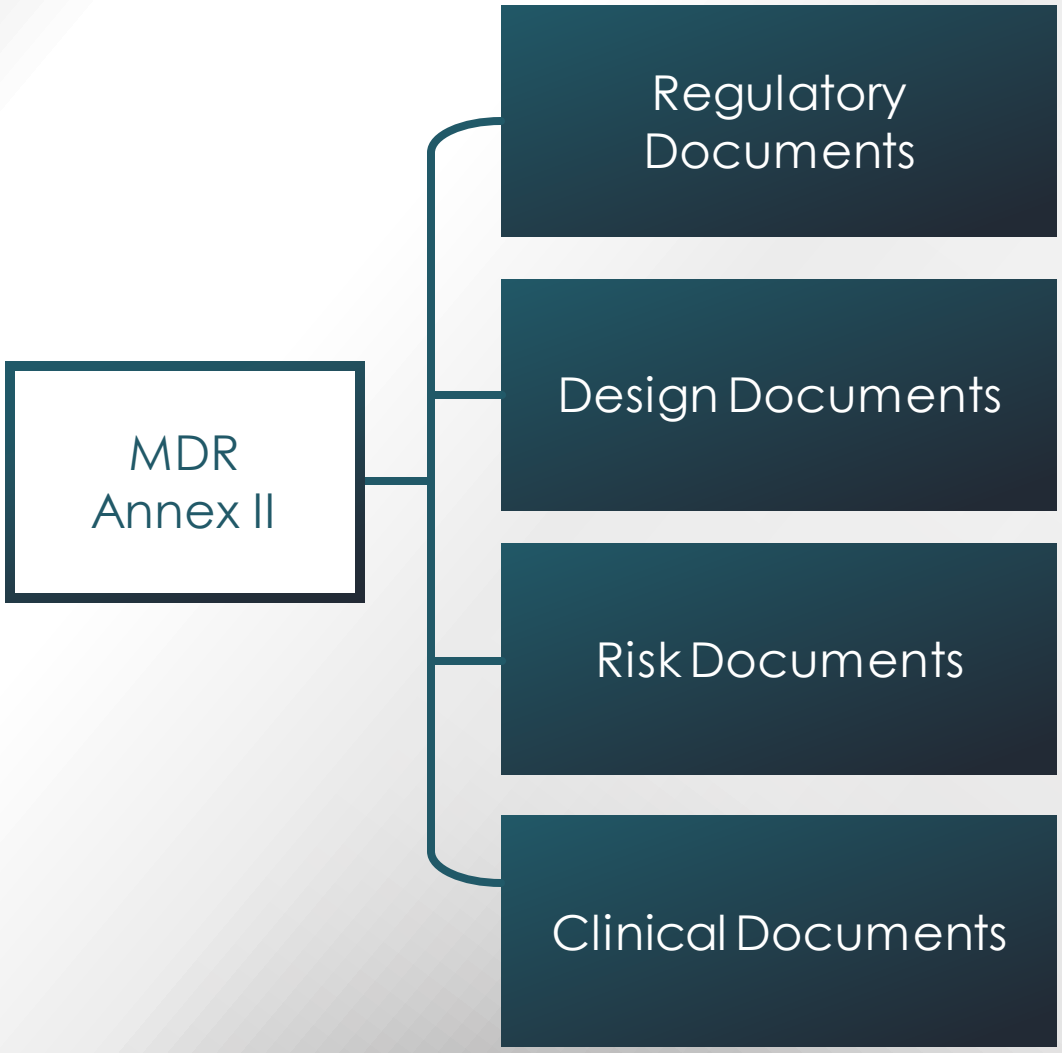
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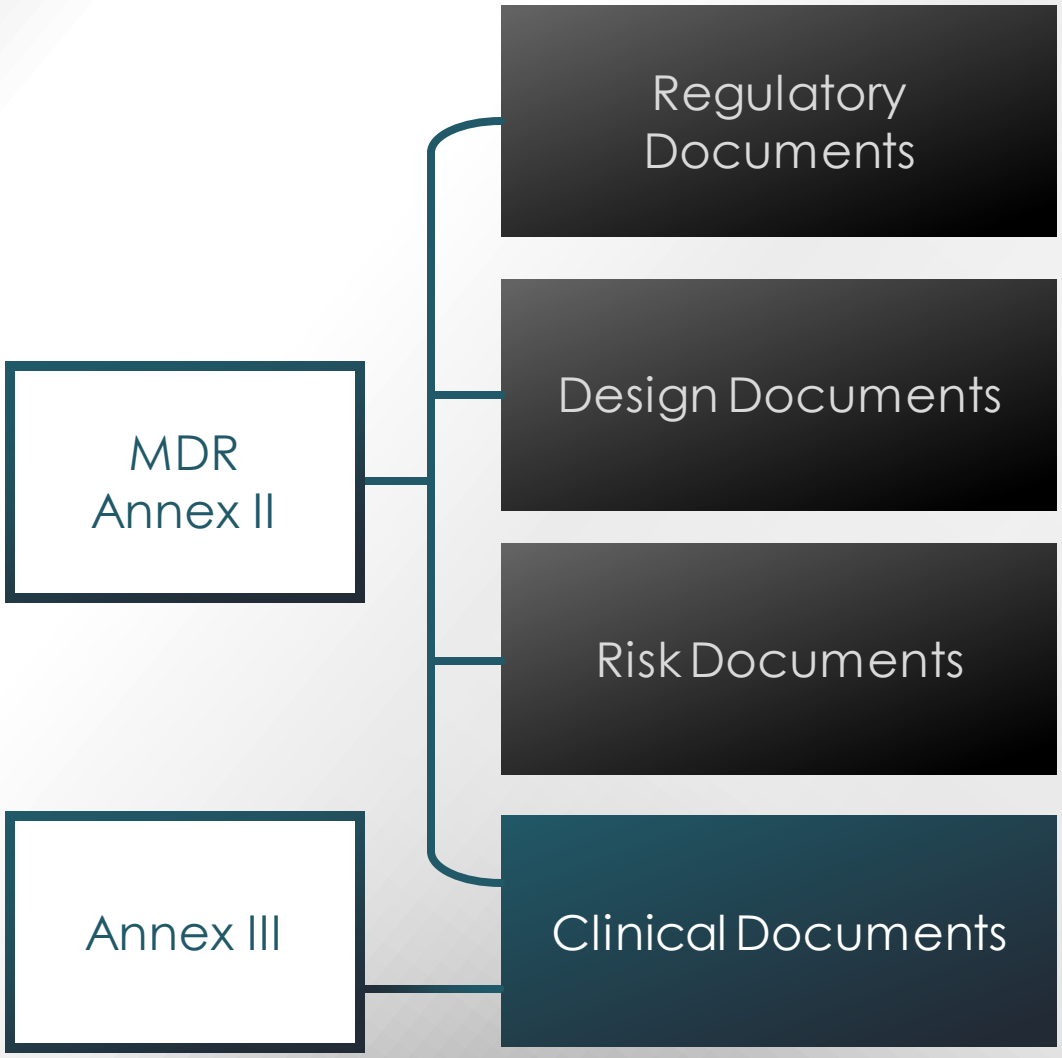
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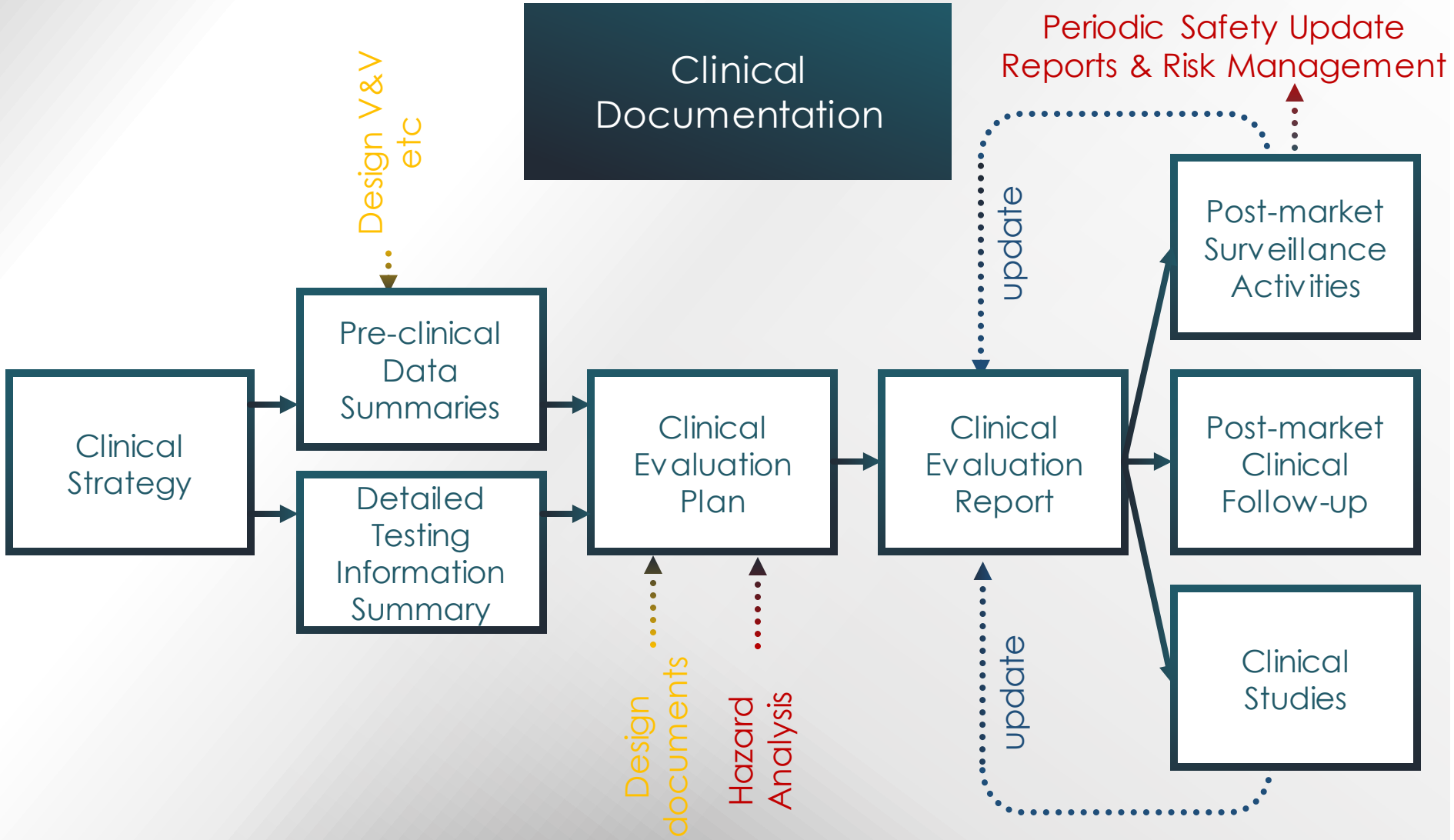
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Technical Documentation



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Technical Documentation



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Summary

WHO ARE SCIMED

WHERE TO START WITH YOU RA WORK

PRIMARY AREAS OF FOCUS

STRUCTURING TECHNICAL DOCUMENTATION

SciMed Consultancy Ltd

e | info@scimedconsultancy.co.uk

p | +44 7841 099357

w | www.scimedconsultancy.co.uk

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Agenda - PM

SME'S AND CONFIDENTLY TACKLING THE MEDICAL DEVICES REGULATIONS

Time	Session Details
13:45 – 14:15	NICE's Evidence Framework for digital health technologies
14:15 – 14:45	NHS England Tariff & reimbursements
14:45 – 15:15	Femeda case study & Q&A
15:15 – 15:30	Close

NICE National Institute for Health and Care Excellence

Digital Evidence Standards Framework

13th February 2019

Deborah Morrison, Principal Scientific Adviser

NICE Scientific Advice

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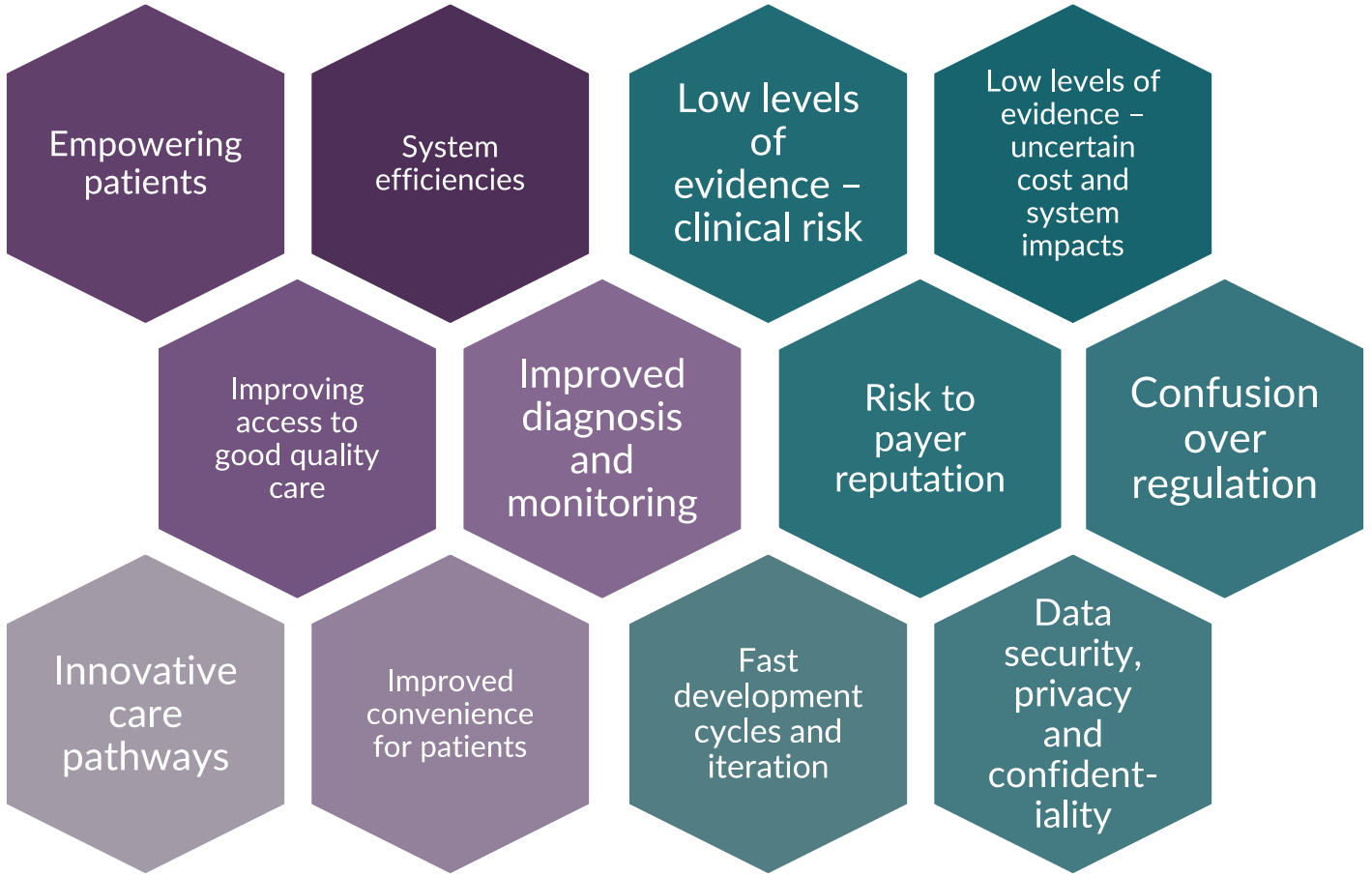
Challenges in assessing digital technologies

NICE

Why is NICE interested in digital healthcare?

Potential benefits

Challenges



NICE is interested in digital healthcare……

Policy landscape in the UK

- Matt Hancock - New secretary of state for health and social care (2018)
  - Digital enthusiast, keen to promote the use of digital health technologies in health and social care

- September 2018 – Code of conduct for data-driven health and care technology (update due February 2019)
  - 10 principles for developers of digital healthcare
  - 5 commitments from government

- October 2018 – Policy Paper: The future of healthcare: our vision for digital, data and technology in health and care

- October 2018 – NHS digital, data and technology standards

Digital healthcare evaluation at NICE to date

- Guidelines — Inclusion of DHTs in care pathways for a condition

- NICE advice — Rapid HTA using existing methodologies
  - Medtech innovation briefings (MiB)

  Bespoke methodologies for digital healthcare?
  - Healthcare app briefings (pilot work)
  - IAPT assessment briefings

- NICE Scientific Advice
  - Medtech Early Technical Assessment Tool (META)
  - Medtech Advice

- **Guidance — For named digital healthcare technologies (DHT) – not yet!**

- **Evidence frameworks for digital healthcare (Dec 2018)**

Rationale for the Digital Evidence standards…..

When considering new technologies for use in the NHS……

…..the 3 E's



Does it work in Clinical Trials?

Does it work in Clinical Practice?

Does it contribute to more efficient use of resources?

Value for Money?

NICE

When considering new technologies for use in the NHS……

…..the 3 E's



Does it work in Clinical Trials?

Does it work in Clinical Practice?

Does it contribute to more efficient use of resources?

Value for Money?

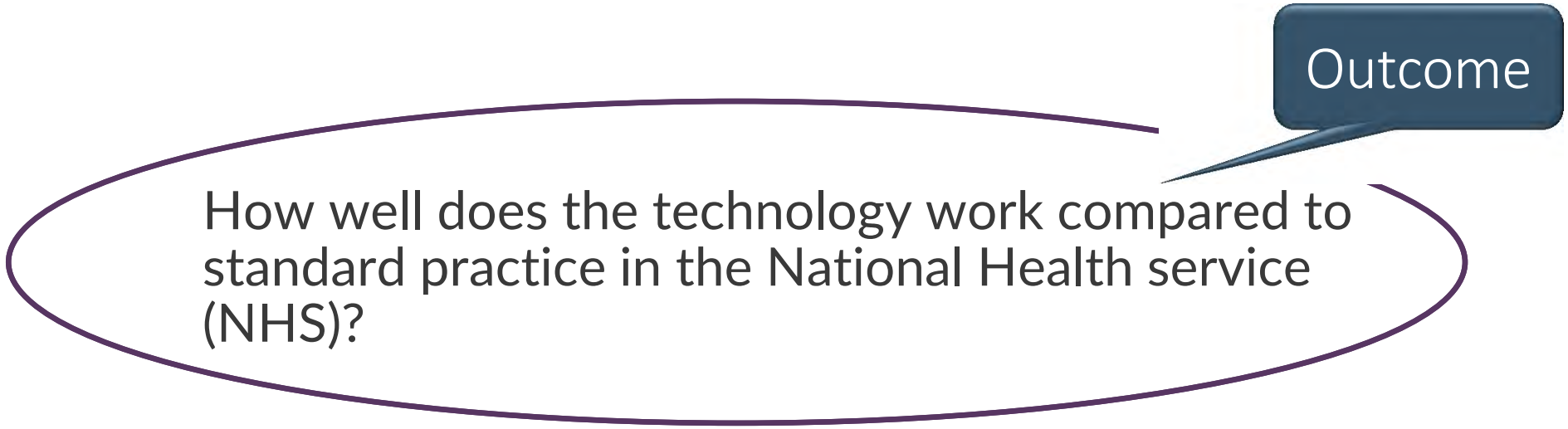
NICE and NICE SA

Two key questions that NICE considers:

How well does the technology work compared to standard practice in the National Health service (NHS)?

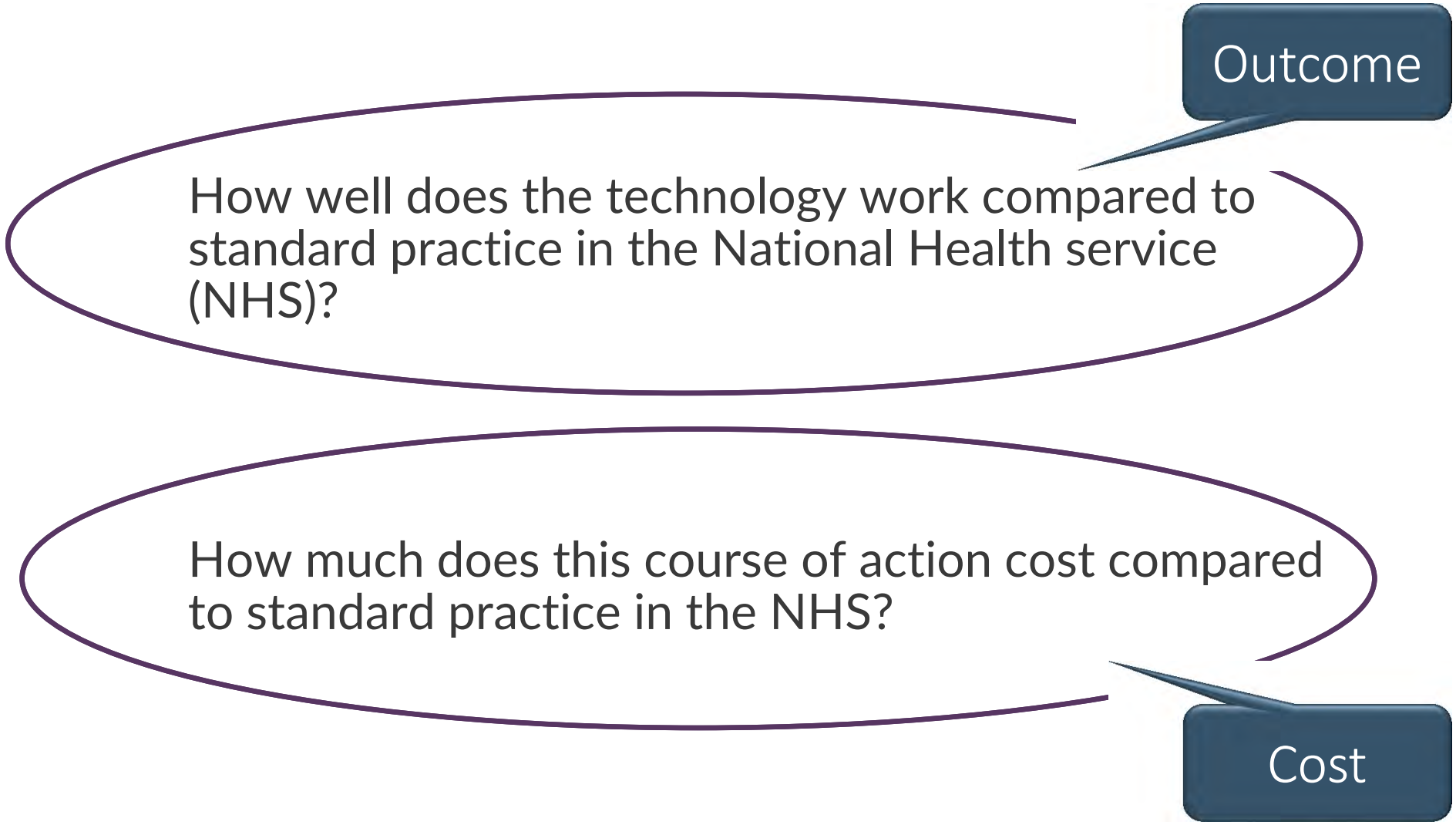
How much does this course of action cost compared to standard practice in the NHS?

Two key questions that NICE considers:



How much does this course of action cost compared to standard practice in the NHS?

Two key questions that NICE considers:



…. Cost versus Value

- **For every decision made for a health technology there is an opportunity cost**

- **Economic analysis - used for the optimal allocation of scarce resources**

How much evidence is enough?

How much evidence is enough?



NICE

How much evidence is enough?



It depends on what you're trying to demonstrate…

How much evidence is enough?



It depends on what you're trying to demonstrate…

….your Value Proposition

NICE

Introduction to the Evidence Standards framework for digital health technologies (DHT)



Published 10th December 2018

The aims of the Digital Evidence Standards Framework (ESF) are to:

- **Provide advice to digital health innovators:**
  - What does good look like?; the standards of evidence developers will be expected to produce for different types of digital technologies.

- **Help NHS commissioners make better informed decisions**

- **Improve the approach to developing and commissioning digital health technologies**

Evidence standards framework for digital health technologies

Key Questions:

- How much/what kind of evidence is needed to show effectiveness?

- How much/what kind of evidence is needed to show the economic impact?

The structure of the digital ESF

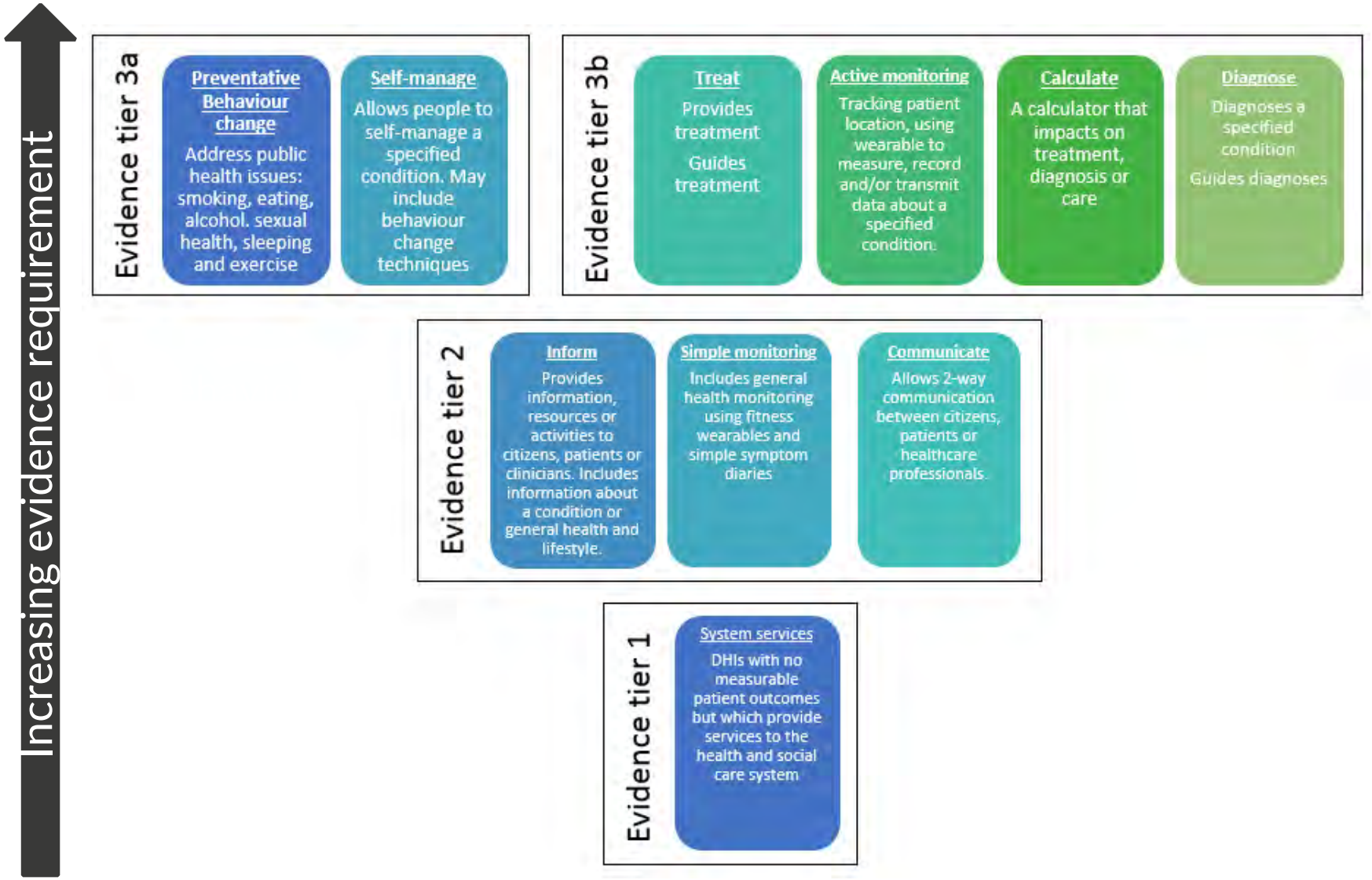
- The evidence standards framework is made up of 2 sections:
  - **Evidence for effectiveness for intended use.**
    - Approach for (clinical) effectiveness considers:
    - Risk-based classification of DHT function:
    - higher risk to user = greater evidence requirement
  - **Evidence for economic impact.**
    - Approach for economic impact considers that:
    - Higher expected cost of purchase and implementation = greater economic evidence requirement

The context and what you need to think about:

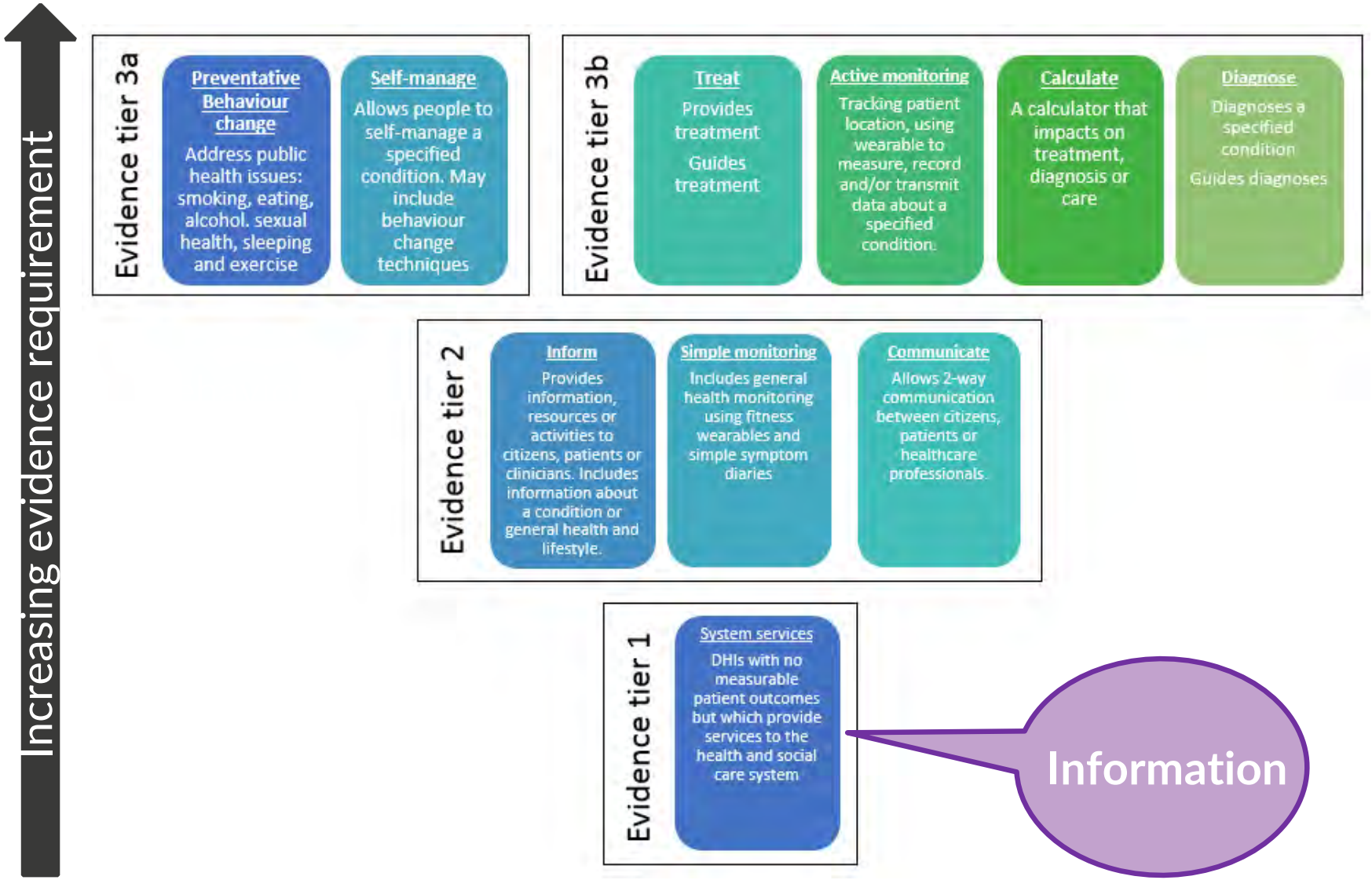
…four contexts which may influence the level of evidence needed:

1. The type of product (functionality)
2. The risk to the patient
3. The need for CE marking
4. The budget impact (risk to the healthcare system)

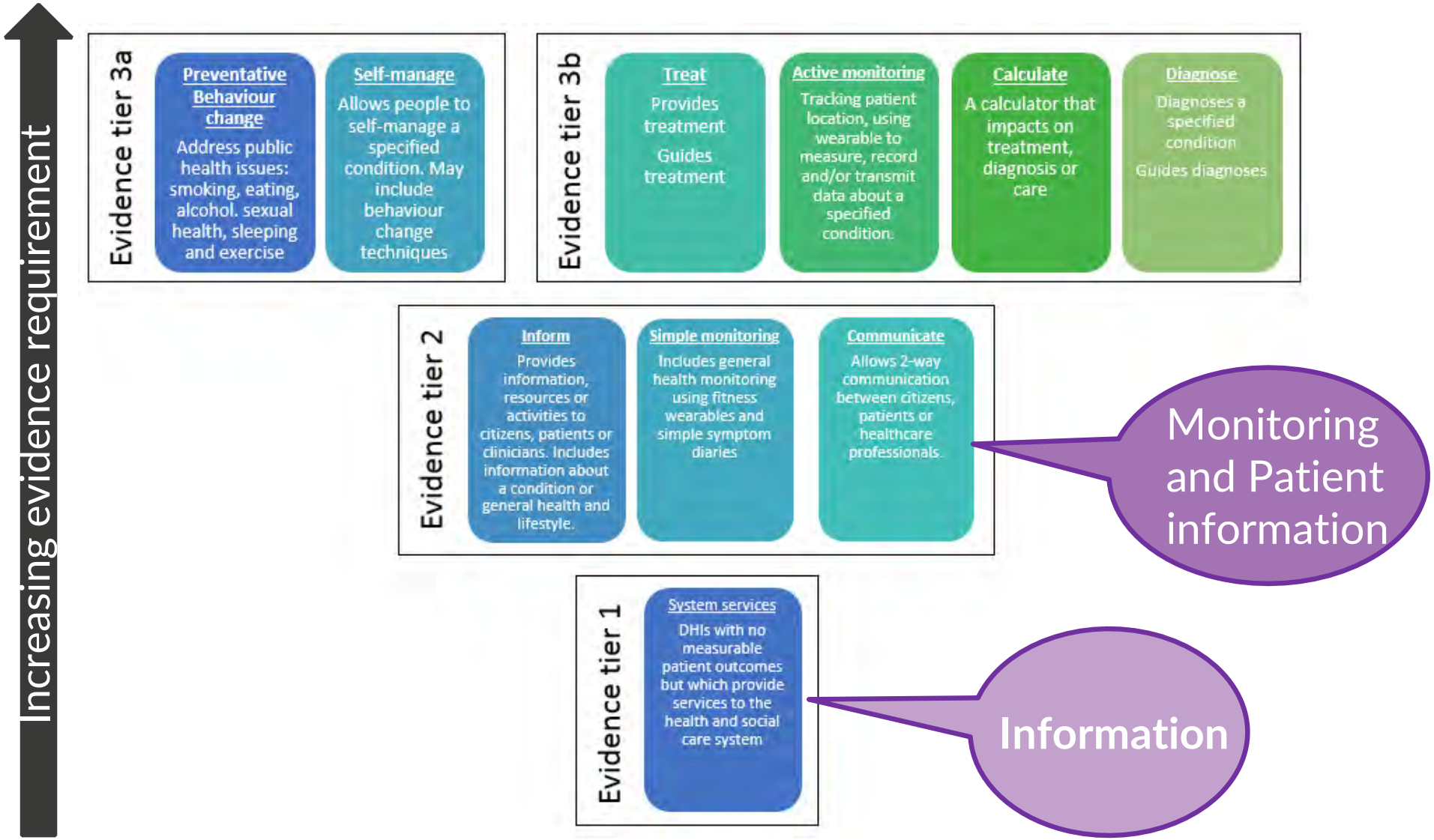
Risk-based functional classification



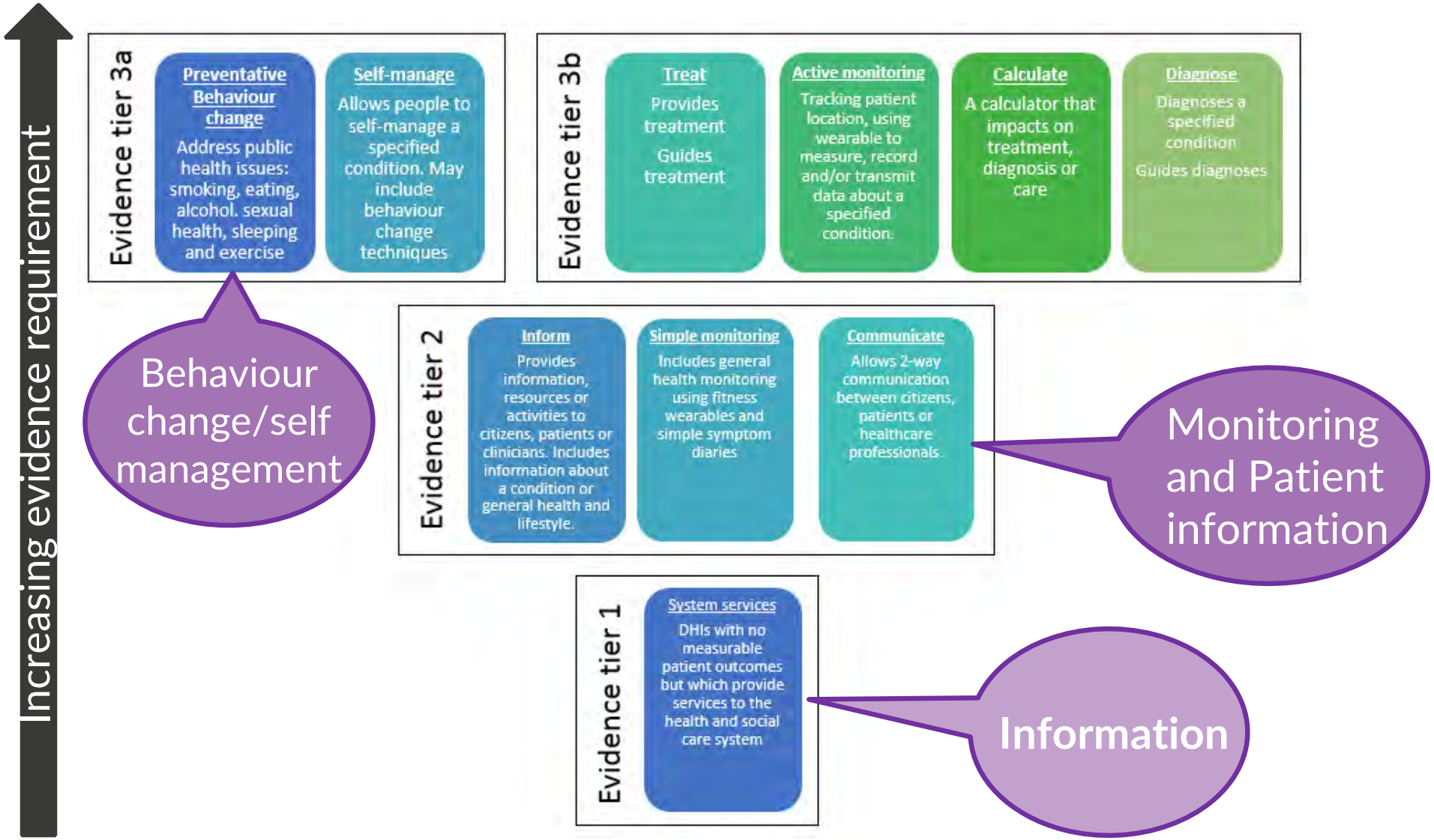
Risk-based functional classification



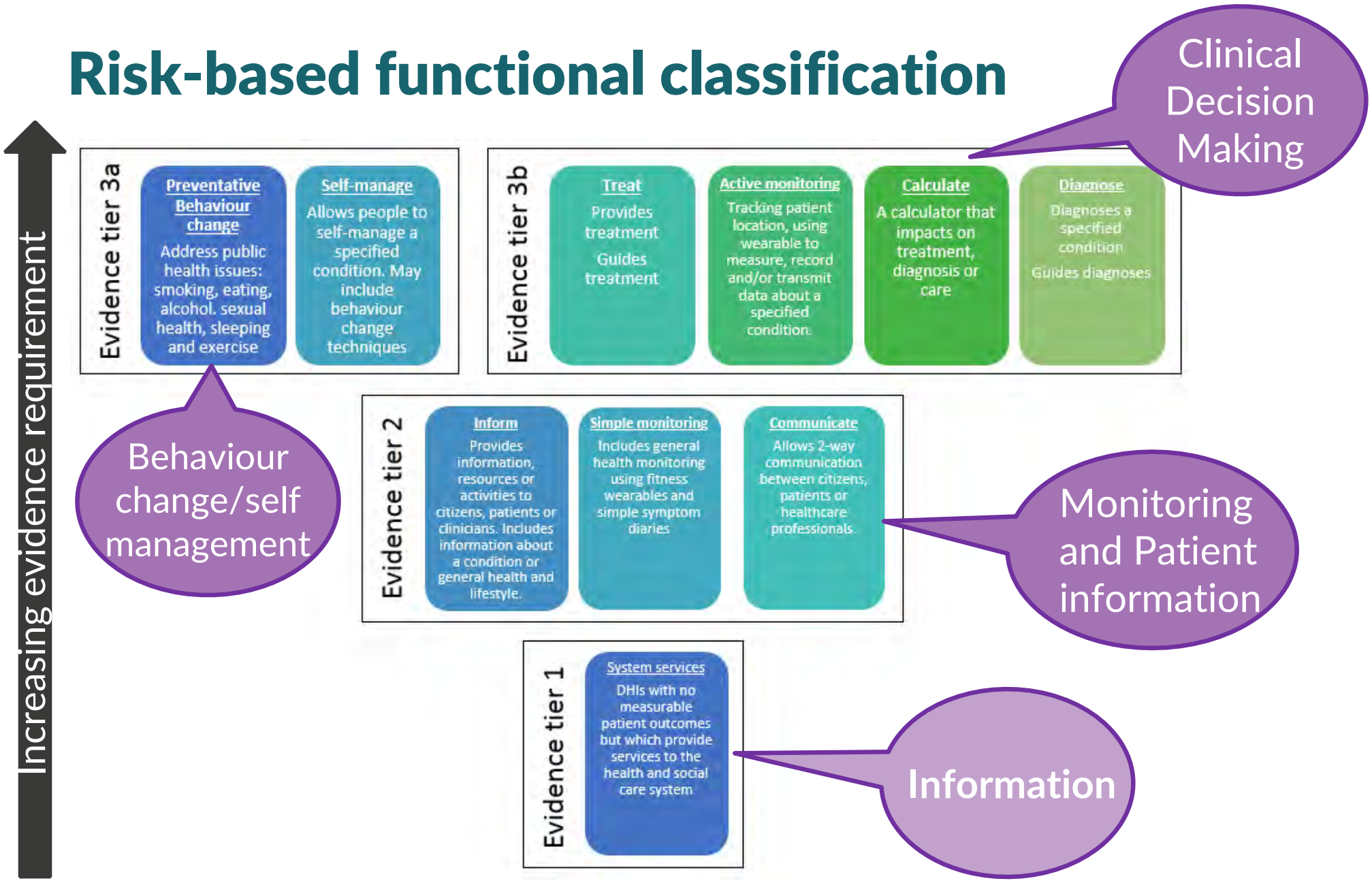
Risk-based functional classification



Risk-based functional classification



Risk-based functional classification



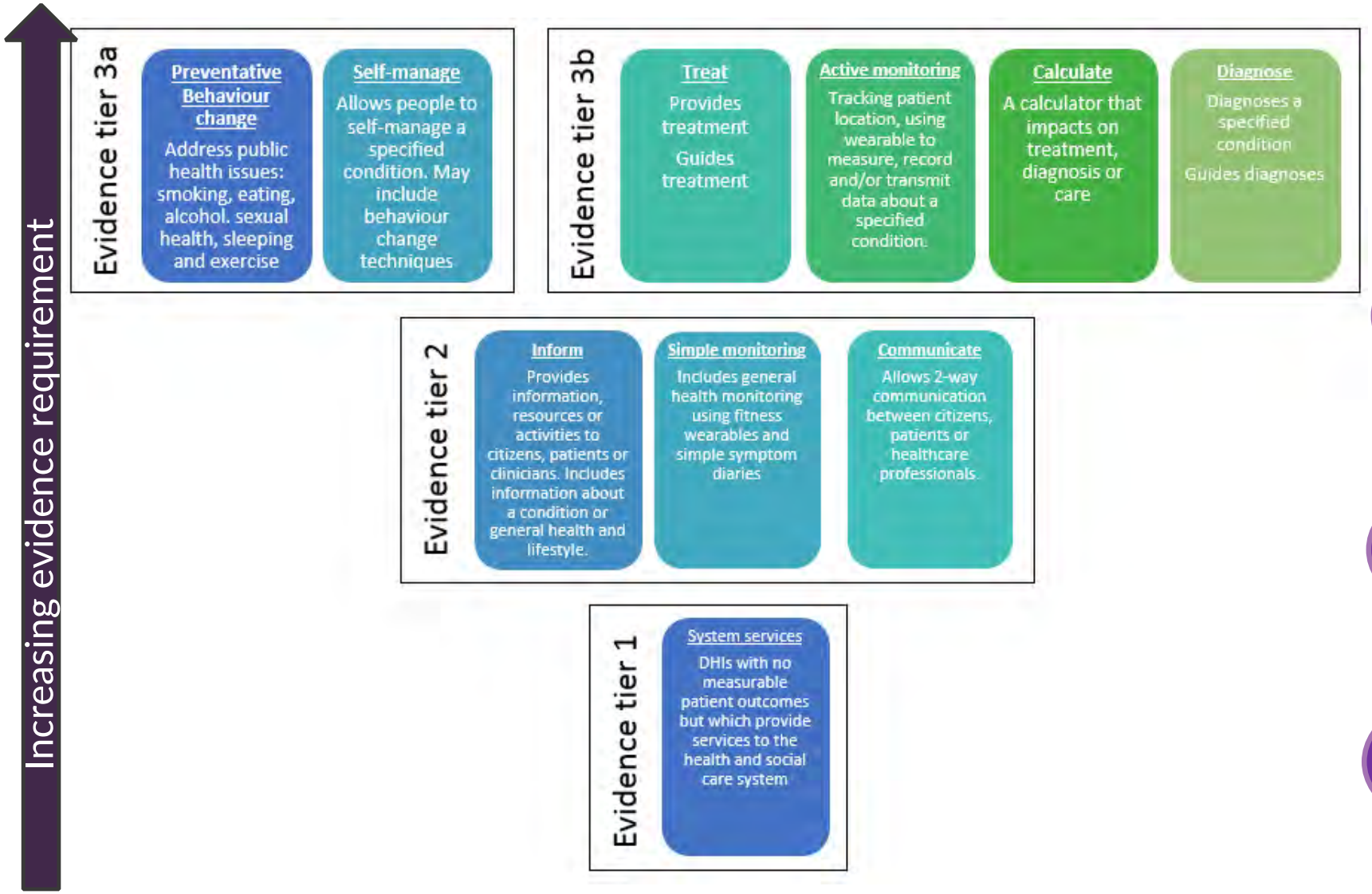
ESF and regulation

- The ESF does NOT consider whether a CE mark is necessary

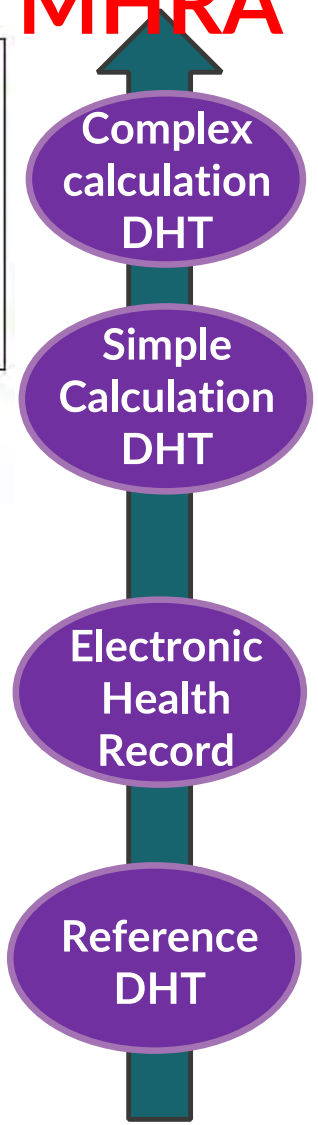
…however, the evidence standards in tier 3b are broadly complementary to requirements for CE marking

You may not need a CE mark – this does not mean you do not need evidence….

Risk-based functional classification



MHRA



NICE

(Clinical) effectiveness tiers and evaluation

There is an evidence table associated with each evidence tier:

The tables show 2 levels of evidence for the criteria in each tier: a minimum evidence standard and a best practice standard.

Best practice evidence standards in each relevant evidence tier should be used for DHTs that present a potential high risk

Evidence requirements (in brief)

3 cumulative tiers of evidence

- **Tier 1 evidence includes:**
  - Documenting the role of health/care experts in the design, development, testing or sign off of the DHT
  - Demonstrate successful pilot in UK H&SC system
  - Demonstrate user testing and satisfaction

- **Tier 2:**
  - Demonstrate that health information is valid, accurate, up to date, sufficiently comprehensive and is reviewed and updated regularly
  - Commitment to ongoing data collection to show usage and value in line with value proposition

- **Tiers 3a and 3b**:
  - Good quality comparative trial evidence

Evidence for effectiveness standards for tier 3b DHTs

Demonstrating effectiveness: minimum standard	Demonstrating effectiveness: best practice standard
• High quality quasi/experimental comparative study reporting difference between groups having different/no treatment. • Requires statistical considerations, relevant and inclusive reporting of outcomes • Ideal comparator is standard of care, could also be before-and-after • Outcomes should reflect best practice for reporting improvements in the specific condition, using validated measures such as in the COMET core outcome set.	• High quality RCT trial randomly assigning people to DHT or comparator • Requires statistical considerations, relevant and inclusive reporting of outcomes, relevant follow-up • Ideal comparator is standard of care, could also be before-and-after • Outcomes should reflect best practice for reporting improvements in the specific condition, using validated measures such as in the COMET core outcome set.

(Cost) effectiveness tiers and evaluation

Economic evidence standards

- aim to provide a consistent and streamlined pathway for appropriate economic assessment of DHTs

- Improve capacity for economic analysis, accuracy of business cases and increase confidence in investment in DHTs

- describe a set of information developers will need to collect to facilitate an economic analysis of the DHT
  - Including population size, describing changes to care pathway and parameters for the economic model
  - Using a hierarchy of data sources from the NICE DSU document 'identifying and reviewing evidence to inform the conceptualisation and population of cost-effectiveness models (TSD13)'

- All DHTs will complete a budget-impact analysis, using a model template

Which type of economic analysis?:

- depends on the financial risk

Low expected financial risk DHTs

- Budget impact analysis
- Cost-consequence analysis

High expected financial risk DHTs

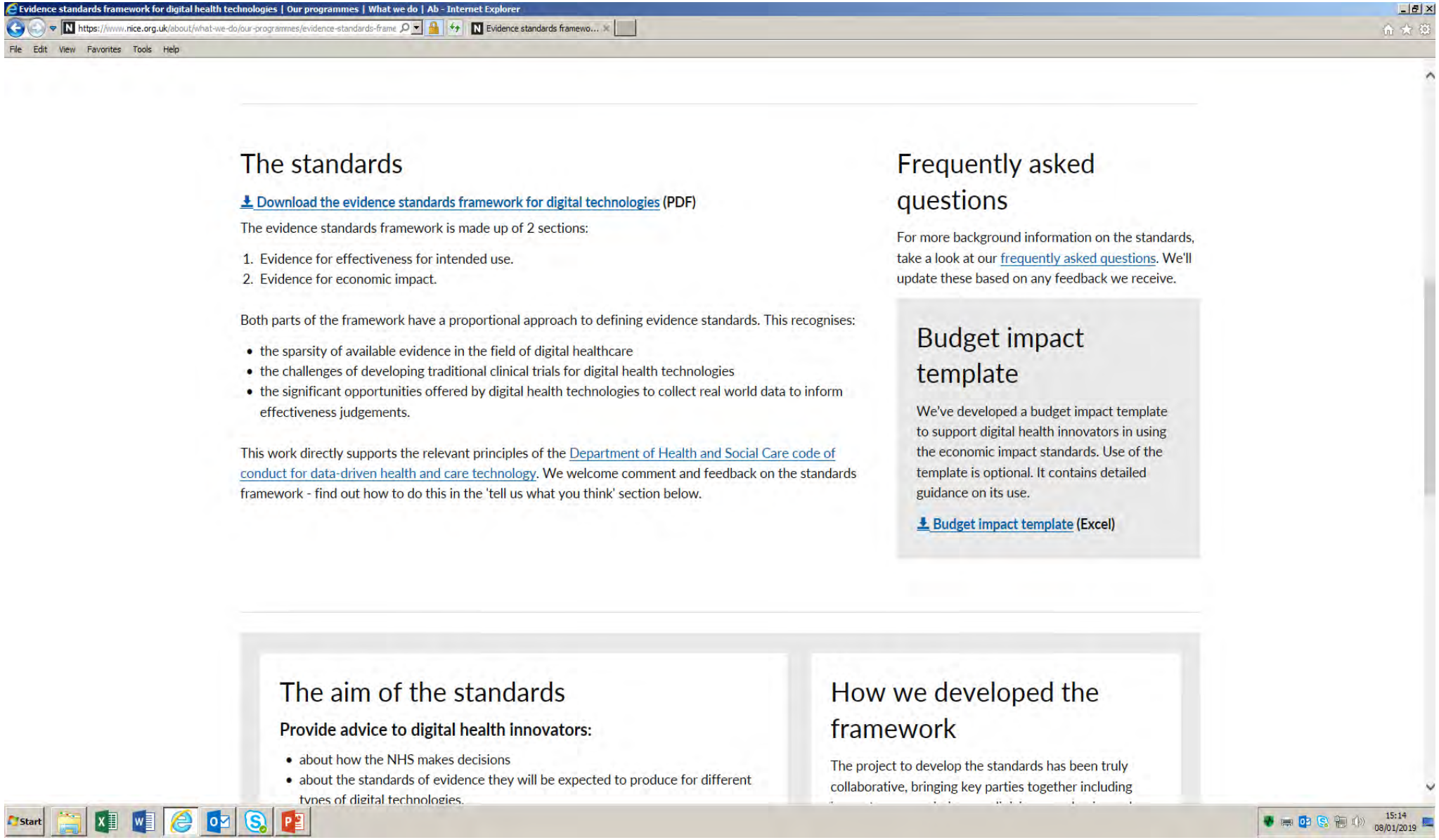
- Budget impact analysis
- Cost utility analysis (health and non-health outcomes as appropriate)
- If not possible, cost-consequence analysis may be acceptable

Resource impact assessment

- NICE estimates the costs or savings (resource/budget impact) associated with technologies and guidelines to support planning for and implementation of guidance
- Annual figures 2017/18

TAs	Guidelines	MT & DT		Total
55	35	6		96

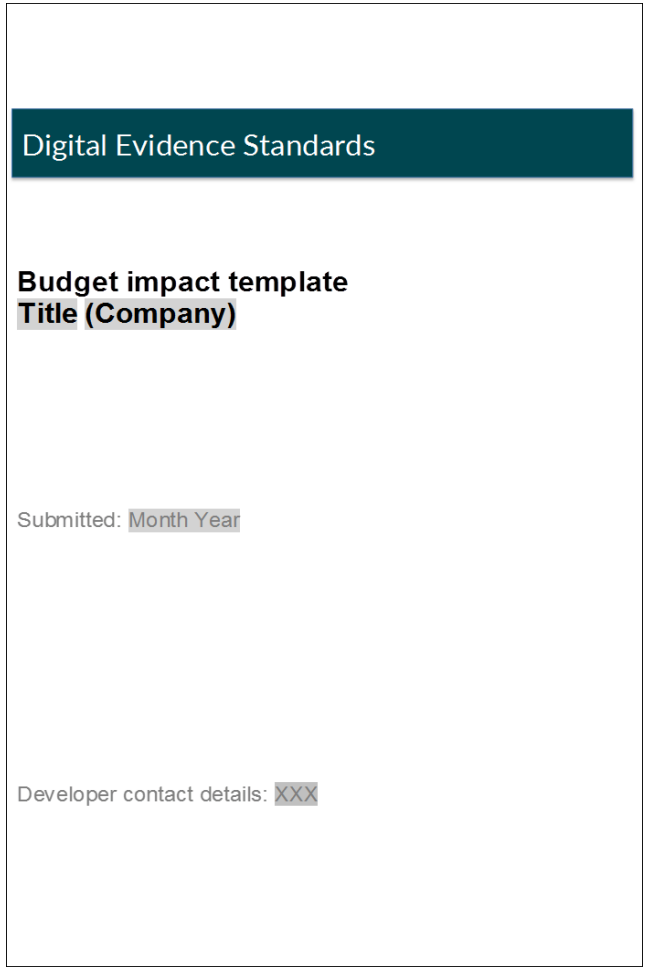
- The Resource impact assessment team at NICE builds on economics by: stating the estimated budget impact in the first five years of the guidance
- Looking at the difference between current and future costs
- Provides tools alongside guidance to be used at a local level to look at resource/budget impact


Evidence standards framework for digital health technologies | Our programmes | What we do | Ab - Internet Explorer
https://www.nice.org.uk/about/what-we-do/our-programmes/evidence-standards-frame
Evidence standards framewo...
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The standards
Download the evidence standards framework for digital technologies (PDF)
The evidence standards framework is made up of 2 sections:
1. Evidence for effectiveness for intended use.
2. Evidence for economic impact.
Both parts of the framework have a proportional approach to defining evidence standards. This recognises:
• the sparsity of available evidence in the field of digital healthcare
• the challenges of developing traditional clinical trials for digital health technologies
• the significant opportunities offered by digital health technologies to collect real world data to inform effectiveness judgements.
This work directly supports the relevant principles of the Department of Health and Social Care code of conduct for data-driven health and care technology. We welcome comment and feedback on the standards framework - find out how to do this in the 'tell us what you think' section below.
Frequently asked questions
For more background information on the standards, take a look at our frequently asked questions. We'll update these based on any feedback we receive.
Budget impact template
We've developed a budget impact template to support digital health innovators in using the economic impact standards. Use of the template is optional. It contains detailed guidance on its use.
Budget impact template (Excel)
The aim of the standards
Provide advice to digital health innovators:
• about how the NHS makes decisions
• about the standards of evidence they will be expected to produce for different types of digital technologies.
How we developed the framework
The project to develop the standards has been truly collaborative, bringing key parties together including
Start
15:14
08/01/2019

NICE

Budget impact template - features

- User guide
- Population selection and budget impact summary
- Assumptions and patient flowchart
- Budget impact over time
- Capital costs
- Sensitivity analysis
- References
- Standard sources for companies to use



NICE

Digital health technologies – resource impact remit

- Support digital health innovators in using the economic impact standards
- Provide a simple excel-based budget impact template which can be used by companies to demonstrate first level of economic impact
- Use is optional
- Similar style to existing resource impact templates

Who will take ownership going forward?

NHS England: Code of Conduct for Data Driven Technologies updated in February 2019 - will give the structure for a compliance regime.

NHS Digital pathway - NHS apps Library

NICE to be the regulator for notified bodies?

NICE and their partners are looking at incorporate these standards into future versions of the Digital Assessment Questions (DAQ).

Artificial Intelligence Executive Council –regulation at the population level

Thank you for listening



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Pricing, Payment and Innovation

Tal Cohen

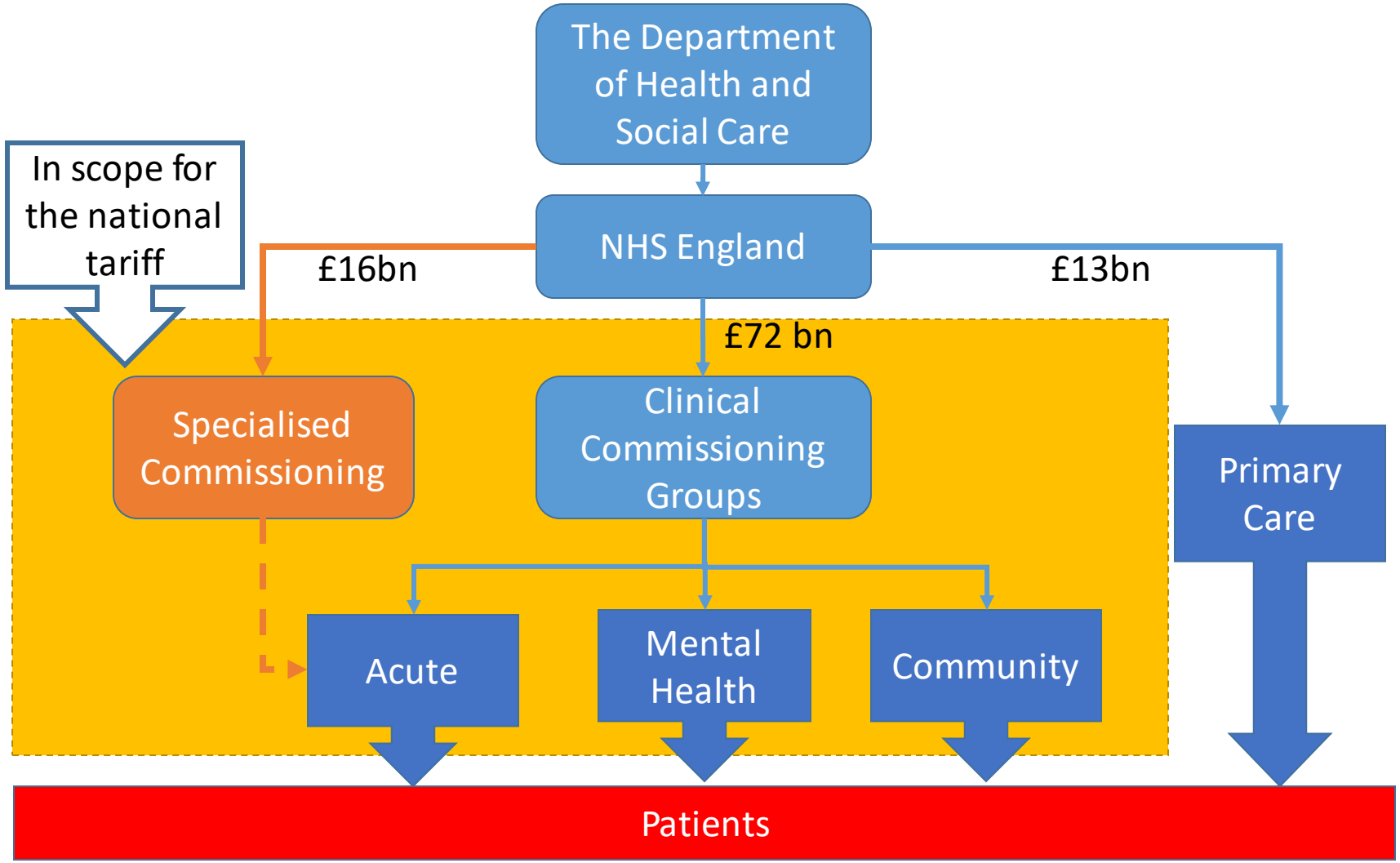
13th February, 2019

Aim of the presentation

To explain:

- How does the NHS payment system work?
- What impact does it have on innovation?
- What do innovators need to know about the payment system when selling into the NHS?
- For us to find what else you need to know and how we can communicate it

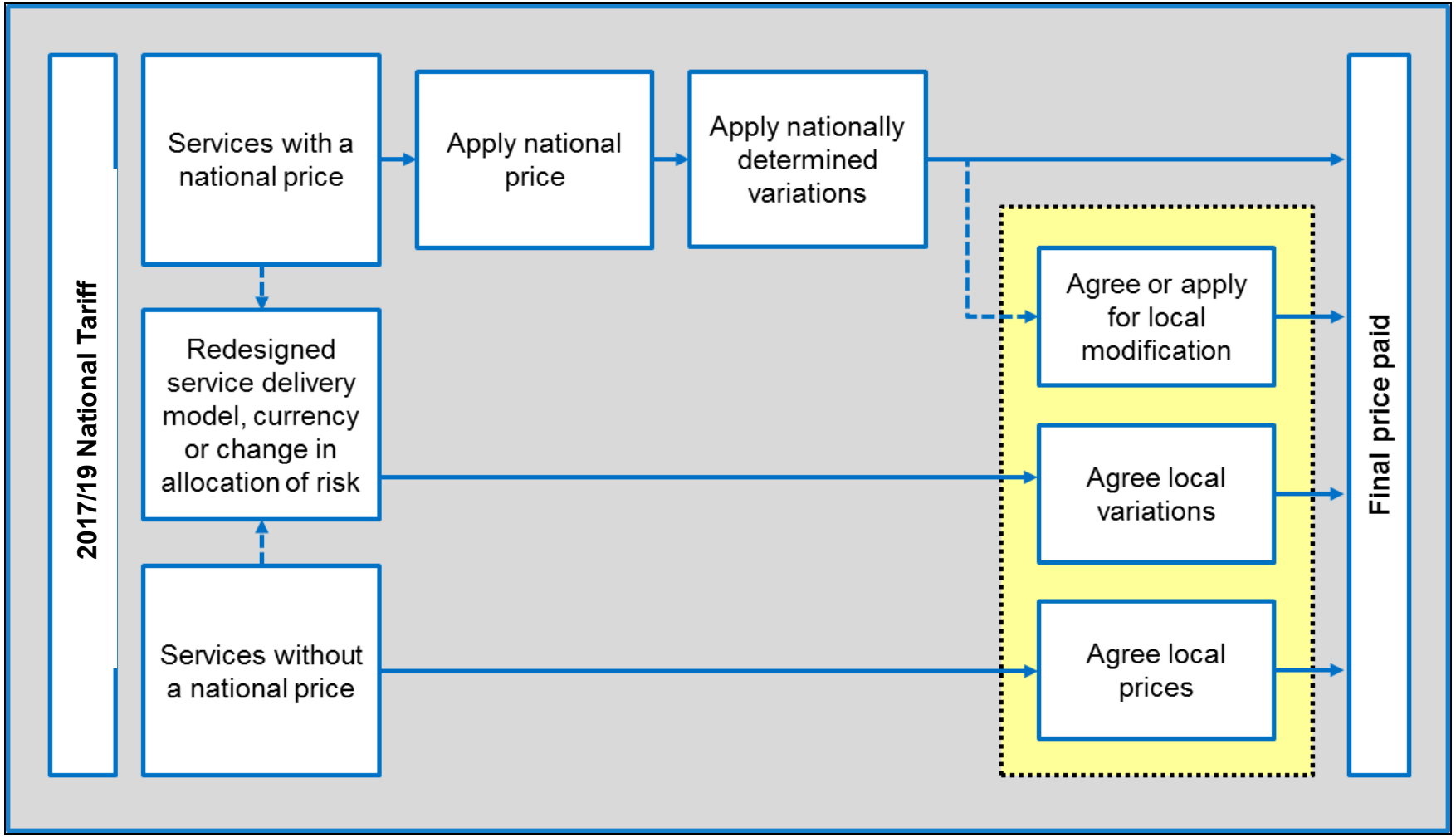
The NHS Payment System



Purpose of the national tariff

- Reduce waiting lists
- Support patient choice
- Provider efficiency – yardstick competition
- Focus providers and commissioners on quality not price

How the national tariff works



National prices* are based on Healthcare Resource Groups (HRGs)

Spell in hospital



Patient Records



Grouper Software



Grouping Criteria:

- o Clinically meaningful
- o Iso-resource



* For Admitted Patient Care and some unbundled services

The majority of the tariff is locally priced

- Mental health, community services and ambulance services
- Some acute services - most specialised commissioning and some CCG commissioned services
- Proposed for 2019/20 – Urgent and Emergency Care – Blended payment
- In practice most local pricing is some variation of a block contract

Pricing is a barrier to innovation

But not the only one ……



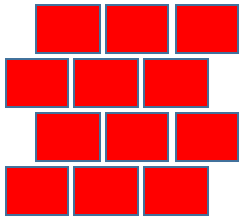
Internal stakeholders



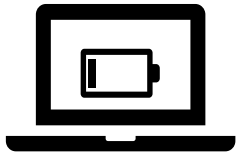
Funding and payment



Legislation and policy



Barriers to innovation



Technological limitations

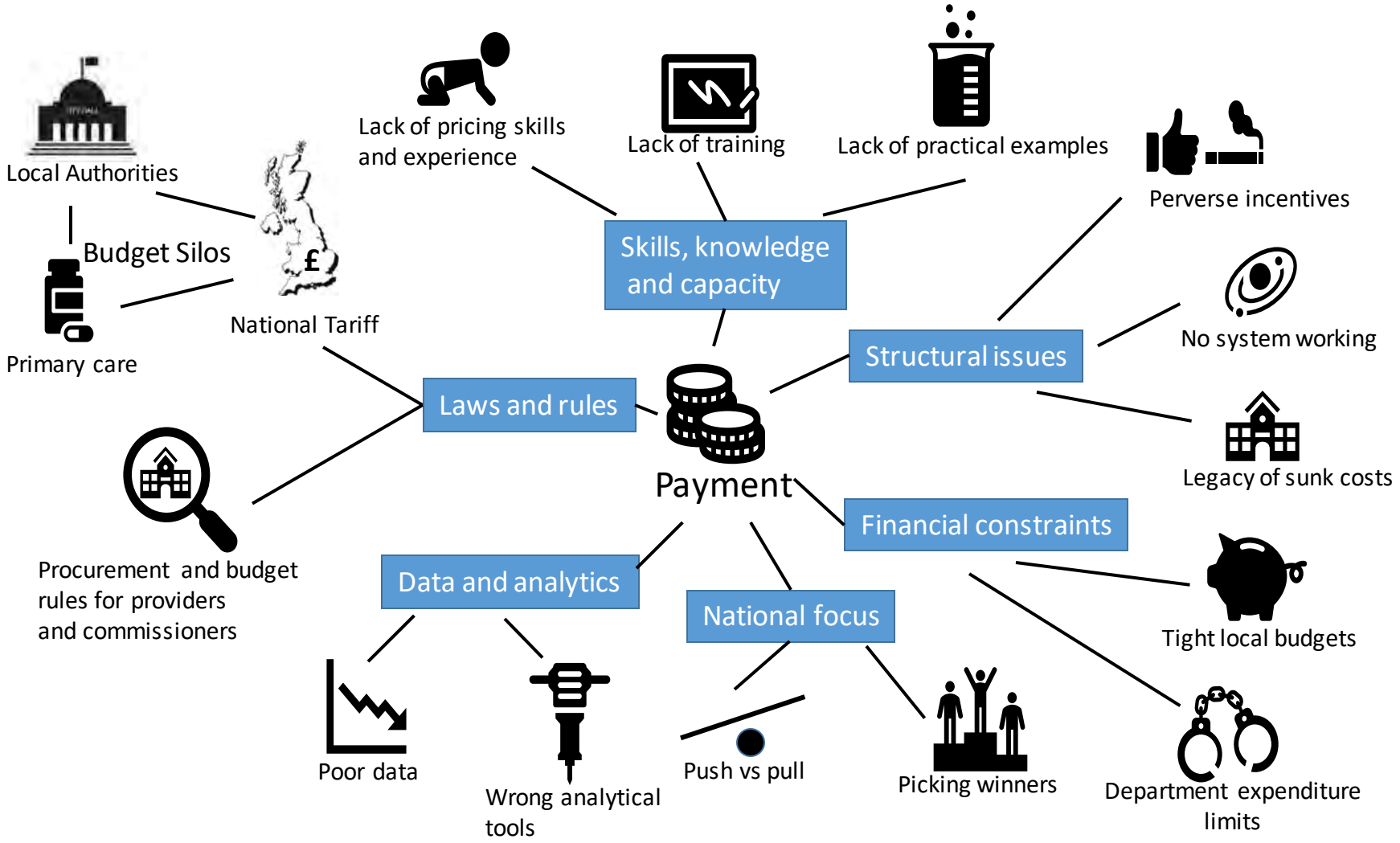


Patients and consumers

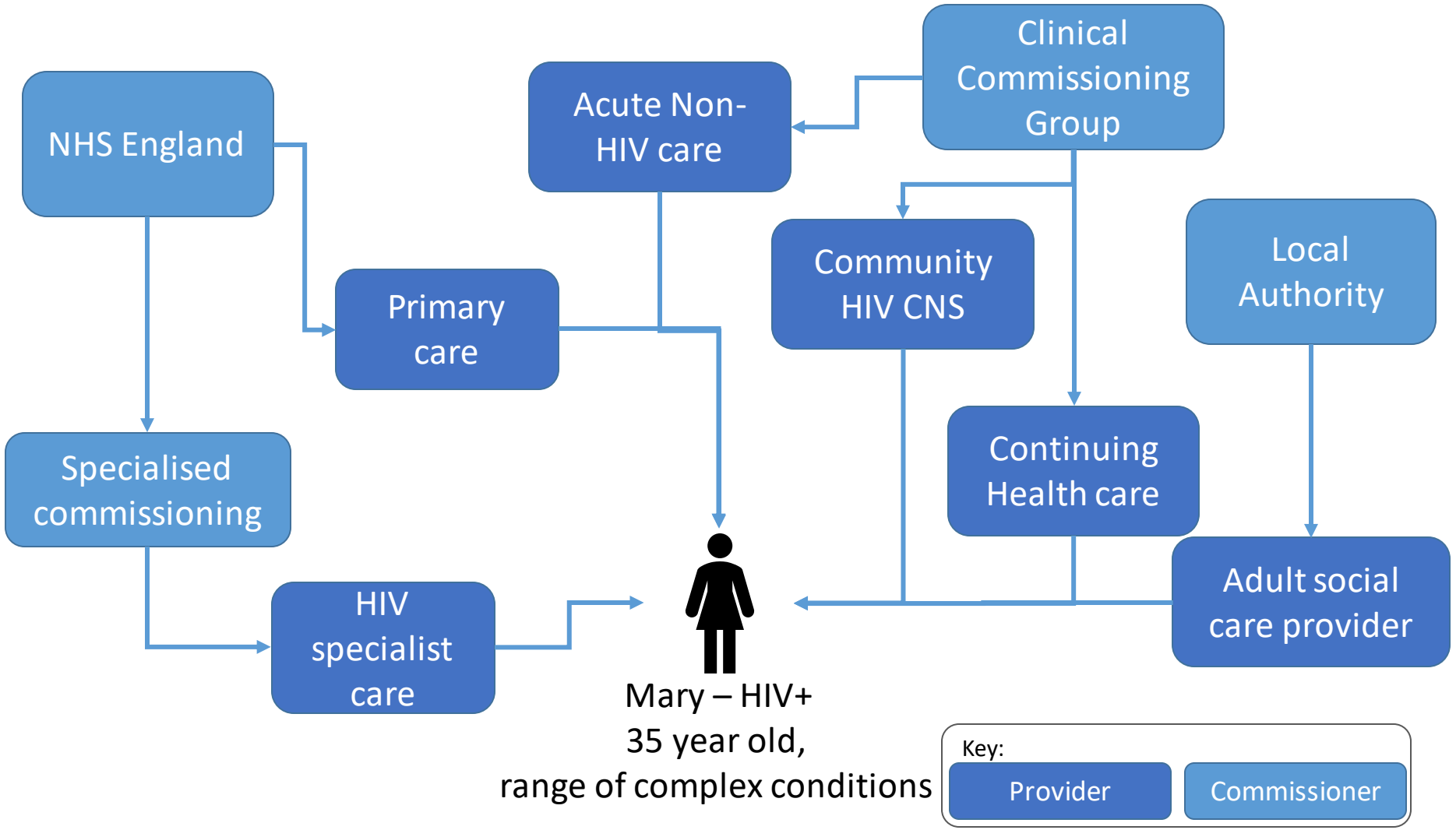


Regulation

Pricing – it's complicated



Siloed care, siloed commissioning



How does this affect you?

- The tariff affects the bottom line. The bottom line affects appetite for innovation. The national tariff sets:
  - the NHS revenue of secondary care providers
  - the expenditure of commissioners
- Provider and commissioner staff act in the way they do because of the situation they are in, often they:
  - Have no ‘headspace’,
  - Limited training,
  - Limited analytical support, and
  - Few examples to fall back on.
- If the innovation affects revenue for more than one provider or commissioner, successful implementation may need more than one party at the table.

What do you need to think about?

- How does your product fit into the system? Does it change care pathways or back office functions?
- If it affects a pathway, where on the pathway does your innovation fall? Does it change:
  - A whole nationally priced HRG?
  - Part of a nationally priced HRG?
  - The cost structures outside of nationally priced HRGs?
  - A number of nationally priced HRGs?
- How will the data necessary to support and monitor the implementation of the innovation be captured and understood?

What do you need to think about?

- Where do the benefits and costs fall in the system? Who do you need to get in the room to overcome the financial implications. How can the benefits be shared?
- The NHS is risk averse. How can you de-risk or share the risk in a way that encourages adoption?

How can we help you?

- This is our first time in front of innovators.
  - What do you need more detail on?
  - What guidance do you need?
  - Which tools do you need access to?
  - Which potential payment approaches do you want to try?

Our next steps

- Developing an education programme – mostly aimed at NHS providers and commissioners but partly aimed at innovators
- Developing payment approaches to the ITT and ITP innovations where possible
- Developing new local payment models – outcomes based commissioning, year of care etc.
- Piloting new payment models to support innovation
- Finding out a lot more about what is happening in practice

Key links

- National tariff (2019/20 proposals) –https://improvement.nhs.uk/resources/national-tariff-1920-consultation/
- Casemix classification – https://digital.nhs.uk/services/national-casemix-office
- Cost data – https://improvement.nhs.uk/resources/reference-costs/

Contact us: pricing@improvement.nhs.uk



Pioneering Medical Device Treating Female Urinary Incontinence (UI)

Developed by Femeda

SME's and Confidently Tackling the Medical Devices Regulations

February 2019

Introduction to Femeda

Who we are ?

- North East based medical device business
- Formed over 10 years with objective of launching Pelviva – a Pelvic Floor muscle re-trainer
- Achieved CE revalidation October 2018
- Combination of manufacturing in Cramlington with outsourced manufacture
- Highly experience team with medical device and pharmaceutical experience



Personal Experience

- Extensive commercial and regulatory experience across broad range of categories, geographies and regulatory systems – Pharma and Device
- Commenced work with ISO/ CE marked products with Allergan with introduction of initial medical device directive
- Experience of different corporate approaches in implementation and evolution of directive
- Worked with number of different notified bodies and competent authorities across Europe

Our Product: Pelviva Life-Changing Technology



- **Pelviva** - developed by Femeda Ltd
- NEW <u>active</u> TREATMENT for female UI
- Easy to use consumer healthcare product
- Health professional recommended therapy
- Innovative, discreet and easy-to-use Pelvic Floor muscle re-trainer, clinically proven to improve bladder control in 84% of women
- Developed to solve the problems caused by a lack of adherence and the inability to perform Pelvic Floor exercises correctly
- Unique waveform digital feedback technology

Addressing the Biggest Unmet Condition in Female Health

The Problem

- UI is the single largest condition in female health
- Affects 1 in 3 women across all ages

Background

- Major cause of UI in women is Pelvic Floor muscle weakness
- 50% of women cannot do their Pelvic Floor exercises correctly

The Market Size

- Large and growing global market for UI is approx $13.6bn, growing at 8% CAGR
- Limited investment and ineffective treatment options
- Pelviva projected annual sales >$200m+ in Europe; >$1b globally
- Significant secondary commercial opportunity for female sexual health



The Femeda journey…

Requirement to address core development challenges within the regulatory framework

Development pathway had multiple challenges and unforeseen hurdles

- Company formed 2006
- Initial Clinical work 2009/11
- ISO 13484 Nov 2011
- CE approval Oct 2013

Technical development challenges faced after setting up supply chain

- US manufacturing partner (FDA/MHRA approved site) not able to deliver to our standards
- Full review of corporate model, set up of our ISO13485 facility
- Requirement to revalidate CE mark…a two year project

Challenges increased by Intertek UK closure and then divisional relocation……

CE Survival strategy required!!!

Our experience: Notified Bodies for Medical Devices

Engaging a Notified Body…

A challenge!!!

- Notified bodies generally lack corporate imagination
- Recognition normal ‘support’ services do not apply
- No recognition of commercial pressures



Notified Body & EC Certification experiences

Notified Bodies - Creaking at the Seams

Three key challenges

Excessively long pick up times

8 month lead time to transfer EC certification

6 month notice required to review change of materials

Appalling customer services

Often no response to questions and queries

Lack of information and speed of reporting

6+ months to provide audit reports

Audit plans delivered only 2 days before audit

Notified Body & EC Certification

Femeda's Experience

LOST Audit Report

Surveillance audit never received

Multiple requests go unanswered

Contacted only when time for next Audit

Provide our notes on findings

NBOG Code Designation Withdrawn

Required to change notified bodies with just 6 months notice.

Full technical file review required on transfer

8 month lead time for technical file transfer

No market activity so orphaned status not required

Forced Change to ISO Audit body

Future Challenges MDR & Brexit the Perfect Storm?

MDR

- Most significant change to regulatory environment since the introduction of the MDD.
- Impacts Quality Systems and Technical Documentation
- Continued increase in Clinical Evaluation requirements
- Many / Most Notified Bodies not yet designated
- Notified Bodies already closing doors to MDD applications
- Much greater responsibility placed on Authorised European Representative

Will result in significant reduction in numbers

Brexit

- Most significant change with potential to impact business continuity in 40 years.
- No clarity on certification validity or arrangements particularly for organizations with UK based NB's
- No clarity on UK approval for companies with European notified body
- Certainty that UK Manufacturers will need to appoint Authorised European Representative if they wish to continue to trade

Required just as the MDR will result in reduced numbers

Navigating Regulations in a Changing Environment

Find someone with in-depth knowledge of regulatory affairs to help and advise on what you need to do

- Internal as an employee or external consultant – decision will be dependent on how much change you are trying to manage
- Required by MDR as a "Person Responsible for Regulatory Compliance"; can be employee or contracted consultant
- Make sure they have experience dealing with Notified Body bureaucracy

Allow plenty of time for regulatory activities

- Notified Bodies can take 6+ months to pick up a technical file to review; and that's the time before they ask questions!
- MDR is going to swamp Notified Bodies with recertification applications – Get your submission ready a year in advance of certificate renewal

Start Planning for Brexit NOW



- Consider where your Notified Body should be located, put them in Europe if you want to assure continued access to your European markets
- Start identifying Partners for your Authorised Representatives and don't forget to check out their credibility for taking on the revised requirements of the MDR

Clinical Evidence: Raising the standard

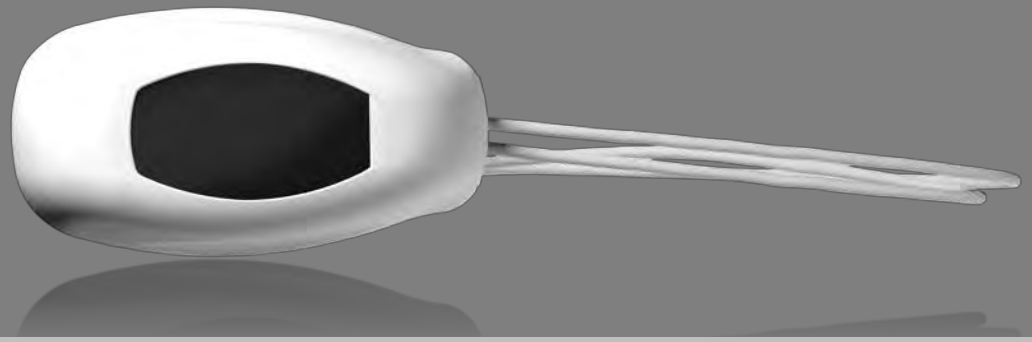
The revision of the Medical Devices Regulation (MDR) places increased emphasis on having sufficient clinical evidence to support the safety and performance of medical devices

New, innovative medical devices have limited ability to leverage existing Clinical Data based on clinical equivalence

Costs to SME's of obtaining high quality, sufficiently powered, randomised clinical trials to produce robust clinical data, is significant

There are considerable benefits for SME's of working in partnership / collaboration with academic and other business organisations

Our Approach: Pelviva Clinical Evidence



Pivotal Clinical Study

Conducted in partnership with University of Manchester and the Wellcome Trust Research Centre

A randomised controlled trial (RCT)[1], involving **123** community dwelling women with urinary incontinence.

12 week study; women were randomised to using Pelviva v's active control.

Primary outcome measure

ICIQ-UI-SF – condition specific quality of life tool

- Women using Pelviva® for 12 weeks experienced a statistically significant more than **four times greater** reduction in the impact that bladder leaks had on their lives when compared to women doing unsupervised pelvic floor muscle exercises

Secondary outcome measure

Patient global impression of severity and improvement

- **84%** of women in the Pelviva® group reported improved bladder control



Clinical Evaluation plan to support MDR

Human Factors usability investigation – 5 phases completed, Phase 6 ongoing

Post market clinical follow up (PMCF) plan to include:

GP Practice based Clinical study – Planned start Q2 2019

Primary care study involving 330 women, in partnership with Greater Manchester Clinical Research Network, Northwest 'e' health, Manchester University and Corridor Manchester Health Innovation.

RCT comparing Pelviva v's usual GP care for the treatment of UI

- To provide enhanced clinical, maintenance and health economics data & strengthen strong consumer claims and health professional messaging
- Support reimbursement
- Data sets at 3 months, 12 months 1 & 2 years

Human Factors Longitudinal Usability study (Phase 7) – Q1 2019

- A 6 month unpriced, usability study of the Pelviva device in women with stress, urgency and mixed UI

NHS National Institute for Health Research

mimit Manchester

MANCHESTER 1824 The University of Manchester

Achieving commercial success with the regulatory framework: Key Learnings

- Timelines are longer than initially expected
- High level of internal skill and experience required, with continual updating and training
- Total company engagement is essential…includes everyone including the board
- Opportunity to ensure clinical requirements translated into strategic benefits