



pmi
Pharma Summit 25
evolving through change

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 **uniphar**



Sharon Rice

Incoming President

pmi THE PHARMACEUTICAL
MANAGERS' INSTITUTE

On behalf of the Committee of the PMI, it is my great pleasure to welcome you all to our 2025 Pharma Summit – Evolving through Change.

Those of us who've been in this sector for a good number of years would say that change has always been part of our industry. New innovations and new medicines move us forward and challenge the status quo, always we hope, to the benefit of patients. As a result, we've all become good at innovating and collaborating to ensure patients are getting the treatments they need when they need them, and the PMI has always been a great forum for sharing ideas and learnings about how best to manage through that change.

I don't think I'm exaggerating when I say that the current pace and extent of change in the industry has never been greater. We need to learn from each other, connect with each other and collaborate across disciplines and companies more than ever before. The pharmaceutical industry in 2025 and beyond will be characterized by rapid innovation and significant shifts in how drugs are developed, delivered, and accessed.

With advancements in personalised medicine, digital health, sustainability, and global health equity, the industry is clearly moving toward a more patient-centric, efficient, and sustainable healthcare system. As managers and leaders in the industry, we will be at the forefront of that change.

This transformation is driven by breakthroughs in technology, evolving regulatory landscapes, and a growing demand for solutions that prioritise the needs of patients. As we navigate this period of change, the pharmaceutical industry's unwavering commitment to improving patient outcomes remains at the core of what we do, ensuring that every advancement contributes to a healthcare system that benefits those who rely on our medicines.

Cell & gene therapies that cure diseases that would once have been a death sentence, the use of GLP-1 drugs to reverse diabetes and obesity, chronic illnesses that have traditionally put huge burdens on health systems worldwide, are just two examples of the new hope but also new complexities that come with innovations in the industry. We're seeing substantial change to how patients access therapies but also changes in the how payors need to consider their cost/value calculations. Our jobs as leaders in the healthcare industry is to evolve with this change, to highlight the potential of new treatments for patients and to help to manage the complexities surrounding their incorporation into the healthcare framework in Ireland.

As ever, the PMI is focused on giving our members the opportunity to learn, connect and grow. I'd like to take this opportunity to thank the speakers and sponsors, whose generosity enables the PMI to run this event.

And of course, I'd like to thank you all for taking a day out of your busy schedules, to share your knowledge, meet your colleagues and counterparts and maybe learn a little about how to deal with the demands of the current environment.

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Session Two: Pharmacy CHANGES



Dom Foley,
Global Capabilities
Consultant


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Joanne Kissane,
Registrar and Chief Officer



Denis O'Driscoll,
Superintendent Pharmacist



Jan-Pieter Hallema,
Managing Director



Dr Pat O'Mahony,
Chairman



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Session Three contents on page 17



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Dom Foley

Global Capabilities Consultant

Google

Dom has a wealth of experience in both learning and development having previously held senior roles in HR and Training departments.

He has over 20 years of experience as an organisational development professional, driving meaningful change. Through a combination of domain expertise in people strategy and a genuine enthusiasm for showing teams how to harness their creativity.

With a background in Psychology, he's passionate about helping leadership teams use innovation to design and deliver a strategy and culture that engages their business for the future.

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Connecting with Gen Z

Dom Foley



Dom Foley

- Psychology Graduate
- 21st year at Google
- Initially a Financial Analyst
- 10 years in HR
- Org Dev since 2018
- People Strategy geek



Generation Years *

- 1946 - 1964 : Baby Boomers
- 1965 - 1979 : Gen X
- 1979 - 1994 : Millennials (Gen Y)
- **1995 - 2009 : Gen Z**
- 2009 - 2024 : Gen Alpha
- 2025 - : Gen Beta

** According to popular opinion*



1



2

“Gen Zers flock to corners of the internet where they can discuss their passions and interests with those who share them.”

Mckinsey Research





1. Always Lead with the Headline

1. Operate as if you're very busy

1. Consciously build a partnership





**The past is a foreign country;
they do things differently
there. ”**

L.P.Hartley

The Go-Between



Thank You





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Panel Discussion:

"Empowering Pharmacists: Tools and Strategies for Thriving Amid Change"



Joanne Kissane – Registrar and Chief Officer at the Pharmaceutical Society of Ireland (PSI)

Joanne was a member of the Department of Health's Expert Taskforce to support the expansion of the role of pharmacy in Ireland. Joanne also oversaw the establishment of the current multi-stakeholder Pharmacy Workforce Working Group with the Department in line with recommendations in the PSI's Workforce Intelligence report (2023). Before joining the PSI, Joanne was the Director and National Coordinator for APPEL, a joint office of the three Schools of Pharmacy in Ireland, which manages the student experiential learning placements for the integrated master's degree programmes in pharmacy. She has worked in community pharmacy as a practicing pharmacist and for seven years was the superintendent pharmacist for Lloyds Pharmacy before becoming Head of Operational Excellence for the organisation.



Dr Pat O'Mahony – Chair IMVO, HIQA and Taskforce supporting Expansion of Role of Pharmacy

Pat provides strategic management consultancy to selected clients across various sectors including Biopharmaceuticals, Med Tech and Health Care Systems. Particular interests at present include Value Based Healthcare, Clinical Research and Genomics. He is also the Chairman of the Board of the Health Information and Quality Authority (HIQA) and Chairman of the Board of the Irish Medicines Verification Organisation (IMVO). Pat was appointed Chair of the Ministerial Expert Taskforce to Support the Expansion of the Role of Pharmacy in 2023.





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Panel Discussion:

"Empowering Pharmacists: Tools and Strategies for Thriving Amid Change"



Jan-Pieter Hallema - Managing Director at McCabes Pharmacy

As the Retail Managing Director at Phoenix McCabes Pharmacy in Dublin, Jan Pieter currently oversees retail operations and strategy, driving innovation and excellence in community pharmacy services. Previously, he served as Group Director Retail at BENU Nederland, where he led the company's retail division with a focus on enhancing pharmacy performance and patient engagement. Prior to that, he was the Director of Pharmacies at Ceban Medsen Pharmacies, where he guided the organisation through significant operational growth. His career began as a pharmacist at Apotheek in Hoorn, laying the foundation for his lifelong commitment to the profession.



Denis O'Driscoll - Superintendent Pharmacist at McCabes Pharmacy

With over 30 years of experience in the pharmacy sector, Denis is a seasoned expert in the field, specialising in addiction services and pharmacy management. He spent 22 years with the HSE Addiction Services, where he served as Chief Pharmacist, becoming a recognised leader in addiction care. In 2018, Denis transitioned to the role of Superintendent Pharmacist at LloydsPharmacy Ireland, where he oversaw the delivery of high-quality pharmacy services. Following the acquisition of McCabes Pharmacy in 2024 by the Phoenix Group, Denis now holds the position of Superintendent Pharmacist for McCabes Pharmacy.



Shane O'Neill - Director of Pharmacy at Uniphar

Shane is a qualified pharmacist with over 15 years of experience across both the UK and Ireland, spanning community pharmacy, clinical practice, and operational leadership roles. After returning to Ireland in 2018, he joined McCauley Health & Beauty as a Supervising Pharmacist before being appointed Superintendent Pharmacist. Following McCauley's acquisition by Uniphar, Shane played a key role in integrating the business and later became Operations Manager for Uniphar's owned pharmacy brands. In 2025, he was appointed Director of Pharmacy for Uniphar, where he now leads the development and delivery of the pharmacy agenda across the organisation.



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Session Three: Stakeholder CHANGES



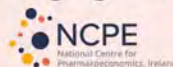
Siobhan Dunphy,
Assistant National Director, Strategic
Sourcing and Contracting for Procurement



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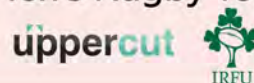
Dr Roisin Adams,
Head of HTA Strategy and External
Engagement



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Gary Keegan,
CEO - Uppercut
Performance Coach of Ireland's Senior
Men's Rugby Team - IRFU



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Siobhan Dunphy

Assistant National Director, Strategic
Sourcing & Contracting for
Procurement



With over 30 years of experience in the Health Sector, Siobhan has worked across both community and acute hospital services and is leading an ambitious programme of work for HSE Procurement with a €5.2bn annual spend.

Siobhan was previously responsible for managing a multi-million euro portfolio of expenditure incorporating Facilities Management across the health sector.

Having a keen interest in change management and transformation, she progressed change across a range of function areas including introducing new technologies and the integration of business functions following the rationalisation of activities in the Health Sector. She was also responsible for developing the model to implement "One Voice" for the health strategy, designed to reduce costs and achieve better value for money while maintaining excellent service for the public sector.

A firm advocate for digital innovation, Siobhan set up and implemented a new portfolio of digital health and innovation within strategic sourcing and contracting, as part of the suite of portfolios for HSE-led categories, signifying the importance of driving digital transformation within the HSE. She also holds a strong passion for sustainability and is committed to promoting environmentally responsible practices in procurement processes. Siobhan places significant value on the power of collaboration and fosters strong partnerships with internal and external stakeholders such as engagement with suppliers, trade organisations and HSE funded agencies.

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Navigating Procurement in the Health Service

Siobhan Dunphy

Assistant National Director

Strategic Sourcing and Contracting

HSE Procurement

3rd April 2025



What Matters

Is that we are putting the patient service users at the centre of what





**Procurable annual spend of
€5.4 billion approximately**

Largest purchaser in the State



**The patient is the
focus and all procurement
opportunities should
contribute to
improved patient care**

**Accountable for effective &
compliant procurement**

Continuity of supply

**Working together with the
Regional Health Areas to protect
frontline patient services**

**Delivering value for money with
security of supply**



HSE - Changing Environment - Health Regions



The HSE remains a single HSE organisation with 6 health regions. Services are integrated across hospitals and community organisations in these health regions.

- ❑ Each health region provides integrated health and social care services for the people in that area.
- ❑ The 6 health regions replace Hospital Groups (HGs) and Community Healthcare Organisations (CHOs).



Patient benefits include:

- ❑ A more patient-centred approach to healthcare
- ❑ Care closer to home
- ❑ Consistent quality of care



Changes, Challenges and Opportunities



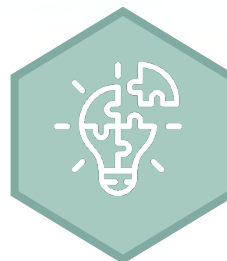
Introduction of Health Regions



Sláintecare



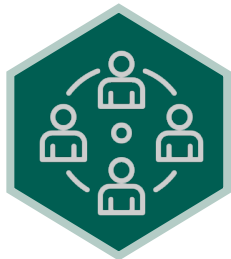
Procurement



Digital Health Strategy



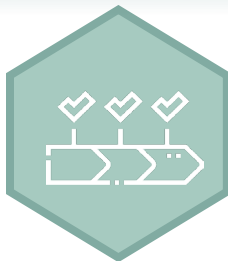
IFMS Roll out



Resourcing



Global Pricing



HSE Corporate Plan 2025 onwards



Pipeline of upcoming tenders



Green Procurement

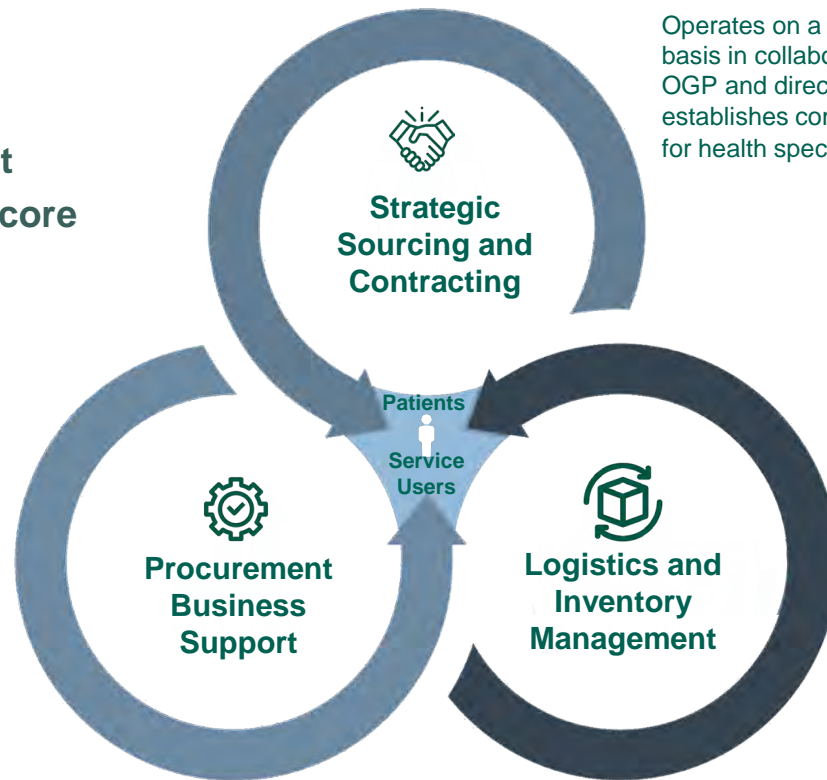
HSE Procurement

Procurement provides a range of specialist procurement services nationally across three core business areas

Integrated Procurement approach for the health sector and the Sláintecare Programme

Supporting:

- Health Service Divisions
- HSE Health Regions
- Section 38 Agencies
- Section 39 Agencies
- Office of Government Procurement
- Tusla
- Other Government Departments and Agencies



Operates on a public sector wide basis in collaboration with the OGP and directly procures and establishes compliant contracts for health specific categories.

Provide business and system analyst support for procurement related systems. Responsible for coordinating multiannual procurement planning and compliance improvement.

Manage the purchase, storage and distribution of goods to optimise efficiencies for service delivery. Drives greater efficiencies through management of stock at the point of use.



Ensuring compliance with:

- **Procurement Regulations**
- **EU Directives**
- **Government Policy and Guidelines**
- **HSE National Financial Regulations (NFR)**





Procurement Objectives



Support service delivery across the health sector

Provide continuity of supply; ensuring availability of appropriate quality goods and services where needed, when needed



Maintain effective governance and compliance

Ensure the HSE and all staff members comply with procurement directives, legislation, circulars and other legal requirements



Achieve greater value for money to support reinvestment into patient care and service delivery

Ensure that purchasing is carried out in a coordinated and strategic manner that maximises opportunities for savings and improved compliance



Facilitate environmental, societal and economic objectives through procurement

Encourage and stimulate opportunities for green procurement, innovation, social inclusion and participation by SME's and Micro Enterprises in the procurement process

HSE Corporate Procurement Plan



- Setting the HSE Procurement strategic direction
- Importance of ensuring value for money and attaining savings where possible
- Strengthening procurement support for Health Regions
- Progressing green procurement
- Increasing compliance
- Digital transformation

**HSE Corporate
Procurement Plan
2025 - 2027**



2022 – 2024 Corporate Procurement Plan

- Significant progress achieved across procurement
 - Spend under Management (SUM)
 - IFMS
 - Roll out of NDC
 - Roll out of Point of Use
 - Improved SME participation and collaboration
 - Procurement Compliance Improvement Programme
 - Green Procurement

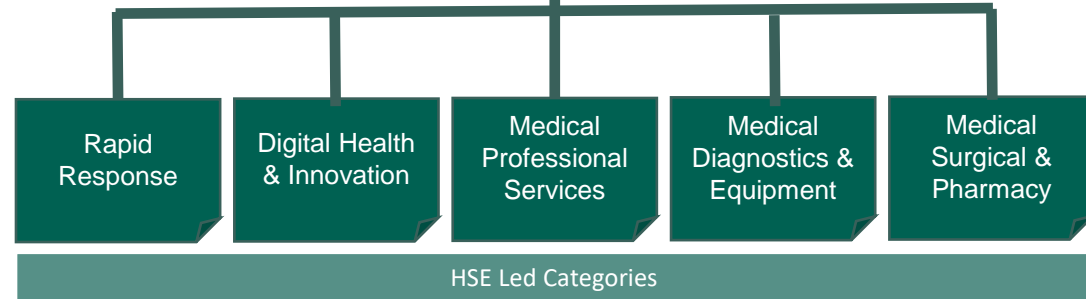


Strategic Sourcing & Contracting - Health Sector Procurement

Sector Specific

- ❑ Medical Professional Services
- ❑ Medical & Diagnostic Equipment & Supplies
- ❑ Medical, Surgical & Pharmaceutical Supplies
- ❑ Minor Building Works & Civils
- ❑ Plant Hire
- ❑ Veterinary & Agriculture/Library Book Purchase
- ❑ Laboratory, Diagnostics & Equipment
- ❑ Defence & Security

HSE Procurement



HSE Led Sector Specific Categories

The HSE leads on the procurement for health sector specific categories and unique health needs not addressed within other sector-led categories



HSE Procurement Strategic Sourcing & Contracting

Categories within Portfolios

Digital Health & Innovation (DHI)	Medical Professional Services (MPS)	Medical Surgical & Pharma (MSP)
eHealth and Disruptive Technologies	Healthcare Consultancies	Drugs & Medicines
Health Innovation Hub Ireland	Community Based Diagnostics & Treatment Services	Vaccines & Cold Chain
Digital Transformation	Carers (Disability and social care)	Dental & Orthodontic
Cyber Response	Homecare Svs	Nutritional Products & Services
ICT capital programme	Agency / Locum Services	Infusion Consumables
	Screening Services	Continence Products
	Waiting List Initiatives	Contract Maintenance & Wound care
	Outsourced Allied Health Services	Surgical PSRs various
	CAWT	NERP PSRs Various
	Daycare Services	A & A Recycling
	Agency / Locum Services	Medical Gases
	Health Related Training	Respiratory Therapies
	Convalescence Services	Aids & Appliances
	Step down and long stay	Contract Extensions Only
	Covid testing services	AIM Level 5 – Pobal
	Laboratory External Testing Services	Audiology – Consumables
	Managed Laboratory Services	NDC Compliance
	Residential Services	Renal - Legacy Only
	Community Insourced Services	MSP1 CBUGs & PASS
	Nursing Beds & Units	

HSE Progressing Green Public Procurement

HSE Climate Action Strategy 2023 – 2050



Apply appropriate procurement processes, award criteria and weighting to support innovation, social inclusion, economic and environmental sustainability priorities into all procurement processes



Tender competition for the **Supply and Delivery of Fresh Meats, Poultry Fish and Egg Products** to HSE including GPP

- A minimum of 10% by value (€) of Fresh Beef, Lamb, Pork Poultry & Fish sought must be certified organic
- A minimum of 10% by value (€) of cereals sought must be certified organic

Total marks to be awarded under GPP Criteria is 20%

Mandatory Green Public Procurement Requirements



Road transport vehicles and services	Indoor and outdoor lighting (including road lighting and traffic signals)
ICT products and services (including data centres)	Heating equipment (including cogeneration, trigeneration and heat pumps)
Food and catering services	Energy-related products (white goods/appliances, electronic displays, vacuum cleaners)
Cleaning products and services	Paper products and printing services
Building design, construction and management (due to be updated in 2024/5)	Textile products and services (including uniforms and laundry services)
Furniture and related services (new criteria set published in 2024)	



2025 – Increase Green Criteria



Progressing Green Procurement



- Multilateral Group – bringing together global representation of health providers from various countries on green procurement
- HSE and HealthTech Ireland Sustainability Group
- OGP Collaboration
- Climate Action Steering Group
- Sustainability training



Integrated Financial Management and Procurement System

- ❑ IFMS is the single national integrated financial management and procurement system for the health sector.
- ❑ IFMS is being rolled out on a phased implementation basis to all publicly funded health organisations

Implementation

- ❑ Group 1 (IG1) went live on 3 July 2023 in HSE East
- ❑ Group 2 (IG2) went live April 1 2025 in the following Health Regions: HSE West & North West and HSE Mid West
- ❑ Group 3 (IG3) will go live in July 2025 in the following Health regions: HSE South East, South West, Midlands & North East
- ❑ Communications issuing to Suppliers regarding the implementation of IFMS in IG2 & IG3 regions



IFMS will involve changes for people, processes and technology



Key Changes for Suppliers

- A valid HSE Purchase Order (PO) number must be printed on all invoices.
- For Pharma Suppliers, what constitutes a valid PO may change to the new IFMS 10 digit PO Format or remain the same. This depends on the arrangements you have in place with us.
- Some pharmacy locations have pharmacy specific application, like HMMS and Cliniscript, their PO numbers will not change.
- You will be given a single vendor number for all HSE orders and services.
- BIC/IBAN to be included on all invoices.
- Invoices submitted via email should be in .pdf format. One invoice per PDF.
- No personal details for a patient/service user to be included on invoice.

See HSE IFMS webpages for FAQ and Good Practice Guide

<https://www.hse.ie/eng/about/who/finance/financereformprogramme/technologyfinancereform/>





Regulation and Standardisation

Driving Innovation & Safety in patient care



Manufacturer



Distributor



Healthcare Provider



Point of Care / Scan4Safety



GTIN (01) 05391234560015
 Expiry Date (17) 230331
 Batch (10) BA1597
 Serial Number (21) 1597869933

I am a product (GTIN)

I expire on 31 March 2023

My Batch Number is BA1597

My Serial Number is 1597869933

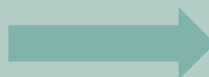


Without standards-based traceability, it is impossible for organisations to accurately assess the sustainability of their products and supply chains

Why Traceability?



- ✓ Safety
- ✓ Security
- ✓ Efficiency
- ✓ Sustainability



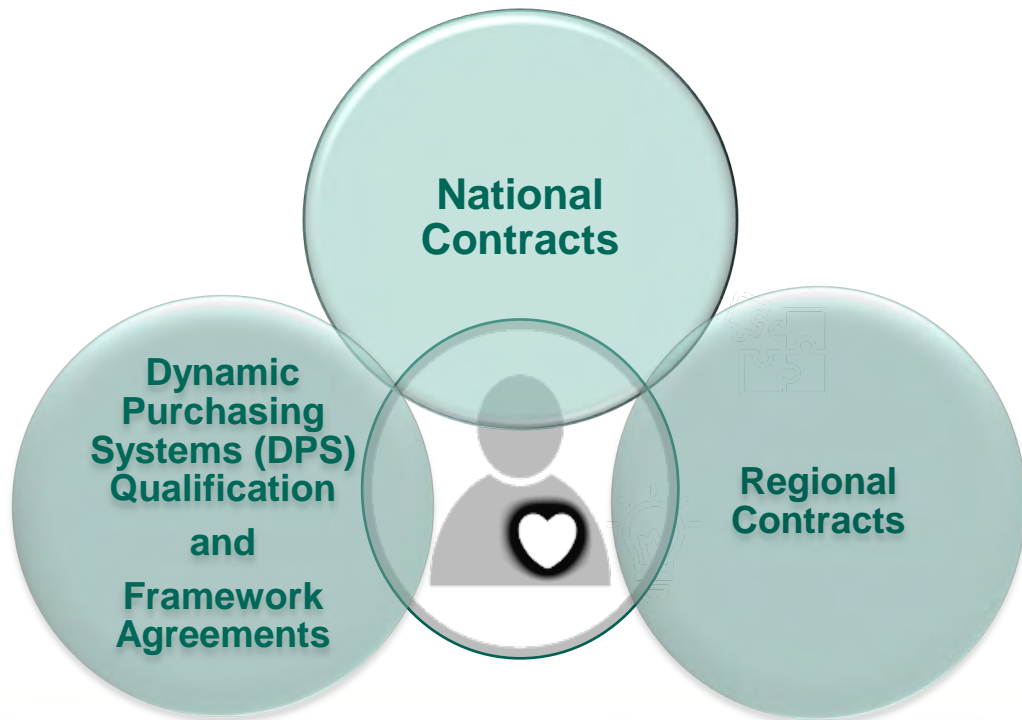
Standards-based Traceability is an enabler for Sustainability

- ✓ Reduced waste
- ✓ Visibility of stock usage
- ✓ Improved planning means less stockouts (reduced carbon footprint)
- ✓ Accurate data relating to product packaging

Master Data

An Overall Enabler for integration and IFMS facilitating HSE requirements and business solutions

HF Contracts, Frameworks, Dynamic Purchasing Systems





Supplier Engagement – Drugs, Medicines, Vaccines



Drugs and Medicines

- Ensure registration on eTenders - www.etenders.gov.ie
- DPS published on eTenders
- Companies can apply to join a DPS during lifetime of DPS
- Application evaluated and if successful, automatic appointment to DPS
- Once appointed to DPS companies will have opportunity to submit tenders for mini competitions
- Contracts duration usually – Initial 2 year period with 2 x 12 month extension option



Vaccines

- Specific Procurement Portfolio leading out on vaccines
- Alignment with the National Immunisation Advisory Committee (NIAC) and working closely with the HSE National Immunisation Office (NIO)



Supplier Engagement



**Annual Supplier
Engagement Meetings for
companies registered on
DPS**



**Generic email address for
queries for Drugs and
Medicines**

nppst@hse.ie



Tips for doing business with the HSE

Things to Consider when Tendering

- ✓ Is the requirement clear? If not seek clarification in line with communication protocol specified in the Tender Documents
- ✓ Answer all the questions as fully as possible giving examples and referencing previous relevant experience
- ✓ Be clear and concise
- ✓ Follow the requested format and Instructions to Tenderers
- ✓ Attach all requested documentation and/or sample as requested
- ✓ Make sure to get your tender submission complete and submitted ON TIME



Make sure to register on the eTenders Irish Government's electronic tendering platform administered by the Office of Government Procurement
www.etenders.gov.ie



The platform is a central facility for all public sector contracting authorities to advertise procurement opportunities and award notices



Etenders will flag when contract is advertised or when there is market sounding

If you need technical support please email irish-eproc-helpdesk@eurodyn.com or call 0818 001459 (Ireland) or +353 818001459 (International)



Take away Messages

HSE Changing Environment

Procurement in the HSE

Progressing the Sustainability Agenda with Green Public Procurement

Overview of Frameworks, Contracts, DPS

Supplier Engagement

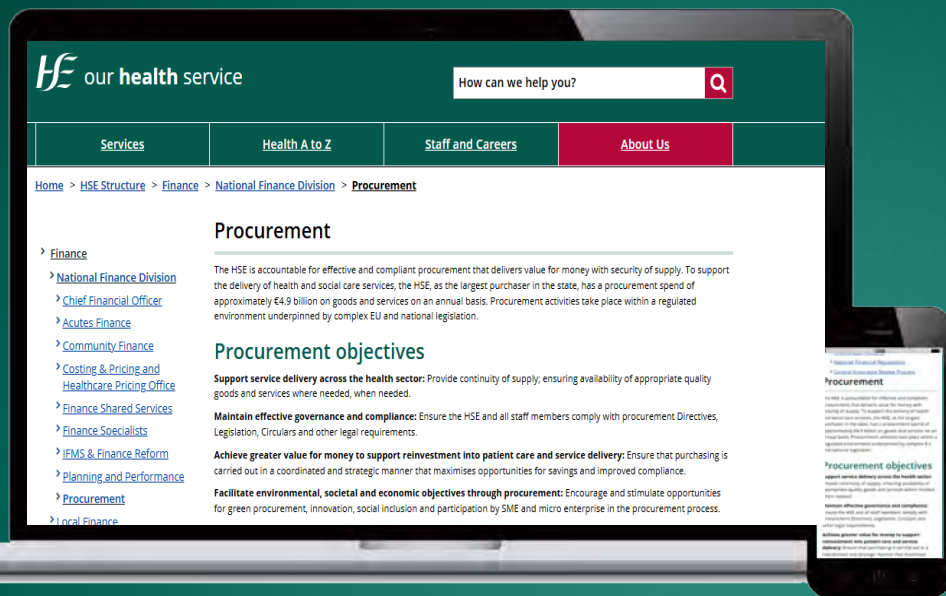
Tips for doing business with the HSE



A Better Patient Experience



Find out more about HSE Procurement



Visit the HSE Procurement webpage on [hse.ie](https://www.hse.ie)

Connect with HSE
Procurement





Thank You!



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Dr Roisin Adams

Head of HTA Strategy and
External Engagement



Roisin led the HTA team for a number of years before being seconded to the HSE to lead a new unit tasked with overseeing and managing high cost drugs in acute hospitals. She is the elected Chair of the Health Technology Assessment Coordination Group which is the governance body responsible for the EU HTA Regulation.

Roisin also co- chairs the HTA domain of the BeNeLuxA initiative and is a Director on the Board of the International Horizon Scanning Initiative.

She has been awarded a number of grants from the Health Research Board to examine health preferences in Ireland. Her areas of interest include methods for preference elicitation, combining different data for evidence synthesis and reimbursement mechanisms for high cost drugs. Roisin has held advisory positions for Department of Health, the Health Information and Quality Authority and policy direction at EU level.

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EU HTA: The Changing Face of HTA

Roisin Adams, MPharm, MSc, PhD

Chair, EU Member State HTA Coordination group,
Head of HTA Strategy, NCPE, Ireland

Where is Europe at currently?

- ⦿ *2025 Polish presidency
- ⦿ 2025 Denmark
- ⦿ 2026 Cyprus
- ⦿ 2026 Ireland

Olivér Várhelyi

COMMISSIONER (2024-2029) | Health and Animal Welfare



Where is Europe at currently?

Critical Medicines Act

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

laying a framework for strengthening the availability and security of supply of critical medicinal products as well as the availability of, and accessibility of, medicinal products of common interest, and amending Regulation (EU) 2024/795

EU Pharmaceutical Package Reform

Where is Europe at currently?

Critical Medicines Act

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

laying a framework for strengthening the availability and security of supply of critical medicinal products as well as the availability of, and accessibility of, medicinal products of common interest, and amending Regulation (EU) 2024/795

MDR and IVDR

New Biotech Act

EU Pharmaceutical Package Reform

Three main areas of contention:

- Data Exclusivity
- Compulsory licensing
- Unitary Supplementary Certificates

EU HTAR

Came into force 12th January 2025

Where is Europe at currently?

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

laying a framework for strengthening the availability and security of supply of critical medicinal products as well as the availability of, and accessibility of, medicinal products of common interest, and amending Regulation (EU) 2024/795

Belgium first called for a law to tackle drug shortages in May 2023.

Where is Europe at currently?

Belgium wanted a drug shortages bill. It's not happy with the EU's plan.

Belgium first called for a law to tackle drug shortages in May 2023.

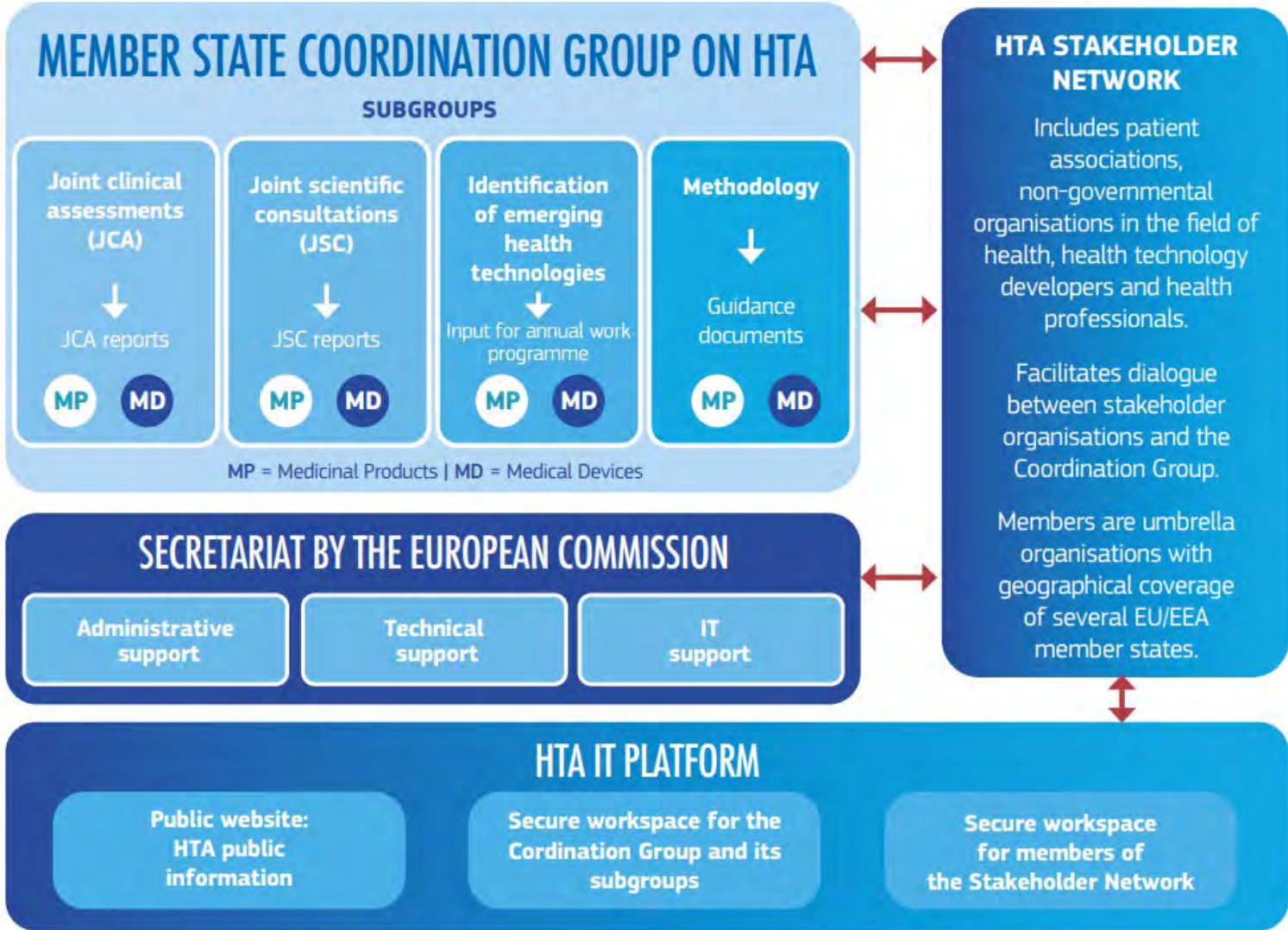
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Belgium first called for a law to tackle drug shortages in May 2023.

Governance



HTA CG



Joint Clinical Assessments – where are we at?

- ⦿ Predict to assess approx. 25 products in 2025
- ⦿ Submissions monthly in line with Market Authorisation Application
- ⦿ First reports in early 2026
- ⦿ Summary report and dossier will be published after the joint work is completed.
- ⦿ EC will not develop a public side of the IT platform and will use the Europa website to publish.

HTAR became available on 12 January 2025

- New active substance in oncology and ATMP are in scope for JCA
- 2 JCA have started

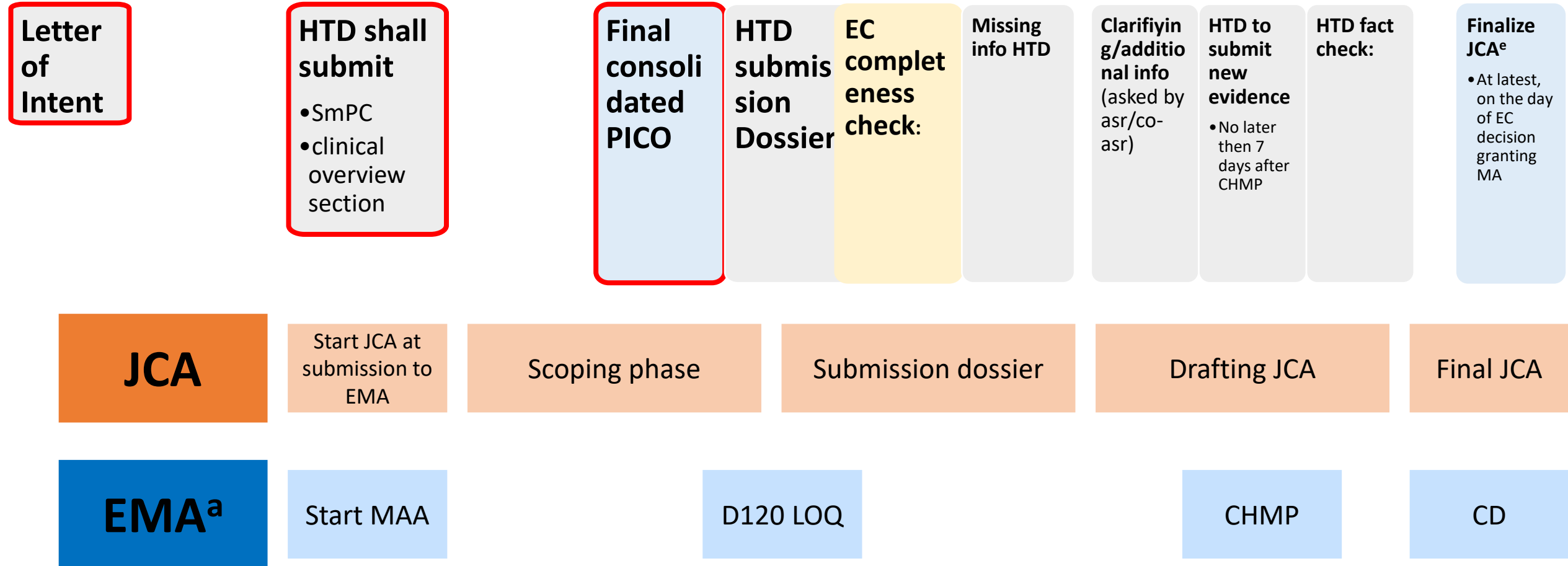
10 JCA guidances, endorsed by the HTACG are available here:

- [Key documents - European Commission](#)

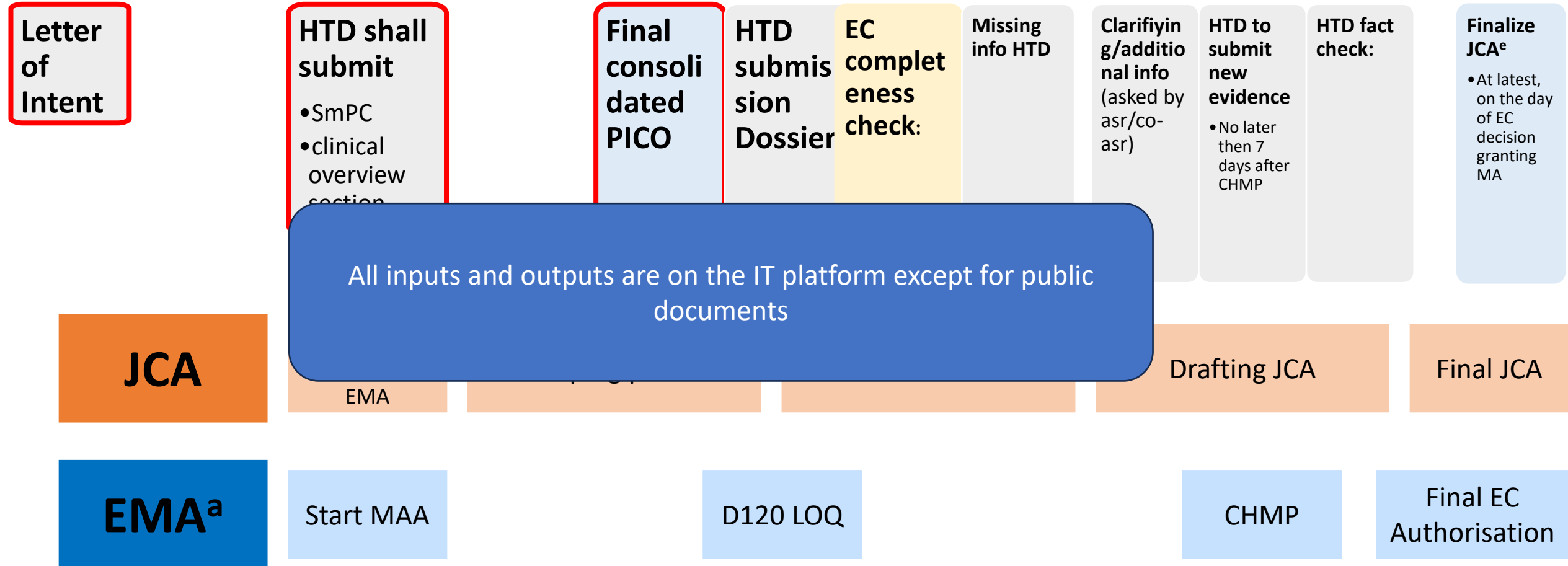
Work Programme 2025

- 5 MD/IVD guidances (with MPG SG)
- Guidance on how to fill the JCA report template – MP (with MPG SG)
- Interim versions are available of the patient/clinical expert input template, for situations in which the JCA SG wants to seek their input
- Production of JCAs

JCA timeline in parallel to EMA



JCA timeline in parallel to EMA



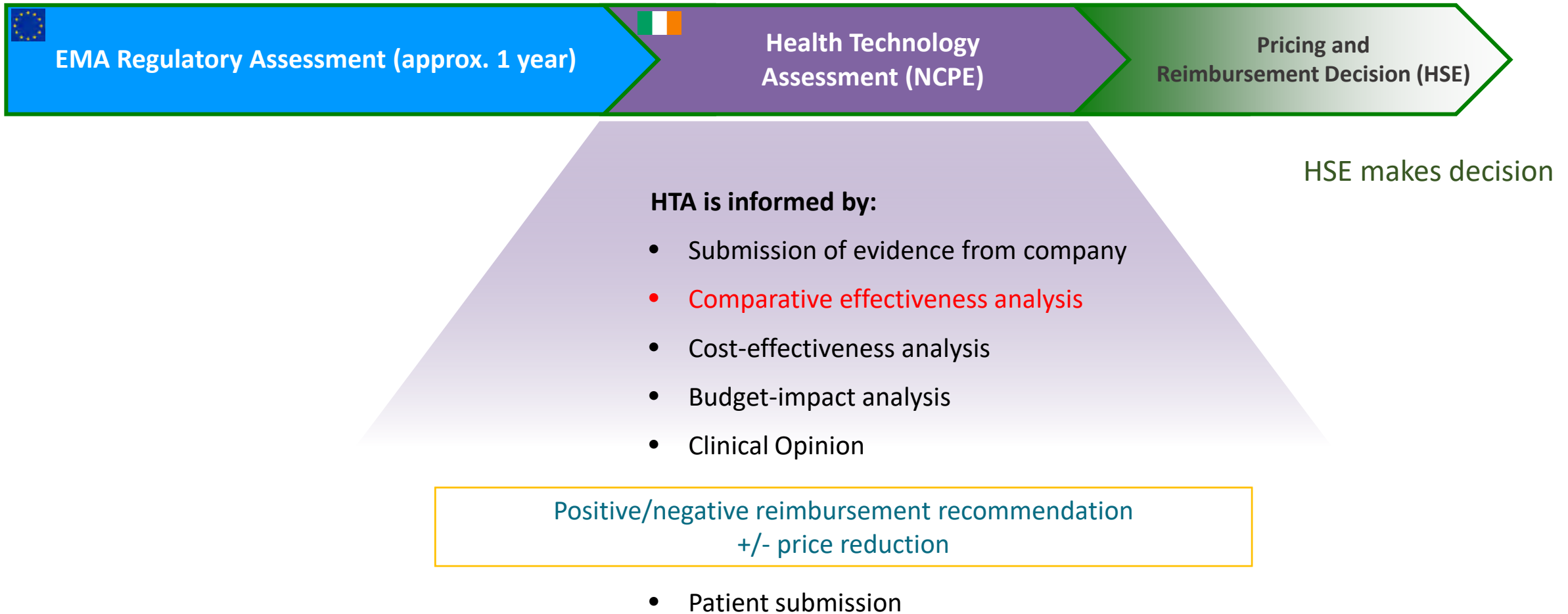
Joint Scientific Consultations (Early advice)

Number of JSC defined in [2025 work programme of the HTACG](#)

- **2025: 10 JSC planned with the aim to continuously increase capacities in the coming years**
 - **2nd request period: 2-30 June 2025**
 - **HTD can request to have with HTA and EMA or with HTA alone.**
- ⊙ **Outcome of the JSC procedure:**
 - **JSC Outcome document with common position + individual positions by Member states (MS) in an annex (further specifications)**
 - **Not in the public domain**

What does this mean for Ireland?

Current process for drug licensing/assessment/reimbursement



1. Company application for marketing authorisation of Drug X

4. Marketing authorisation granted by EU Commission

EMA Regulatory Assessment (approx. 1 year)

Joint Clinical Assessment (approx. 1 year +30 days)

Health Technology Assessment

Pricing and Reimbursement Decision

3. PICO survey sent to all Member States - determines the EU Assessment Scope

2. JCA of Drug X starts

5. JCA Report published jointly by Member States, & EEA countries

- “Scientific analysis of the relative effects...and degree of uncertainty”

- JCA must be “**given due consideration**” in national HTA
- Member states draw their **own conclusions** on overall clinical added value within their national context

Collaboration with Regulatory Bodies



1 April 2025
EMA/115125/2025

Joint HTAb-regulatory perspectives on understanding evidence challenges, managing uncertainties and exploring potential solutions

Outcome of a workshop series between HTA bodies and regulators

- Combined needs of regulatory and HTA had common themes
- Randomised evidence preferred and acknowledgement that Making trials easier to do in practice (and cheaper)
- Multiple estimands could be helpful for market access decisions
- Improved data sharing from trials and registries would allow easier interpretability

Thanks to Dr. David McConnell, NCPE

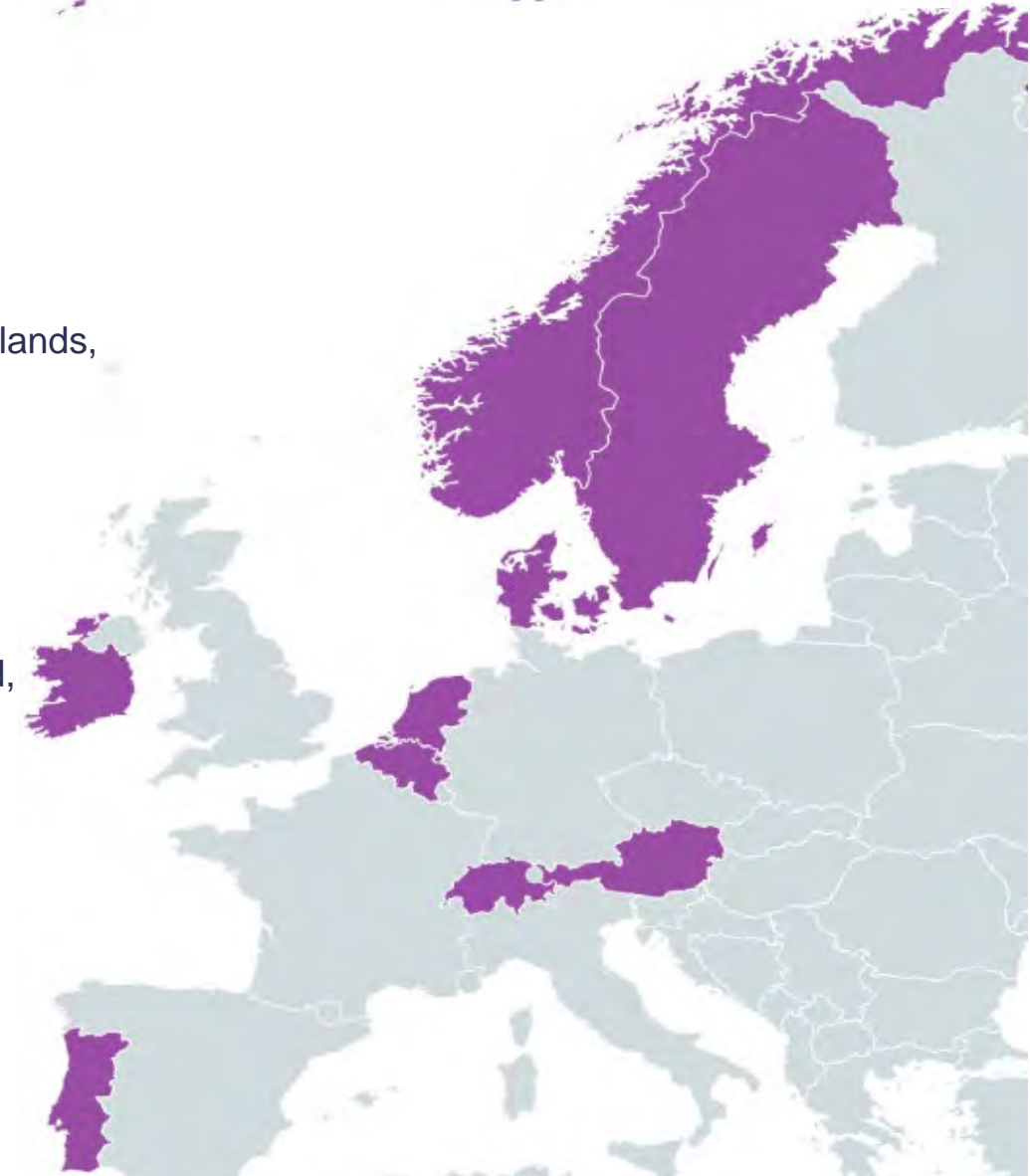
International Horizon Scanning Initiative

Why IHSI?



- Collaboration between Member States
- Consolidation of Horizon Scanning experts
- Publicly funded

- Belgium,
- The Netherlands,
- Ireland,
- Denmark,
- Sweden,
- Norway,
- Switzerland,
- Portugal,
- Austria.



Challenges facing National Horizon Scanning Systems

Manual burden is so high – challenging to scan all clinical trial registries, company materials (pipeline, press releases), regulatory agencies to define the complete horizon for medicinal products



Horizon Scanning data are commercially sensitive. Terms of use and data availability are decided by pharmaceutical companies



ClinicalTrials.gov

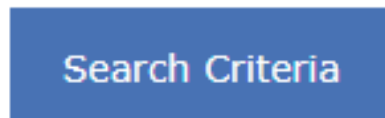
Search Results

Viewing 1-10 out of 530,051 studies

Showing results for: All



Clinical Trials



8813 results found



EUROPEAN MEDICINES AGENCY
SCIENCE. MEDICINES. HEALTH

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How can IHSI support health system preparedness in Ireland via Health Technology Management

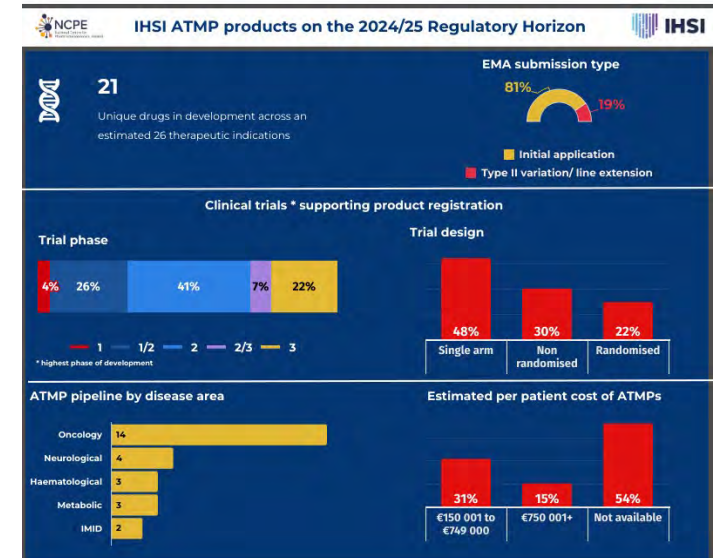
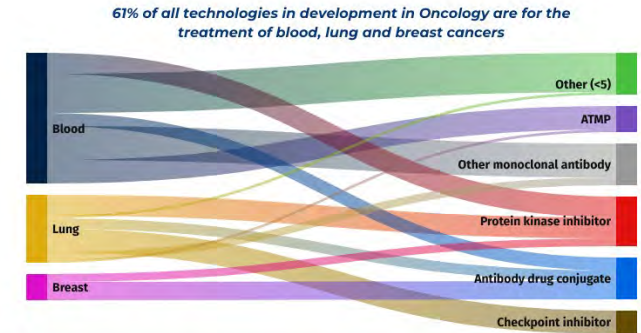
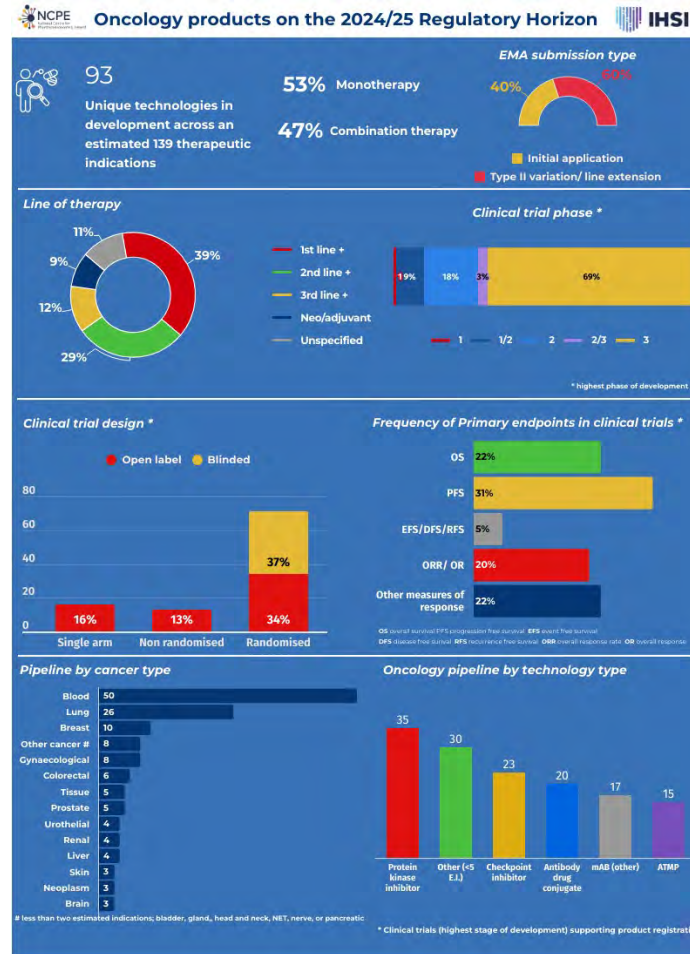
- ⦿ Effective planning for health technology assessment e.g. early PICOs, targeted disease area analysis
- ⦿ Early signal volume risk to the system (multiple type II variations) for expensive medicines
- ⦿ Savings opportunities – Biosimilars and generics on the horizon
- ⦿ Mitigate system risks - evergreening
- ⦿ Identify emerging classes of technologies



Drive efficiencies through effective planning for health technology assessment

Targeted analysis of evidence landscape underpinning oncology and ATMP products

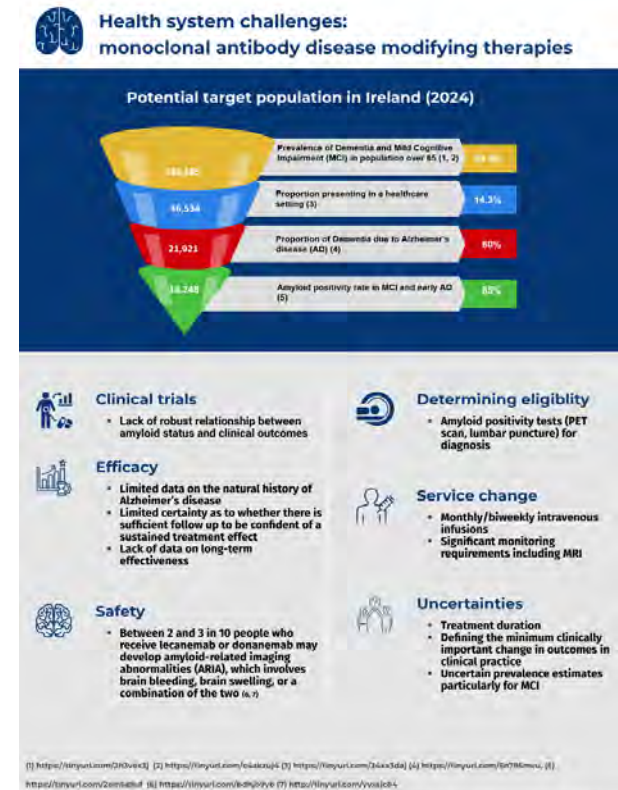
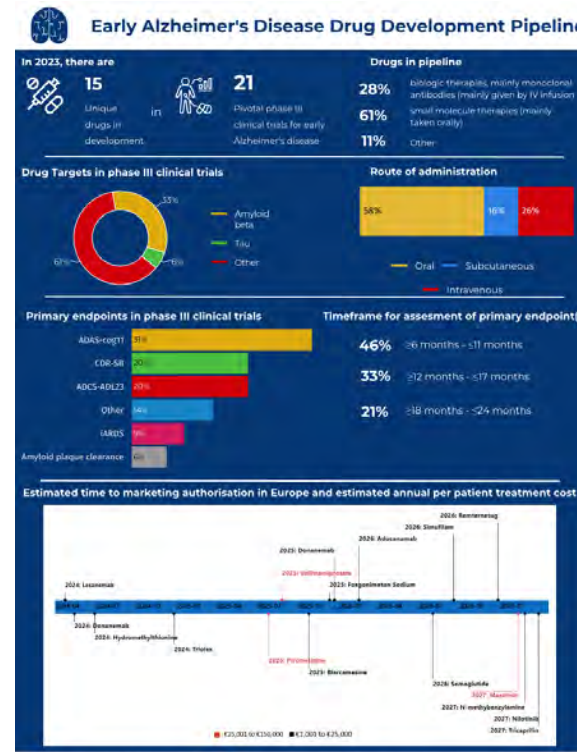
Early PICO – supporting JCA



Identify 'high cost' and 'high volume' emerging classes of technologies

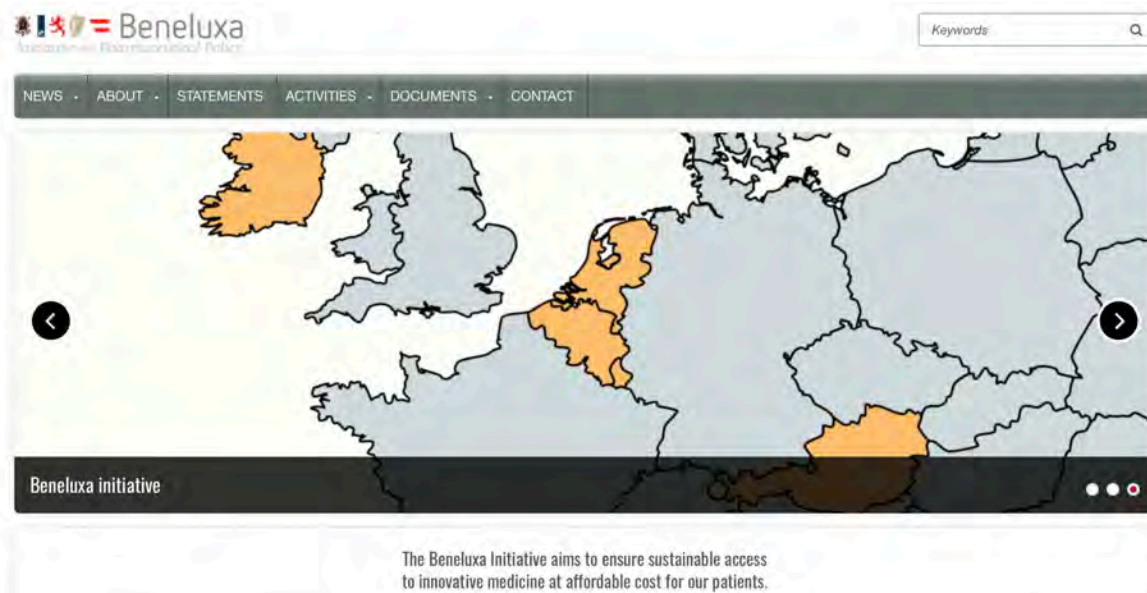
Early reporting and deep dives into therapeutic areas which will have considerable impact across health system domains

- Organisational
- Financial
- Efficacy



Beneluxa

- ⦿ 2025 Ireland will chair Beneluxa, Luxembourg as co-chair
- ⦿ How horizon scanning can help planning of joint work
- ⦿ Role of EU HTA Regulation and its outputs for Beneluxa
- ⦿ Continue to develop this model for cross country collaboration.



Thank you!



**Pharma
Summit 25**

evolving through change



Gary Keegan

CEO & Founder - Uppercut

u^{pp}ercut

Performance Coach to Ireland's
Senior Men's Rugby Team – IRFU



Gary is the leading high performance advisor for business & sport across a diverse range of industries & sporting associations globally. Gary's experience & achievements are unparalleled. A former Director of the Irish Institute of Sport & High Performance Director with the IABA's High Performance Boxing Programme. Gary was the driving force behind previously unseen success for Irish teams and athletes on European, World and Olympic stages.

Gary formerly sat on the IRFU National Professional Games Board and Chaired Cricket Ireland's High Performance Advisory Group. Gary is currently the Performance Coach to Ireland's Senior Men's Rugby Team and the Cork Senior Men's Hurling Team. Outside of the sporting arena, Gary works with leading organisations, CEOs & Executive teams, enabling them to develop the same culture of winning that he has achieved with Olympians, professional sports teams, All Ireland & World Champions. Gary lectured on Leadership, High Performance Systems, and Strategy at the London Business School, Smurfit Business School, and at the Irish Management Institute. From sports stadiums to the boardroom, Gary's unique thinking on high performance has inspired a culture of excellence in execution that is at the foundation of what Uppercut do.

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INTENTION FOCUSES ATTENTION



LEADING HIGH PERFORMING ORGANISATIONS

PMI ANNUAL PHARMA SUMMIT

APRIL 3RD 2025 – CROKE PARK CONFERENCE CENTRE

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SESSION AIMS

- 1. SHARE INSIGHTS FROM OUR WORK IN THE FIELD WITH HIGH PERFORMING LEADERSHIP TEAMS**
- 2. HIGHLIGHT KEY CONSIDERATIONS/CHALLENGES FOR LEADERS LEADING TEAMS**

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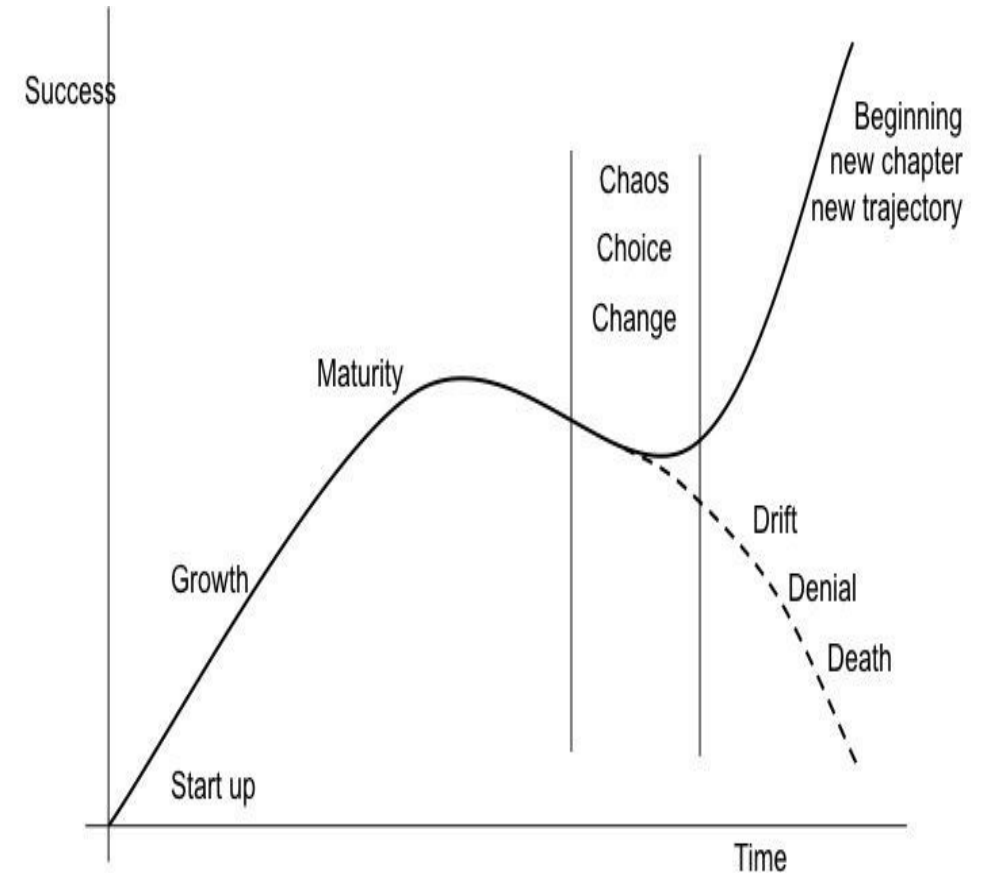
Where are we?



- Life is best understood backwards, but we must live it forwards

- What got us to here is unlikely to get us to where we want to be

- “Between stimulus and response is a space. In that space is our power to choose our response. In our response lies our growth and our freedom.”



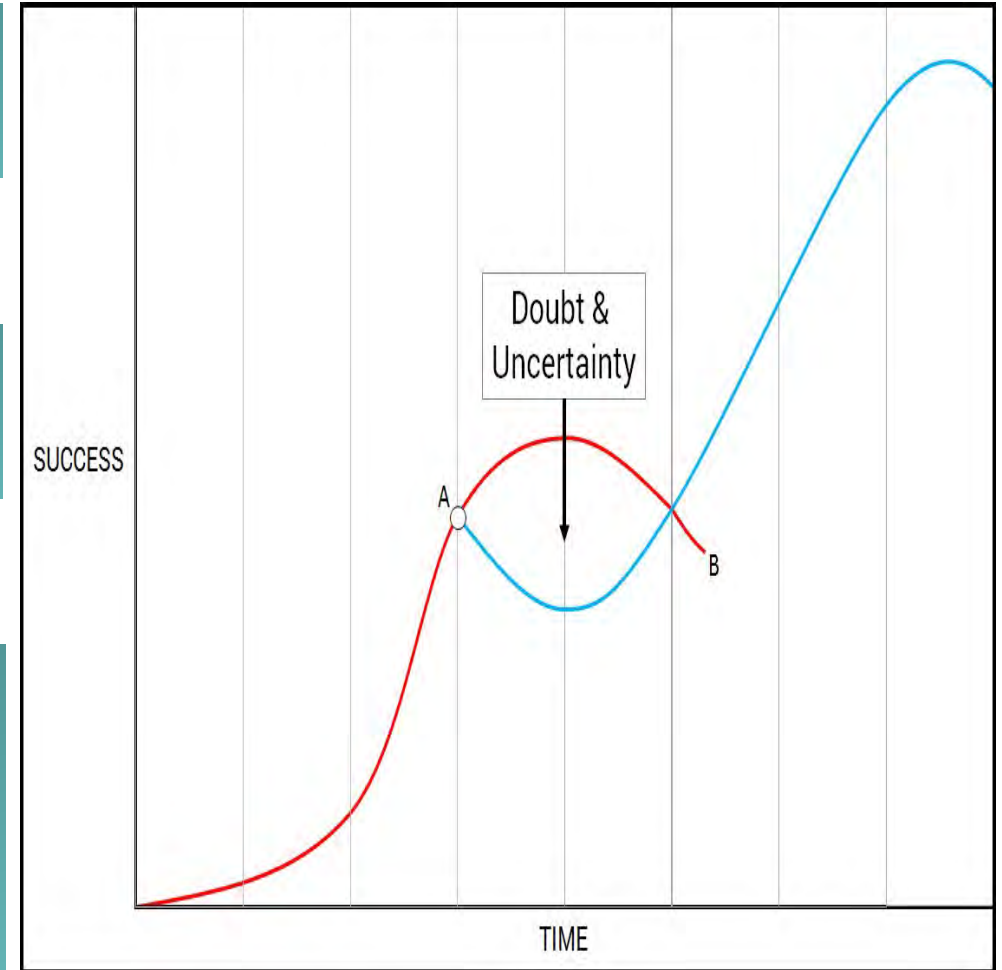
Based on work of Charles Handy, The Empty Raincoat

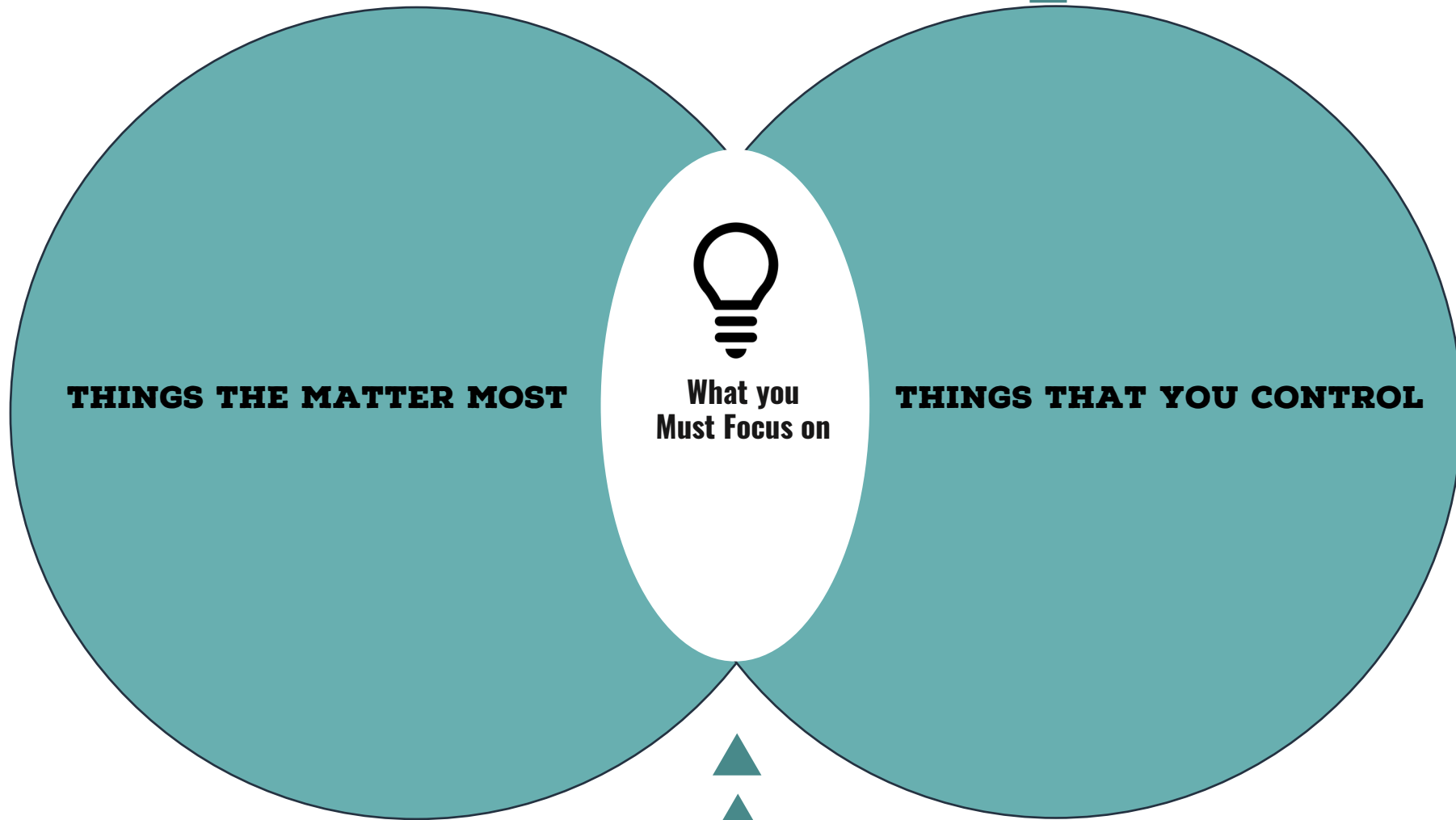
Where are we?

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THINGS THE MATTER MOST

**What you
Must Focus on**

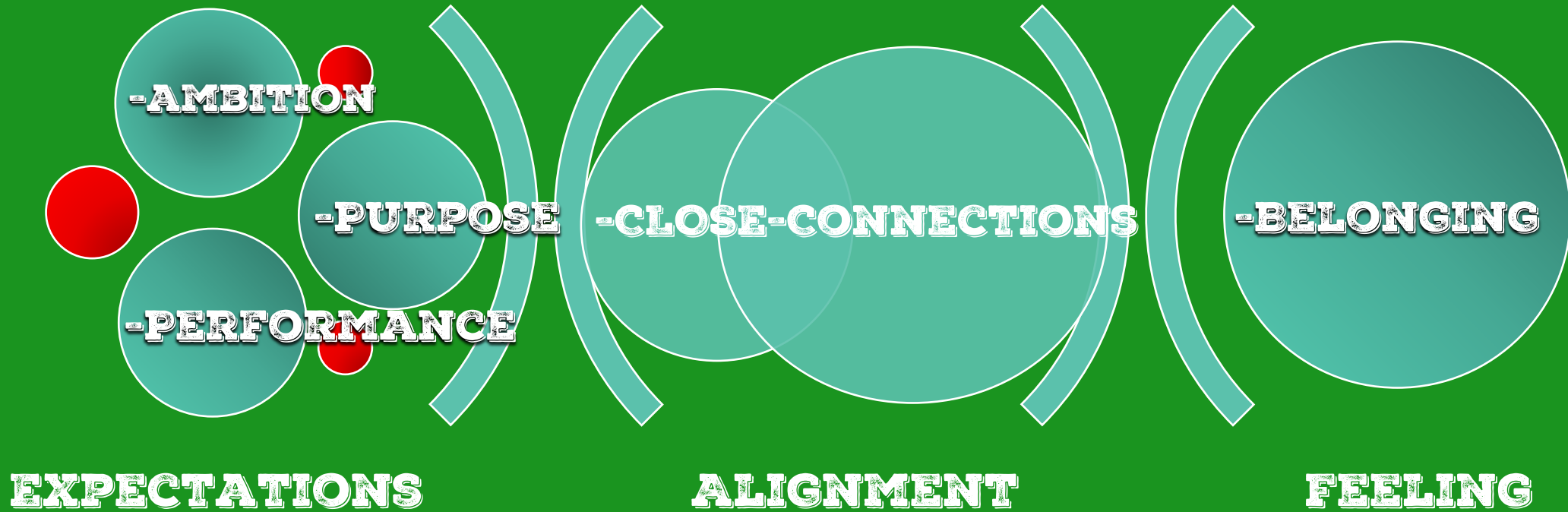
THINGS THAT YOU CONTROL

A vertical yellow line with circular ends at the top and bottom, passing through the center of the text.A series of vertical white bars of varying heights, resembling a bar chart or a stylized background element, positioned behind the text.

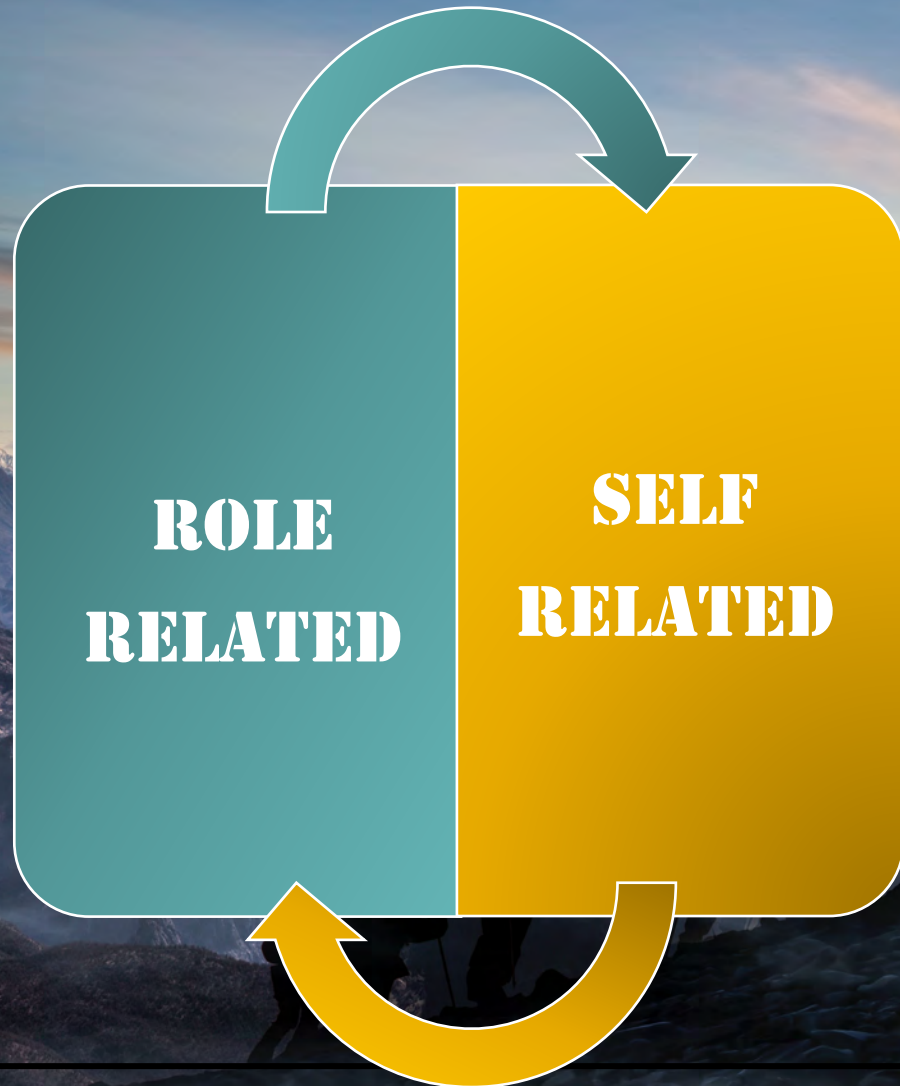
**WE WILL BE MEASURED BY
WHAT WE DO TOGETHER**

**NOT BY WHAT WE HAVE
AS INDIVIDUALS**

TOGETHER WE GO FURTHER



WHERE WILL YOU MINE FOR GOLD ?



WHAT WE CAN BECOME MUST INSPIRE US ALL!

WHAT WE INVEST OUR
TIME ON AND THE
QUALITY OF OUR MOST
CONSISTENT DECISIONS
& BEHAVIOURS

PREPARE
TO
PERFORM

THE PURPOSE

BELONG

SELF
BELIEF
AND
MENTALITY

WHAT WE CAN BECOME AND
WHY IT HAS A DEEP SENSE OF
MEANING FOR US AS A TEAM.

OUR SENSE OF INNER
BELIEF, AND OUR ABILITY
TO MAINTAIN OUR MINDS IN
A STATE OF PRODUCTIVE
OUTPUT.

Crucial Enablers for High Performing Teams

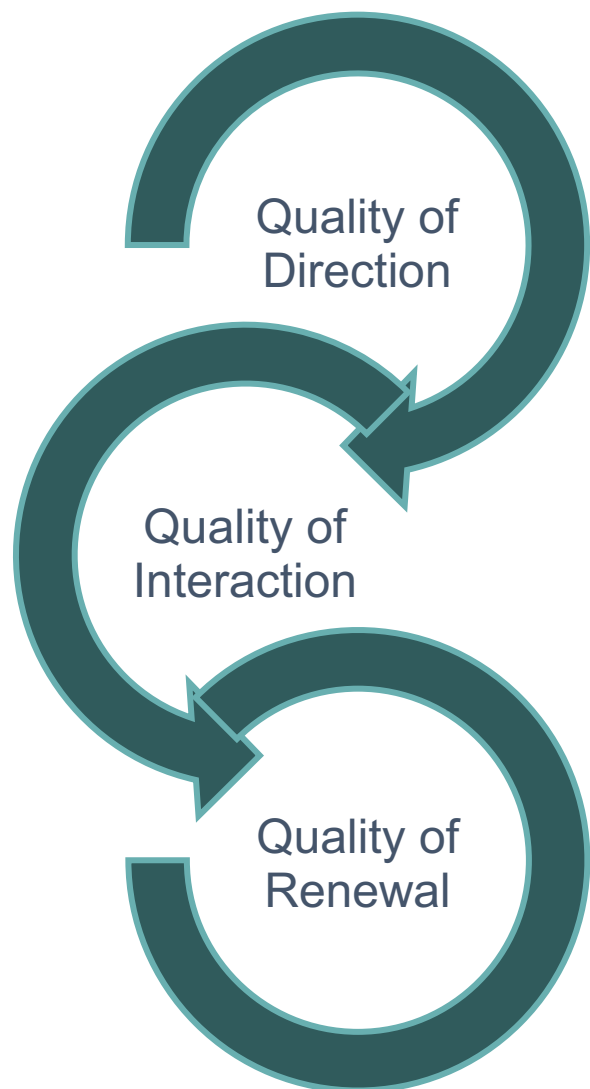
EXPECTATIONS



CONSEQUENCES



CHARACTERISTICS OF SENIOR TEAM PERFORMANCE



Aligned on Priorities, Focus strategically on team goals and direction, Developing talent, Driving growth initiatives

Encourage critical thought through effective dialogue & capitalise on diverse viewpoints and teamwork

Encourage personal development and risk taking, Avoid insularity, Utilize insights and knowledge from outside the company & Provide mentoring and coaching to leadership talent

A TOP PERFORMING SENIOR TEAM CULTIVATES

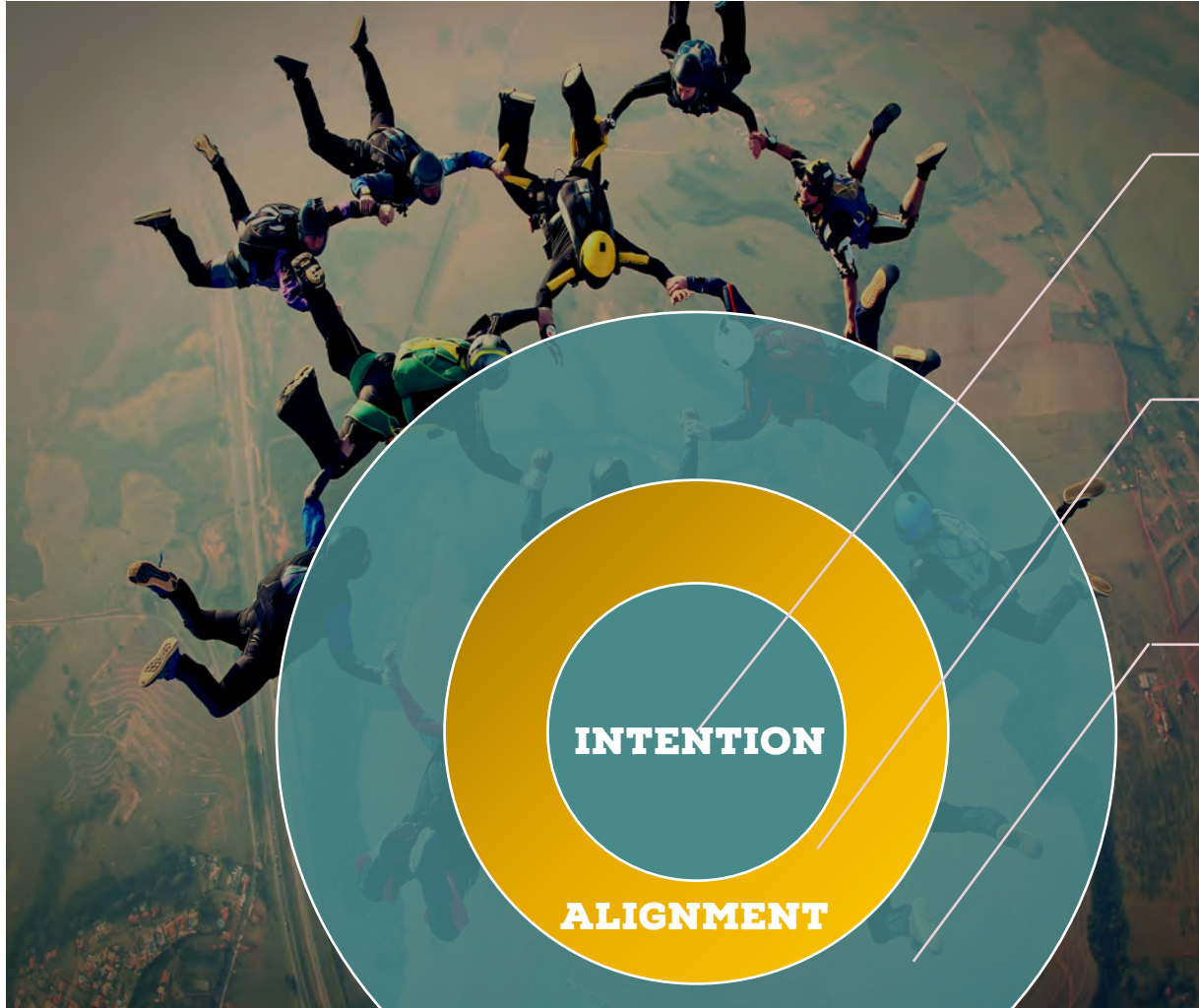


- ❑ **CLARITY OF PURPOSE & PRIORITIES**
- ❑ **A FOCUS ON CORE PROBLEMS & OPPORTUNITIES**
- ❑ **HEALTHY LEVEL OF COLLEGIABILITY AND COOPERATIVE RELATIONSHIPS ACROSS PEERS**
- ❑ **DEEP RESPECT FOR PERFORMANCE OVER OUTCOMES**
- ❑ **ORGANISATIONAL COHERENCE AND FOCUS**



The team has a multiplier effect therefore skills of interaction are crucial if the team is to go beyond individual expertise to solve complex problems and equally if it is to withstand the scrutiny of the rest of the org.

SOME PRINCIPLES ARE ESSENTIAL



INTENTION

ALIGNMENT

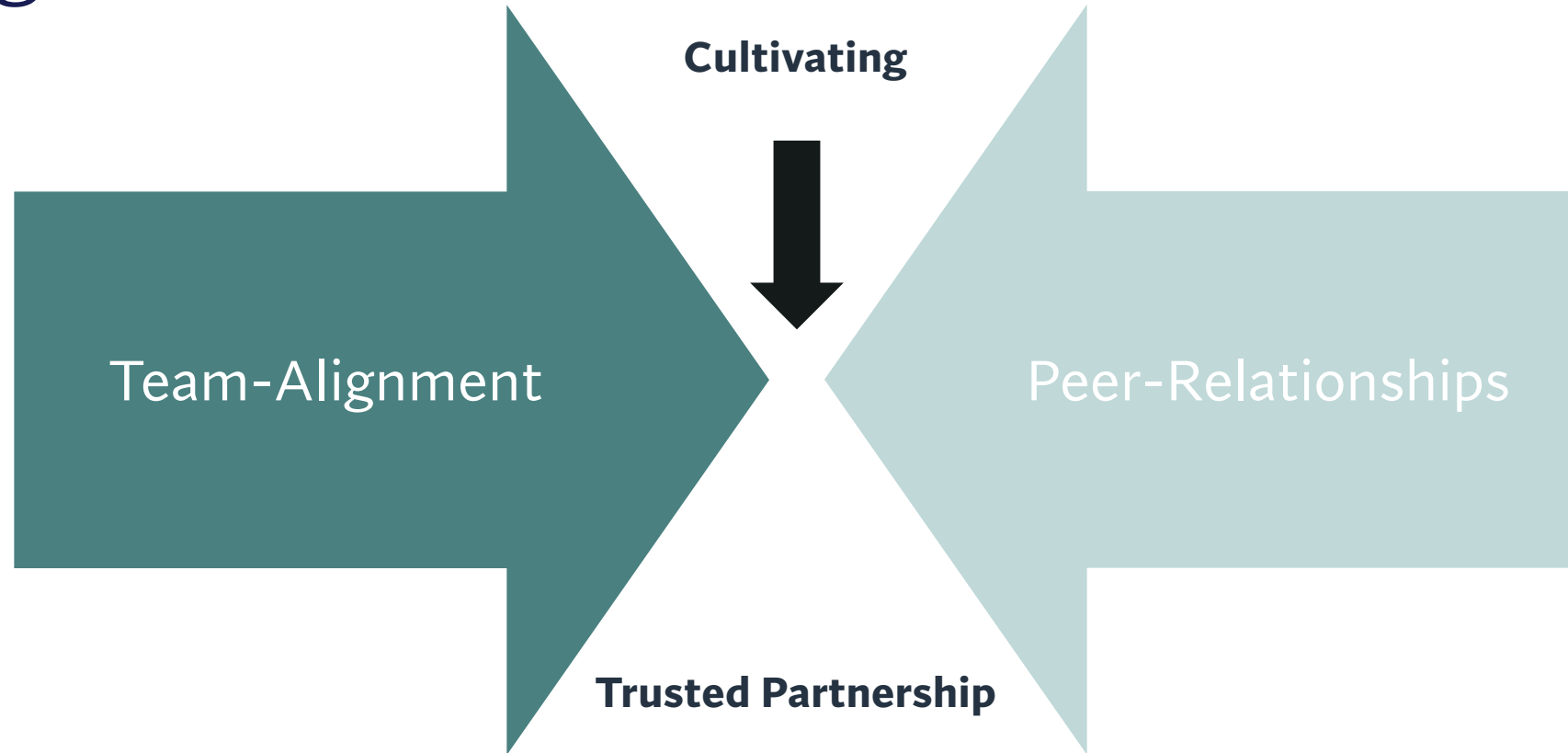
EXECUTION

- **IS THE PERFORMANCE OF THIS TEAM CRUCIAL TO THE ORGANISATION ACHIEVING ITS AMBITIONS?**
- **IS IT THE EXPRESSED INTENTION OF THIS COLLECTIVE TO BE A HIGH PERFORMING TEAM?**
- **WHAT ARE THE TOP 3 STRATEGIC PRIORITIES FOR THE ORGANISATION?**

- **DO YOU HAVE AGREED BEHAVIOURS & RITUALS AROUND YOUR WAYS OF WORKING?**
- **HOW COLLABORATIVE ARE YOUR PEER RELATIONSHIPS AT THE TOP TABLE?**
- **MY SENIOR TEAM PEERS HAVE MY BACK?**

- **THE EXECUTIVE TEAM DELEGATE THE APPROPRIATE AUTONOMY TO NEXT LEVEL LEADERS FOR THE DELIVERY OF TEAM-GOALS LINKED TO STRATEGIC PRIORITIES.**
- **OUR CROSS FUNCTIONAL TEAMS ARE FULLY ALIGNED WHERE THE INTERDEPENDENCY FOR SUCCESS IS CLEAR.**

Highest rated factors for Team Effectiveness



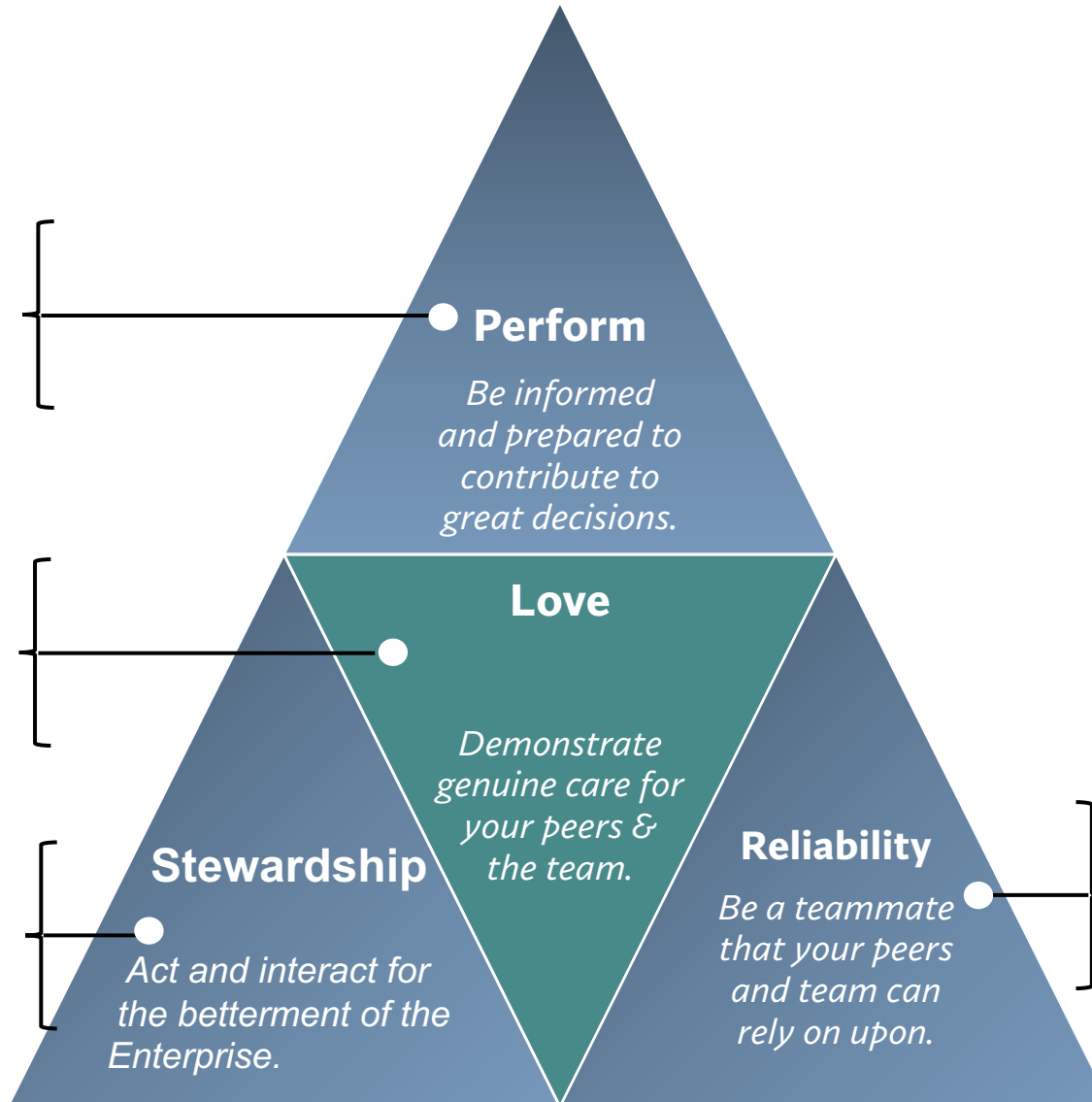
A CONNECTED COLLECTIVE - WHAT WOULD IT TAKE?



GENERATE SPACE TO INTERROGATE INFORMATION RELATED TO TEAM MEETINGS AND BE WELL PREPARED TO CONTRIBUTE TO DEBATES AND DECISIONS.

ACTIVELY SHARE YOUR TIME AND EXPERIENCE WITH YOUR PEERS & THE TEAM. WATCH OUT FOR YOUR PEERS & BE THERE TO CHALLENGE AND SUPPORT WHEN NEEDED.

BE PROACTIVE & CONSTRUCTIVE WHEN DEBATING CRUCIAL TOPICS RELATED TO ENTERPRISE PERFORMANCE AND INTEGRITY.



BE TRUE TO THE COMMITMENTS YOU MAKE, FOLLOW THROUGH AND BE ACCOUNTABLE FOR YOUR ACTIONS AND OUTCOMES.

“TO WIN WHILE HONORING OUR VALUES AND RESPONSIBILITIES MAKES ANYTHING POSSIBLE”

*Thank
you!*



up



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