

Capability Development in the European Medicines Regulatory Network: A Cross- Case Analysis of EU-Funded Joint Actions

Work package 5

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Note: This report is an adapted summary of the publication *Capability Development in the European Medicines Regulatory Network: A Cross-Case Analysis of EU-Funded Joint Actions*. It has been developed for EMRN stakeholders to highlight key findings and practical implications. The full publication is available [here](#).

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1. Introduction

The European Medicines Regulatory Network (EMRN) is operating in an environment of increasing complexity. Advances in science and technology, new regulatory requirements, evolving healthcare challenges, and growing public expectations are placing increasing demands on regulators across Europe. To continue delivering high-quality, timely, and consistent regulatory decisions, the network must ensure that its workforce has access to the knowledge, skills, and support needed to perform effectively in both current and emerging areas of regulation.

Capability development has therefore become an important strategic priority for the EMRN. While network-wide structures such as the HMA/EMA EU Network Training Centre (EU NTC) provide a central platform for training delivery and coordination, a significant amount of capability-building activity is also taking place through EU-funded Joint Actions. These initiatives bring together National Competent Authorities (NCAs) from across Europe to address shared regulatory challenges while simultaneously developing expertise, strengthening collaboration, and promoting harmonisation across the network.

One such initiative is the [IncreaseNET Joint Action](#), which aims to strengthen capability development across the European Medicines Regulatory Network. Through its work, IncreaseNET is helping the network better understand learning and development needs, improve approaches to training, and support greater collaboration between NCAs.

To support these objectives, IncreaseNET has undertaken a range of activities, including a network-wide learning needs analysis, the establishment of a specialist pedagogical team, the development of the Becoming a Regulatory Trainer (BaRT) programme, and an on-the-job training program led by BfARM facilitating agency-agency mentoring. Together, these activities reflect a growing focus on developing regulatory expertise through training, mentoring, knowledge sharing, and collaboration across the network.

As IncreaseNET progressed, it became increasingly apparent that many capability development activities were already being delivered through other Joint Actions operating across different areas of medicines regulation. Although these initiatives were often working towards similar goals, there had been limited assessment of how they collectively contribute to capability development within the EMRN, what approaches are being used, and what lessons could be shared across projects.

This report was therefore undertaken to provide a broader view of capability development across the network. It examines a selection of EU-funded Joint Actions to identify common approaches, successful practices, and opportunities for greater collaboration and coordination. Rather than focusing on individual projects in isolation, the report explores how these initiatives collectively contribute to the development of regulatory expertise, knowledge sharing, and harmonisation across Europe.

The findings provide an opportunity to inform future discussions on how capability development can be strengthened across the EMRN. In particular, they highlight the value

of mentoring, face-to-face collaboration, training development expertise, communities of practice, and stronger coordination between NCAs, Joint Actions, and the EU NTC. By understanding what is already working well across the network, the EMRN can build on existing strengths and move towards a more coordinated, sustainable, and strategically aligned approach to capability development for the future.

This report is based on findings from a [cross-case analysis](#) of capability development activities delivered through selected EU-funded Joint Actions. The report presents the key findings and their implications for the EMRN in a concise and practical format. Readers seeking further detail on the study design, analysis, and full findings are encouraged to consult the accompanying publication.

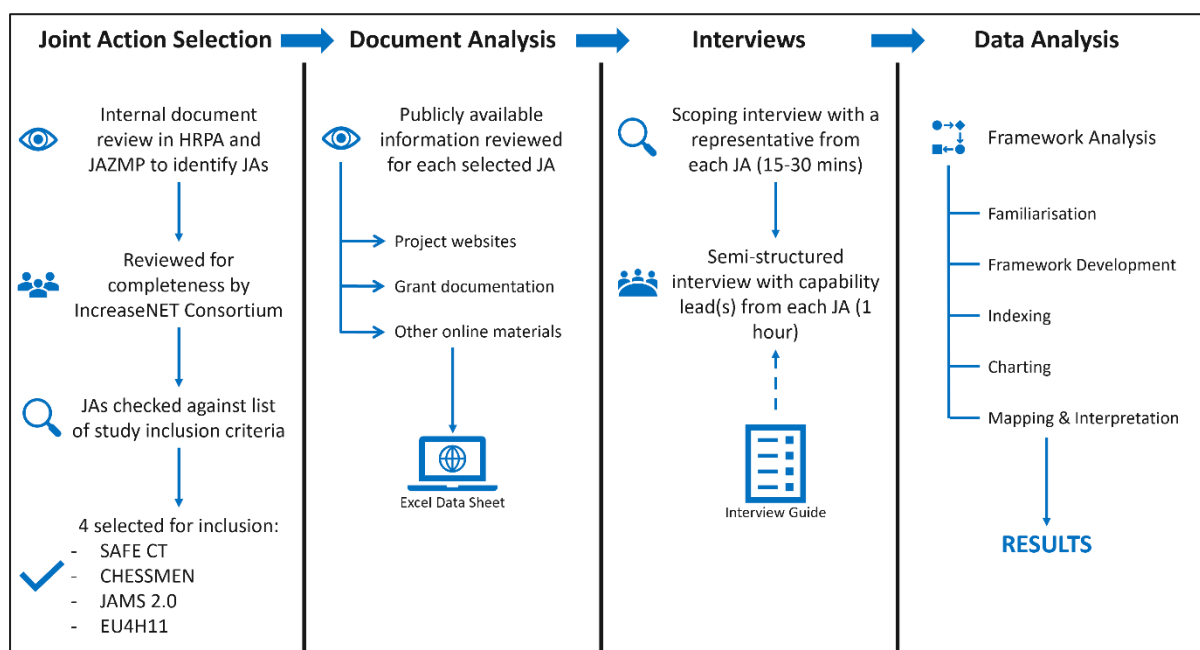
2. Methodology

This report builds on research conducted as part of the IncreaseNET Joint Action to better understand how capability development is being supported across the EMRN.

The study examined capability-development activities delivered through four EU-funded Joint Actions operating in different areas of medicines regulation. These Joint Actions were selected because they included a range of learning and development approaches designed to strengthen regulatory expertise, facilitate knowledge sharing, and support collaboration across NCAs.

The analysis combined a review of project documentation with interviews involving individuals responsible for designing, coordinating, or participating in capability-development activities. Information gathered from each Joint Action was analysed to

Figure 1. Overview of Study Methodology



identify common approaches, recurring themes, and lessons that could be applied more broadly across the EMRN. See Figure 1 for an overview of the methodology.

Rather than evaluating the effectiveness of individual programmes, the study focused on understanding how capability development was being implemented in practice and what factors appeared to support sustainable learning, knowledge exchange, and workforce development across the network.

The findings presented in this report have been adapted from the full cross-case analysis to provide a practical and strategic perspective for EMRN stakeholders. Further details on the study design, data collection methods, analytical approach, and complete findings are available in the accompanying [publication](#).

Joint Actions Included in the Analysis

- [SAFE CT](#) – strengthening clinical trial assessment capabilities through training, mentoring, and collaborative learning.
- [CHESSMEN](#) – supporting medicines shortages preparedness through study visits, staff exchanges, and peer learning.
- [JAMS 2.0](#) – enhancing regulatory expertise through structured training and joint inspection activities.
- [EU4H11](#) – developing inspector capabilities through training programmes, curricula, and collaborative learning initiatives.

Collectively, these Joint Actions represented a diverse range of regulatory disciplines, capability-development approaches and collaborative structures, making them a useful sample through which to explore broader capability-development practices across the EMRN.

3. Results

3.1. Overview

Four EU-funded Joint Actions were examined to understand how they supported capability development across the EMRN. While each initiative focused on different regulatory priorities, several common approaches were identified, including training programmes, mentoring, study visits, peer learning, joint activities, and knowledge-sharing networks.

This section provides an overview of the capability-development activities identified within each Joint Action. See Table 1 for a high-level summary. More detailed findings are available in the accompanying [publication](#).

Table 1. Joint Action Results Summary

Joint Action	Lead NCA for Capability	Key Mechanisms	Main Outputs	EMRN Relevance	Main Challenge
SAFE-CT	FAMHP (BE), BfARM (DE)	Mentoring, learning in practice, peer exchange	Guidance, FAQs, curriculum	Supports knowledge transfer between experienced and less experienced assessors	Limited availability of senior experts
CHESSMEN	AIFA (IT)	Study visits, workshops, exchange of practices	Shared practices and insights	Enables agencies to learn from each other and compare national approaches	Resource-intensive
JAMS 2.0	ANSM (FR)	Joint inspections, training, workshops	Templates, training resources, best-practice guides	Helps align regulatory approaches and strengthen practical expertise	Reliance on voluntary expert contribution
EU4H11	AGES (AT)	Joint inspections, formal and practical training	Curriculum, training resources	Provides a basis for more sustainable and coordinated regulatory training	Coordination and resource requirements

3.2. SAFE CT

SAFE CT focused on strengthening clinical trial assessment capabilities across participating authorities. The project recognised that developing expertise in clinical trial assessment requires more than formal training alone and incorporated a range of learning and support mechanisms.

A significant component of the project was the use of mentoring and collaborative learning approaches. Participants were able to learn directly from experienced colleagues while applying new knowledge in practical settings. This helped support the development of technical expertise while also facilitating the sharing of regulatory experience and good practice.

SAFE CT also highlighted the importance of building relationships between assessors from different authorities. Through project activities, participants were able to establish professional networks that supported continued collaboration and knowledge exchange beyond individual training events.

3.3. CHESSMEN

CHESSMEN supported capability development through a strong emphasis on peer learning and direct collaboration between authorities.

One of the most notable approaches was the use of study visits and staff exchanges, providing participants with opportunities to observe how other organisations approached medicines shortages preparedness and management. These activities enabled participants to gain practical insights into different ways of working while also sharing their own experiences and expertise.

The project demonstrated the value of learning through exposure to real-world practice. Participants were able to discuss challenges, exchange ideas, and identify approaches that could be adapted within their own organisations. Many of these interactions also contributed to the development of lasting professional relationships across the network.

3.4. JAMS 2.0

JAMS 2.0 focused on developing regulatory expertise through a combination of structured training and practical learning opportunities.

The project supported participants in developing inspection-related competencies through training activities that were closely linked to workplace practice. Joint activities allowed participants to apply learning in real regulatory settings while benefiting from the expertise of more experienced colleagues.

The project also demonstrated how collaborative activities can support harmonisation across the network. Bringing inspectors together to work on common tasks not only strengthened individual capability but also promoted more consistent approaches across participating authorities.

3.5. EU4H11

EU4H11 placed a strong emphasis on workforce development through inspector training and curriculum development.

The project developed learning resources and training pathways designed to support the consistent development of inspection capabilities across participating authorities. These activities provided a more structured approach to capability development while ensuring that training was aligned with network needs.

The project also highlighted the importance of collaboration in developing and delivering training. Expertise from multiple authorities was brought together to create learning resources that could be shared across the network, helping to maximise available expertise and reduce duplication of effort.

3.6. Common Themes Across the Joint Actions



Although the Joint Actions differed in scope and focus, several common approaches to capability development emerged.

3.6.1. Learning Through Collaboration

All four Joint Actions provided opportunities for participants to learn from colleagues across the network. This occurred through mentoring, peer learning, joint activities, study visits, and collaborative projects.

3.6.2. Knowledge Sharing and Exchange

Knowledge exchange was a consistent feature across all projects. Participants were able to share expertise, discuss challenges, and learn from the experiences of other authorities.

3.6.3. Building Professional Networks

Many activities supported the development of professional relationships that extended beyond the duration of individual projects. These connections were viewed as an important mechanism for ongoing learning and collaboration.

3.6.4. Combining Formal and Informal Learning

Capability development rarely relied on formal training alone. Instead, projects combined structured learning with practical experience, mentoring, workplace learning, and peer support.

3.6.5. Supporting Harmonisation Across the Network

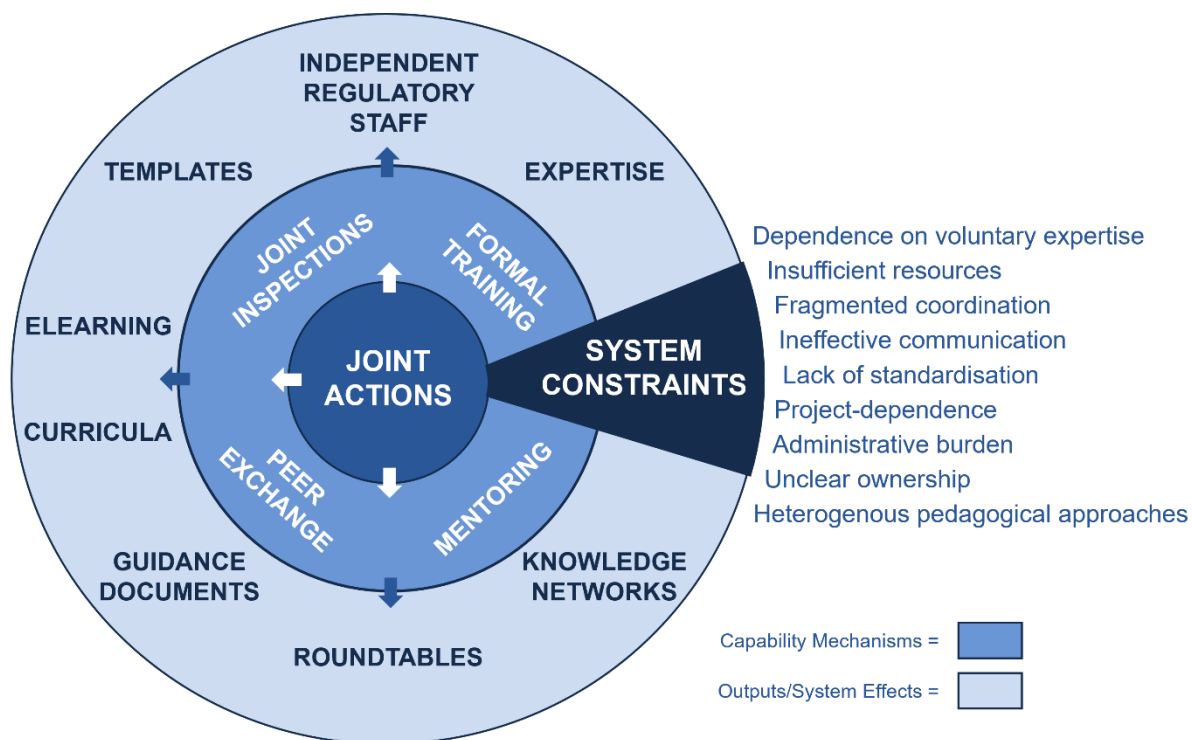
Beyond developing individual capabilities, the Joint Actions helped promote greater consistency in regulatory approaches by bringing authorities together to learn, collaborate, and share expertise.

4. Discussion and Recommendations

The findings from this analysis suggest that capability development within the EMRN is influenced not only by individual learning initiatives, but also by the wider system in which they operate. Factors such as increasing regulatory complexity, workforce pressures, competing priorities, and the need for greater harmonisation create both challenges and opportunities for capability development across the network.

In response to these pressures, a range of capability-development structures and mechanisms have emerged across the EMRN. Figure 2 presents an overview of this evolving capability-development infrastructure, illustrating both the system-level factors influencing workforce development and the key structures that support learning, collaboration, and knowledge exchange.

Figure 2. Conceptual model of the emerging regulatory learning infrastructure within the European Medicines Regulatory Network (EMRN).



Together, these elements provide the foundations for a more coordinated and sustainable approach to capability development across the network. Building on this framework, the following sections explore five opportunities that could further strengthen capability development within the EMRN.

4.1. Invest in the Next Generation of Regulatory Trainers

The findings highlight an important challenge for capability development across the EMRN. While the Network has significant scientific and regulatory expertise, training quality and design approaches remain inconsistent. Many training resources rely on lengthy, presentation-based formats that can be difficult to maintain, update and adapt to evolving learner needs. Learning is often not designed using recognised pedagogical principles, leading to variable levels of quality, engagement and effectiveness.

Outsourcing training development has been trialled to address capacity gaps. However, this approach can be costly and may not fully capture the realities of regulatory practice. It also does little to build and retain training-development capability within the Network itself.

At the same time, the operating environment is becoming more complex. Scientific advances, emerging technologies and regulatory change require assessors to acquire new knowledge and skills more rapidly than ever before. New generations of regulatory professionals also expect learning that is accessible, engaging, visually appealing and available in smaller, easily digestible formats.

Addressing these challenges will require a more sustainable approach to training development. One potential solution is the introduction of a Minimum Viable Product (MVP) benchmark for training resources, establishing a common baseline standard for quality, structure, learner engagement and maintainability across the Network.

Building on this foundation, the [Becoming a Regulatory Trainer](#) (BaRT) model (Annex 1) provides a practical mechanism for developing internal capability. By equipping regulatory experts with simple, effective training design skills, the Network can create and maintain high-quality learning resources while reducing reliance on external providers. Investing in current and future assessors in this way not only improves knowledge transfer today but also builds a sustainable pool of training expertise that will strengthen capability development across the EMRN for years to come.

Recommendation: Establish a network-wide MVP quality benchmark for training resources and support programmes such as BaRT to build internal capability in training design, development and delivery.

4.2. Build Dedicated Capability Development Expertise within NCAs

High-quality capability development requires dedicated ownership, specialist expertise and sufficient capacity to plan, develop and maintain learning resources over time. However, most NCAs face significant resource constraints, with available posts typically prioritised for core regulatory activities such as assessment, inspection and scientific support. As a result, training development is often undertaken alongside existing roles, limiting the capacity to plan, develop and maintain learning resources at scale.

In the longer term, the Network should consider establishing dedicated pedagogical teams within NCAs. Unlike traditional learning and development functions, these roles would be designed for multidisciplinary individuals with strong scientific backgrounds who have expertise in training design and capability development. This combination of subject matter expertise and educational capability is essential for producing high-quality technical learning that is accurate, relevant and aligned with regulatory practice.

A practical first step could be taken through IncreaseNET II, which is expected to commence in 2028. Rather than implementing this approach across all agencies from the outset, a small number of NCAs could be supported to establish dedicated specialist pedagogical roles. Although embedded within individual agencies, these specialists would operate as a coordinated Network-wide community, working to a common framework, sharing methodologies and jointly contributing to training development across the EMRN.

This pilot approach would allow the Network to evaluate the impact and return on investment of dedicated capability-development expertise before considering wider implementation. It would also help to build internal expertise, improve the quality and sustainability of training resources, strengthen knowledge sharing across agencies and reduce reliance on external providers.

Recommendation: Use IncreaseNET II to pilot dedicated specialist pedagogical roles within a small number of NCAs, creating a Network-wide community with specialist capability-

development expertise and evaluate the long-term value of this model for broader implementation.

4.3. Learning Through Relationships: The Strategic Value of Mentoring

Mentoring programmes are an effective way of developing regulatory expertise. Through guidance from experienced colleagues, junior experts gain technical knowledge, practical insights and the confidence needed to progress towards independent work. Mentoring therefore plays an important role in accelerating competence development and transferring expertise across the Network.

Virtual mentoring should continue to be supported as an accessible and cost-effective way of connecting experts across agencies. However, face-to-face engagement offers important additional benefits. It helps to build trusted professional relationships, encourages informal knowledge sharing and creates connections that often continue beyond the formal mentoring relationship.

This is particularly valuable in a network system such as the EMRN. Effective collaboration depends not only on knowing where expertise exists, but also on feeling comfortable reaching out to colleagues in other agencies when support is needed. Face-to-face interactions help break down organisational barriers, strengthen professional networks and foster a greater sense of belonging to a single European regulatory network.

As scientific disciplines become increasingly specialised and experienced experts remain a limited resource, stronger cross-network connections are becoming more important. Mentoring and expert exchanges can accelerate the development of junior experts while also supporting the continued growth of established staff through exposure to specialist expertise in complex topic areas.

For these reasons, mentoring and expert exchanges should be viewed not simply as training activities, but as strategic investments in Network capability. A blended approach combining virtual engagement with targeted face-to-face opportunities offers the greatest potential to strengthen knowledge transfer, collaboration and long-term sustainability across the EMRN. While Joint Actions play an important role in supporting such activities, sustainable Network investment should be considered to ensure these benefits continue beyond individual funding cycles and remain resilient to changes in future funding availability.

Recommendation: Increase investment in mentoring and expert exchanges through a blended model combining virtual and face-to-face engagement to accelerate expertise development, strengthen cross-network relationships and build long-term EMRN capability.

4.4. Harnessing Collective Intelligence Across the EMRN

Across the EMRN, many agencies are developing innovative approaches to capability development, training design and knowledge transfer, a significant proportion of which occurs through Joint Actions. Much of this work takes place in isolation, meaning that valuable experience, lessons learned and effective practices are not always shared across the

wider Network. This can lead to duplication of effort and missed opportunities to build on existing work.

A practical way to address this would be the establishment of a Network-wide Community of Practice (CoP) focused on capability development. The CoP should bring together those who are directly involved in planning, developing and delivering training and capability-development activities within NCAs. By focusing on operational practitioners' discussions can remain grounded in the practical realities, challenges and opportunities encountered when implementing capability-development initiatives.

The purpose of the CoP would be to facilitate knowledge sharing. Members could exchange methodologies, tools, resources and lessons learned, discuss common challenges and identify practical solutions that can be adapted across agencies. This would help spread effective practices more quickly, support innovation and reduce duplication of effort.

The EU NTC should be an active participant in the CoP, contributing experience and insights while maintaining visibility of capability-development activities and emerging needs across NCAs. The CoP could therefore act as an important bridge between national and EU-level capability-development efforts, helping to ensure that future initiatives are informed by operational experience and evolving Network needs.

By connecting those responsible for delivering capability development across the EMRN, a Community of Practice would help capture and scale existing expertise, strengthen collaboration and promote a more coordinated approach to workforce development across the Network.

Recommendation: Establish a Network-wide Community of Practice for capability-development practitioners, bringing together operational colleagues from NCAs and the EU NTC to share expertise, exchange good practices and strengthen coordination across the EMRN.

4.5. Network for the Network: Coordinating Capability Development Across the EMRN

The EU NTC plays a central role in aligning and coordinating capability development across the EMRN. Its work on learning strategies, capability frameworks and assessor learning pathways provides an important foundation for developing expertise across the Network while reducing duplication of effort between agencies.

For this approach to be effective, there must be strong alignment between EU NTC priorities and NCA needs. The EU NTC requires visibility of emerging capability requirements, local initiatives and areas of expertise across the Network, while NCAs need clear awareness of EU NTC activities and planned developments. This two-way exchange helps ensure that Network-level initiatives remain relevant, targeted and responsive to changing scientific and regulatory priorities.

Particularly important is the EU NTC's work on learning pathways, which can provide a more structured and harmonised approach to competence development, from foundational

training for new assessors to advanced development in specialised areas. This can help ensure that capability-development efforts are coordinated across the Network and that resources are directed towards areas of greatest need and impact.

Ultimately, the EU NTC should continue to act as the strategic coordinator of EMRN capability development, working closely with NCAs to ensure that Network-wide priorities are informed by operational realities and evolving workforce needs.

Recommendation: Support the EU NTC's role as the strategic coordinator of EMRN capability development, ensuring learning pathways and Network-wide priorities are informed by NCA needs and supported through strong two-way communication.

Conclusion

The findings suggest that future capability development within the EMRN should focus not only on developing individual expertise, but also on strengthening the systems, structures and relationships that enable expertise to be shared across the Network. Five strategic priorities emerge from this analysis:

1. **Develop regulatory trainers, not just training materials.**
2. **Build dedicated pedagogical teams as a core Network asset.**
3. **Invest in mentoring relationships to accelerate expertise.**
4. **Establish a community of practice to share knowledge on capability building.**
5. **Support EU NTC as the strategic coordinator of EMRN capability development.**

By acting on these priorities, the EMRN can build a more connected, capable and resilient regulatory workforce, equipped to meet the challenges of an increasingly complex scientific and regulatory environment.

Annex 1

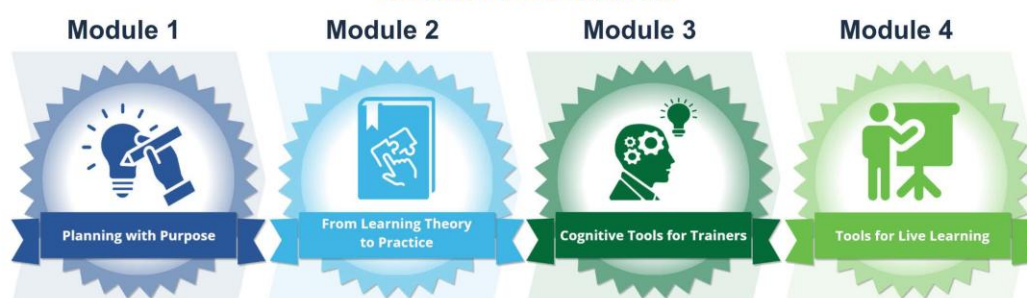


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