Strengthening Regulatory Science:
STARS Core and Comprehensive Curricula

Strategic Analysis and Recommendations by the STARS consortium

Accompanying document to the STARS Common Strategy

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Introduction

Regulatory science is defined as "the range of scientific disciplines that are applied to the quality, safety and efficacy assessment of medicinal products and that inform regulatory decision-making throughout the lifecycle of a medicine. It encompasses basic and applied biomedical and social sciences and contributes to the development of regulatory standards and tools" (EMA Regulatory Science to 2025).

To strengthen regulatory science in academia, the Strengthening Training of Academia in Regulatory Science (STARS) consortium aims to reach out to academia to bridge the regulatory knowledge gap and to enhance the dialogue between regulators and researchers to facilitate the implementation of health research findings in clinical practice (Starokozhko et al., 2020). The consortium recognized that the implementation of regulatory requirements in academic health research is sub-optimal due to the limited level of regulatory knowledge incorporated as part of professional training and qualification courses. This limitation may impact negatively on the development of new medicinal products/technologies and ultimately considerably delay patients' access to new promising treatments (Starokozhko et al., 2020).

To overcome this regulatory knowledge gap, the STARS consortium developed a curriculum to strengthen the awareness of regulatory science in academia. The focus is on the development of a **Core Curriculum (CoC)** dedicated to basic regulatory training, and a **Comprehensive Curriculum (CpC)** focused on a more in-depth training on specific regulatory requirements.

The implementation of the curricula will improve the translation of the research outcomes increasing knowledge and the likelihood of successful development and approval of a new medicinal product/technology and ultimately facilitate their use in clinical practice.

Background and data basis for the development of the Curricula

In order to develop a curriculum that could improve the regulatory knowledge in Europe with the focus on academia, the STARS consortium started from the results obtained through different activities implemented during the project. The survey data clearly revealed that a regulatory science training program in academia is needed and it would be widely welcome by different stakeholders.

a) STARS surveys

Eighteen European National Competent Authorities (NCAs) for medicinal products and the European Medicines Agency (EMA) participated in a survey with the aim to map and detail the support activities already offered to academia. The results of the survey identified that teaching on regulatory aspects is offered by competent authorities to graduate students (GS: 67%; N=12), post-graduate students [1] (PGS: 83%; N=15) and healthcare professionals[2] (HCPs: 44%; N=8). Lectures and guidelines are the most frequent support activities and materials in place. Interestingly, internship is offered slightly more frequently to PGS (39%; N=7) in comparison to GS (33%; N=6), whereas only 22% of the agencies (N=4) offered training programs to both PGS and GS.

Regarding the training topics, the most frequent topics are: Pharmacovigilance (83%; N=15) and regulatory system/legislation (83%; N=15) followed by clinical studies (78%; N=14). Product classification (39%; N=7), clinical statistics (33%; N=6), and research & development (R&D) (16%; N=3) topics are the least frequently addressed topics. Interestingly, NCAs showed agreement on the need

[1] anyone attending any course post-university degree course OR anyone who is studying a postgraduate course, including a master course, an MPhil and a PhD.
[2] anyone who is already employee and is studying any course

to offer educational support to GS, PGS, and HCPs even if it the latter two groups are considered to be the most important target audience. All participating NCAs strongly recommend to include the "Regulatory system/legislation" topic in any educational support activities (100%; N=18). Nonetheless, they indicated that all the topics mentioned deserved to be implemented in an educational format, however no particular preference was specified for the format of the educational support activity at national level.

b) STARS stakeholder workshop

The STARS consortium organized a first European workshop with relevant experts and stakeholders in November 2020, including academia, to exchange knowledge and expertise from different perspectives. Participants supported the STARS project by actively sharing expertise, opinions, and ideas. Stakeholders recognised the lack of basic regulatory knowledge concerning essential aspects of the entire product development and hence identified learning needs/recommended areas of training for academia. Strengthening graduate regulatory training as envisaged by the STARS consortium was strongly supported and the "train the trainer" concept was also identified as an appropriate strategy. Stakeholders suggested that a training concept should be based on a **harmonised and standardised approach to establish a modular system for basic regulatory education**. Consensus was expressed on the need of special training at a deeper level regarding some challenging topics that require new and highly specialised expertise and that are not completely addressed by the regulatory guidance and legislation. To incentivise successful completion of the curriculum/training, a certificate/credit system was suggested by stakeholders.

Finally, as innovative medicinal products will require specific knowledge, it is highly relevant to connect different areas of expertise, including experts from other areas (e.g. ethics committees, patient organisations and industry) to share experience and competence.

c) STARS Comprehensive Inventory

STARS has launched a **Comprehensive Inventory (CI)** of the already existing regulatory courses, trainings, and tools offered by different stakeholders. The purpose of the CI is to assist European academic drug developers in finding support on regulatory affairs. The inventory lists various support services provided by national competent authorities, public actors and private entities. It is a living document and published on the STARS webpage[3].

Concept of the STARS curriculum

Based on the previously mentioned activities within the STARS project, the STARS consortium developed the concept for a curriculum in regulatory science divided in Core and Comprehensive Curricula.

The curricula concept has been conceived as **guidance to achieve a harmonised and common level of regulatory knowledge in academia** in the near future. The present document offers recommendations for the contents and learning outcomes (LOs) to be considered in implementing training activities in academia. The STARS curricula do not aim to substitute or replace any existing European curricula, and can be adapted according to the different needs and requirements of the respective national education systems of the European Member States.

STARS consortium envisages that individual universities could develop their own course based on the following curriculum contents and LOs. Along with those, STARS endorses a partnerships between

[3] https://www.csa-stars.eu/Inventory-1721.html

universities and national and/or European academic networks focussing on academic research in (bio)medical science in order to deliver and organise the courses. Relevant stakeholders in the regulatory field (i.e., regulatory authorities, scientific societies), when appropriate and feasible, could be involved in the courses and it is considered as a plus and strongly recommended by the STARS consortium. When possible, internships at NCAs are also recommended as a unique opportunity to interact with experts and peers in the field.

Additionally, universities are invited to review, complete and disseminate the CI[3], which provides detailed information on the already existing regulatory courses, trainings, and programs offered by different parties (private providers, universities, or NCAs). This consultation could speed up the implementation of the curriculum in the universities.

In regards of the role of NCAs, the STARS consortium encourages the European regulatory agencies in taking an active role in supporting national academia to develop and implement a curriculum in regulatory science. Several actions could be taken by NCAs to promote training of academia in regulatory science balancing the level of involvement in accordance to their own capacity (i.e., human capability, policy). The STARS consortium envisages a network of NCAs that could actively offer training activities and/or mutually support in training. Through such a network, NCAs could facilitate the exchange of training experts and materials among the participants and establish collaboration. Harmonisation of activities and networking across NCAs seems to be a key element for sharing and continuously updating tools and resources thus allowing academia training capacity and sustainability in the future.

STARS consortium recommends considering the "train the trainers" concept in order to reach a wider target, especially where an expertise centre for consultations at universities is established.

Overall, the two curricula share fundamental perspectives in accordance with the STARS principles:

- **Science and patient driven**: topics, gaps, and challenges should be discussed considering the scientific rationale.
- **Multidisciplinary/multistakeholder**: regulatory science needs open dialogue, communication and collaboration between regulators and medicinal products/technologies developers to identify regulatory challenges, possible gaps, and critical issues in the product development as early as possible. The successful outcome of an improved regulatory dialogue among academia and regulators is especially needed when it comes to the development of a novel medicinal product/technology to facilitate translation of a research finding into clinical practice.
- **Exchange of experience and competences:** the curricula are a chance and an occasion for continuous and bidirectional learning, as well as for improving the knowledge of new regulations. Established knowledge exchange, where not only academia is trained on regulatory aspects, but regulators also benefit from academia, learning about the most recent methodologies, tools and technologies from academia.
- **Open discussion:** open discussions between regulators and health researchers in academia about case studies, projects and regulatory challenges emerging from scientific development allow gaining greater knowledge in regulatory sciences.

Core Curriculum

The Core Curriculum (CoC) is mainly targeted at graduate students (bachelor and master's degree) interested in regulatory science and in gaining **basic knowledge / training** of European regulations on medicinal products and borderline between medicines and medical devices. This CoC aims to provide attendees with an overview of regulatory science and the regulatory system in Europe, giving an overview on development pathways, on the EU legislation and the use of guidelines, with an

introduction on the core parts of a clinical trial/marketing authorization application (quality, non-clinical and clinical) and on the post-marketing processes.

Universities will provide graduates with key regulatory knowledge to enrich their professional education for a future position in different areas, such as drug research and development, regulatory authorities for medicinal products, as well as the pharmaceutical industry.

The STARS consortium recommends that the CoC could also be offered to those professionals who are willing to improve, refresh or/and deepen their basic knowledge in regulatory science.

The Core Curriculum has one core module, which covers the basic knowledge in regulatory science illustrating the different levels of regulatory requirements applying at different stages during product development.

Figure 1: Overview and contents of the Core Curriculum.

The contents of the CoC module are listed below:

- EU Regulatory bodies and their roles/activities (NCAs, EMA, Heads of Medicines Agencies and their committees/working parties/groups, European Commission, European Directorate for the Quality of Medicines and Healthcare - EDQM)
- Pharmaceutical legal framework: overview of relevant EU Regulations, Directives, guidelines and of the EU marketing authorization application (Common Technical Document)
- Pharmacovigilance in EU: Eudravigilance, role of EMA and NCAs and other actors
- Regulatory activities of EMA and NCAs in support of innovation, research and product development (scientific advice/protocol assistance procedures, qualification advice/opinion, innovation meetings, support to Small & Medium Enterprises, Regulatory Science Research Needs initiative, PRIority Medicine scheme, etc.)
- Phases of clinical trials, the level of quality/non-clinical/clinical evidence required at each phase and the clinical trial application process
- EU marketing authorization procedures: centralised, decentralised, mutual recognition
- Early access tools (e.g., conditional approval, approval under exceptional circumstances, accelerated approval, compassionate use, etc)
- Post-marketing phase: confirmatory evidence generation and surveillance, PAES, PASS

- Medicines and medical devices: classification issues for borderline products, drug-device combination products, companion diagnostics
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Learning outcomes (LOs):
By the end of the CoC, students will be able to:

1. Describe the EU Regulatory bodies and understand their role
2. Describe the aim of the EU regulation of medicinal products, understand the scope and use of the guidelines and understand the structure and the content of the Common Technical Document
3. Describe pharmacovigilance activities in the EU, actors and responsibilities
4. Describe the phases of the clinical trials and outline quality / non-clinical / clinical evidence required at each phase and the evidence needed to support a clinical trial application
5. Describe various regulatory activities of EMA and NCAs in support of innovation, research and product development
6. Summarize the current European regulatory system supporting the marketing authorization and the early access tools
7. Describe the outline of post-marketing processes
8. Understand the main issues regarding the classification of borderline products and those related to the combined use of medical devices and medicinal products (co-development medicinal product and companion diagnostic; development of drug-device combinations, etc)

Comprehensive Curriculum

With the rapid expansion of pharmaceutical and biomedical products and increasing complexity of innovative technologies and products, more highly skilled professionals who have the expertise to conduct research in compliance with complex regulatory policies and challenging procedures are needed. The Comprehensive Curriculum (CpC) is designed for an **advanced training level** to acquire more in-depth knowledge in regulatory science and to gain more information on different and especially innovative regulatory areas with the overarching goal to successfully develop novel medicinal products and technologies for patients. Target audience is researchers and healthcare professionals involved in medicinal development.

This course will provide an overview of legislation, tools, approaches, standards and latest guidelines that are essential to develop innovative medicinal products with the required level of quality, safety, and efficacy to be marketed within the EU. This specialised education is crucial for professionals to develop a comprehensive understanding of the appropriate regulatory requirements related to their specific field of interest and of the timely use of the NCA support activities during the product development. Hence, professionals will be trained to identify and interpret the specific regulatory framework that will be crucial in driving forward their research to develop a new product.

The CpC aims to:

1. bridge existing regulatory knowledge gaps and improve expertise in regulatory science and processes;
2. increase awareness and promote the importance of early dialogue with regulators on medicinal products development, incentivising the use of the regulatory support activities offered to academia (e.g., scientific advice, innovation meetings, guidance, etc);

3. foster a more focused regulatory approach for academic research, which should be informed since the very beginning by the relevant regulatory standards. This increases the chance that the new product reaches the patient in a timely manner;
4. support professionals to translate successful research activities into treatment solutions for patients by identifying the correct guidelines to drive their research;
5. provide an explanation on how legislation/regulatory guidance are interpreted and applied in practice.

CpC courses will train attendees to plan development pathways, manage common challenges, and pursue science-based solutions within the regulatory framework. Moreover, students will be trained to identify at which stages in the drug development process regulatory support from NCAs would be beneficial and should be sought. The attendees will also delve into all aspects of regulatory affairs, including quality, non-clinical and clinical research.

Modules will extend from a strong core of basic regulatory science courses to more specific modules to delve into single areas of interest. To this end, the modules can either have a standalone feature or can be associated with other modules of the curricula to expand the knowledge on a specific topic (i.e. a complete training on vaccines is obtained combining the topic from each of Quality, Non-clinical and Clinical modules). The modularity could be a tool not to overload researchers and incentivise their attendance to the courses by facilitating the identification of the training material useful to address specific regulatory knowledge gaps.

The Comprehensive Curriculum focuses on the five main areas/milestones in the medicinal product lifecycle: 1) European Regulatory system; 2) Quality; 3) Non-clinical; 4) Clinical; (5) Post-Marketing Surveillance. The relative contents and learning outcomes (LOs) are listed below:

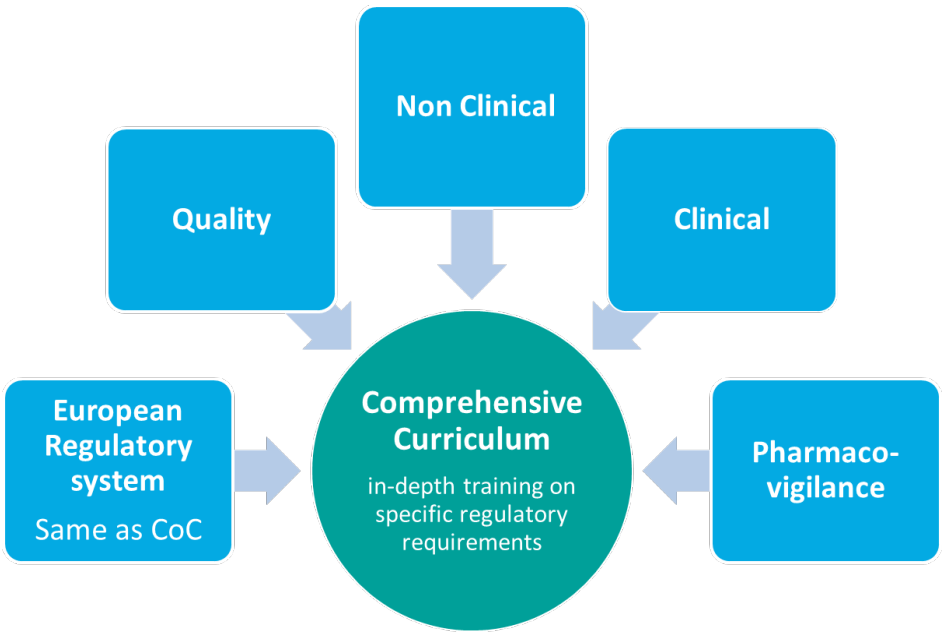

Figure 2: Overview and modules of the Comprehensive Curriculum.

1: European Regulatory system

- The Core Curriculum forms the Regulatory module

Learning outcomes (LOs). By the end of the module students will be able to:

1. Describe the EU Regulatory bodies and understand their role

2. Describe the aim of the EU regulation of medicinal products, understand the scope and use of the guidelines and understand the structure and the content of the Common Technical Document
3. Describe pharmacovigilance activities in the EU, actors and responsibilities
4. Describe the phases of the clinical trials and outline quality / non-clinical / clinical evidence required at each phase and the evidence needed to support a clinical trial application
5. Describe various regulatory activities of EMA and NCAs in support of innovation, research and product development
6. Summarize the current European regulatory system supporting the marketing authorization and the early access tools
7. Describe the outline of post-marketing processes
8. Understand the main issues regarding the classification of borderline products and those related to the combined use of medical devices and medicinal products (co-development medicinal product and companion diagnostic; development of drug-device combinations, etc)

2: Quality

- Principles and guidelines applying to the pharmaceutical development, covering manufacturing, characterization and control of the active substance and the finished product
- The specific regulatory framework to address quality requirements in the relevant field of study, considering those which are particular to the specific product of interest (e.g., chemicals, biopharmaceuticals, vaccines, ATMP, radiopharmaceuticals, herbal medicinal products, nanomedicines, paediatric medicinal products, drug-device combination products, generic and biosimilars, etc.)
- Quality requirements for investigational medicinal products: structure and content of the IMPD (investigational medicinal product dossier)
- Common Technical Document (CTD): Modules 1, 2 and 3
- EU legal framework and national implementation of Good Manufacturing Practice (GMP), role and scope of GMP inspections
- European pharmacopeia structure and relevant monographs
- From assessment to product information

Learning outcomes (LOs). By the end of the module students will be able to:

1. Classify a specific type of product and identify the corresponding regulatory framework to define and address the specific requirements with regard to product development.
2. Identify the minimum quality requirements to build an IMPD for a medicinal product to be investigated in a clinical trial.
3. Understand the structure and content of the CTD modules 1, 2 and 3.
4. Identify the basic GMP requirements applying to the manufacturing of the medicinal product in the different phases of development.
5. Understand the overall structure and relevant content of the European Pharmacopeia as support to the pharmaceutical development.
6. Outline the principles of the assessment of the quality data supporting a MAA, identifying the more critical aspects that may impact the benefit/risk of the medicinal product; identify the relevant pharmaceutical information to be reflected in the European Public Assessment Report (EPAR) and in the Product Information.

3: Non-Clinical

- Principles and guidelines applied to the non-clinical development
- Common Technical Document: Modules 1, 2 and 4

- Proof of principle: *in vitro* and *in vivo* studies addressing mode of action and pharmacological (Pharmacodynamic, PD) activity
- Pre-clinical studies to support first in human (FIH) study: safety pharmacology, pharmacokinetics (PK), PK/PD relationship, genotoxicity, repeated-dose toxicity, toxicokinetic
- Establishing the clinical dose: minimal anticipated biological effect level and no observed adverse effect level (NOAEL)
- Non-clinical studies to support marketing authorisation applications (MAA): long term repeated-dose toxicity, carcinogenicity, reproductive toxicity (male and female fertility, developmental toxicity and pre/postnatal development) and assessment of exposure margins (i.e., the ratio of NOAEL to the estimated human exposure level)
- Importance of animal species selection for extrapolation of results to human setting
- Alternative approaches to animal model: replace, refine, reduce (3Rs principle) the use of animals, organ on a chip
- Basic principles of Good Laboratory Practice (GLP) to assure the quality and integrity of non-clinical studies and their importance for pivotal studies
- Basic principles of environmental risk assessment: active substance persistence and fate in soil, water, air compartments following use and disposal of medicinal product
- Studies in juvenile animals to support paediatric use
- Regulatory and scientific requirements for non-clinical development of chemical and biopharmaceutical (vaccine included) medicinal products
- Integration of non-clinical results with quality (e.g., impurities) and clinical data (e.g., safety data) in the overall assessment of benefit/risk balance
- From assessment to product information

LOs: by the end of the module, students will be able to:

1. Identify which non-clinical studies are needed for a specific: type of product (i.e., chemical or biotech), stage of development, therapeutic indication and target population (e.g., paediatric use)
2. Understand the relevance of results obtained for clinical use, particularly for toxicity predictions for which no clinical data are expected (e.g., genotoxicity, carcinogenicity, reprotoxicity)
3. Identify principles for capturing the most relevant toxicity finding (e.g., dose-response effect, reversibility, adversity and non-adversity of histopathological changes) to establish the NOAEL and exposure margins
4. Understand how GLP principles can affect the reliability of study results
5. Outline key elements for the environmental risk assessment
6. Understand advantage and limitation of *in vitro* and *in vivo* assays, including the animal species selection, and possibility to minimise animal testing during medicines development
7. Understand the structure and content of CTD modules 1, 2 and 4
8. Outline the principles of the assessment of the non-clinical data supporting a MAA, identifying the more critical aspects that may impact the benefit/risk of the medicinal product; identify the relevant non-clinical information to be reflected in the European Public Assessment Report (EPAR) and in the Product Information

4: Clinical

- Clinical trial legislation in the EU (including definitions e.g., intervention – non-intervention – low intervention trials), Good Clinical Practice (GCP), declaration of Helsinki and ethical principles, relevant guidelines
- Clinical Trial Application
- EU clinical trials information system: EUdra clinical trial and clinical trials register
- Pharmacovigilance in clinical trials

- Overview of scientific guidelines on relevant points to consider in the design and conduction of clinical trials to support marketing authorisation applications in the EU (including innovative and complex clinical trials; co-development of medicinal products and diagnostics; special populations, modelling and simulation, etc.)
- Common Technical Document: Modules 1, 2 and 5
- Structure and content of clinical study report: pharmacokinetics, pharmacodynamics, efficacy, statistics and safety data
- Real word data and patient registries
- From assessment to product information
- Paediatric medicines: role of Paediatric Committee, requirements for marketing authorization applications, Paediatric Investigation Plan
- Orphan medicines: designation, role of Orphan Committee (COMP), requirements for marketing authorization applications
- ATMPs: classification, overview of ATMP regulation, role of Committee for Advanced Therapies (CAT), requirements for marketing authorization applications
- Vaccines
- Biosimilars, generics and hybrid applications
- From assessment to product information

Learning outcomes (LOs). By the end of the module students will be able to:

1. Understand the aims and scope of the EU Clinical trial legislation, the GCP requirements, the relevant guidelines and the role of the regulatory bodies in the clinical phase of the drug development
2. Understand structure, content and process of the Clinical Trial Application and the EU clinical trials information system
3. Describe pharmacovigilance management strategies within clinical trials
4. Identify the principles and guidelines in the context of the clinical drug development to support a MAA, and describe regulatory requirements for specific type of products/therapeutic indication/target population
5. Understand the structure and content of the CTD modules 1, 2, 5
6. Understand the structure and content of the clinical study report, identifying pharmacokinetic, pharmacodynamic, efficacy, statistic and safety data required to build a complete and informative report
7. Understand regulatory requirements for using real world data, including patient registries, for evidence generation and decision making
8. Outline the principles of the assessment of the clinical data supporting a MAA, identifying the more critical aspects that may impact the benefit/risk of the medicinal product; identify the relevant clinical information to be reflected in the European Public Assessment Report (EPAR) and in the Product Information
9. Identify regulatory requirements for the ATMPs, paediatric and orphan medicines and the role of the relevant EMA Committees (CHMP, CAT, PDCO, COMP)
10. Identify specific regulatory requirements to develop and authorise vaccines, generics and biosimilars, as well as for hybrid applications

5: Post-Marketing Surveillance

- Pharmacovigilance legislation in the EU, Good Vigilance Practice (GVP), relevant guidelines
- Collection and management of suspected adverse reactions to medicinal products
- Risk Management Plan
- Post-authorisation safety study (PASS), post-authorisation efficacy study (PAES) and other post-authorisation activities
- Risk Minimisation Measures

- Pharmacovigilance systems
- Signal management
- Overview of periodic safety update reports (PSURs) and description of the EU procedures for their assessment, including the PSUR single assessment (PSUSA)
- Referrals for safety reasons
- Renewals and annual re-assessment
- Safety communication

Learning outcomes (LOs). By the end of the module students will be able to:

1. Describe the role and activities of regulatory bodies responsible for pharmacovigilance and understand the principles and guidelines regulating pharmacovigilance activities
2. Understand the general principles of collection, recording and submission of individual reports of suspected adverse reactions associated with medicinal products
3. Understand the structure and objectives of the Risk Management plan
4. Understand the scope of post-marketing studies for gathering further evidence, including strengths and limitations of different protocols
5. Know the differences in PASS designs, and understand the best approach according to the objectives to be achieved
6. Understand the principles of signal detection and management
7. Know the different Risk Minimisation Measures (routine and additional) applied from regulators to manage the risks of medicines
8. Outline the aim, structure and content of the pharmacovigilance reports submitted at defined time points during the post-authorisation phase and describe the procedures to renew the marketing authorisation of a medicinal product

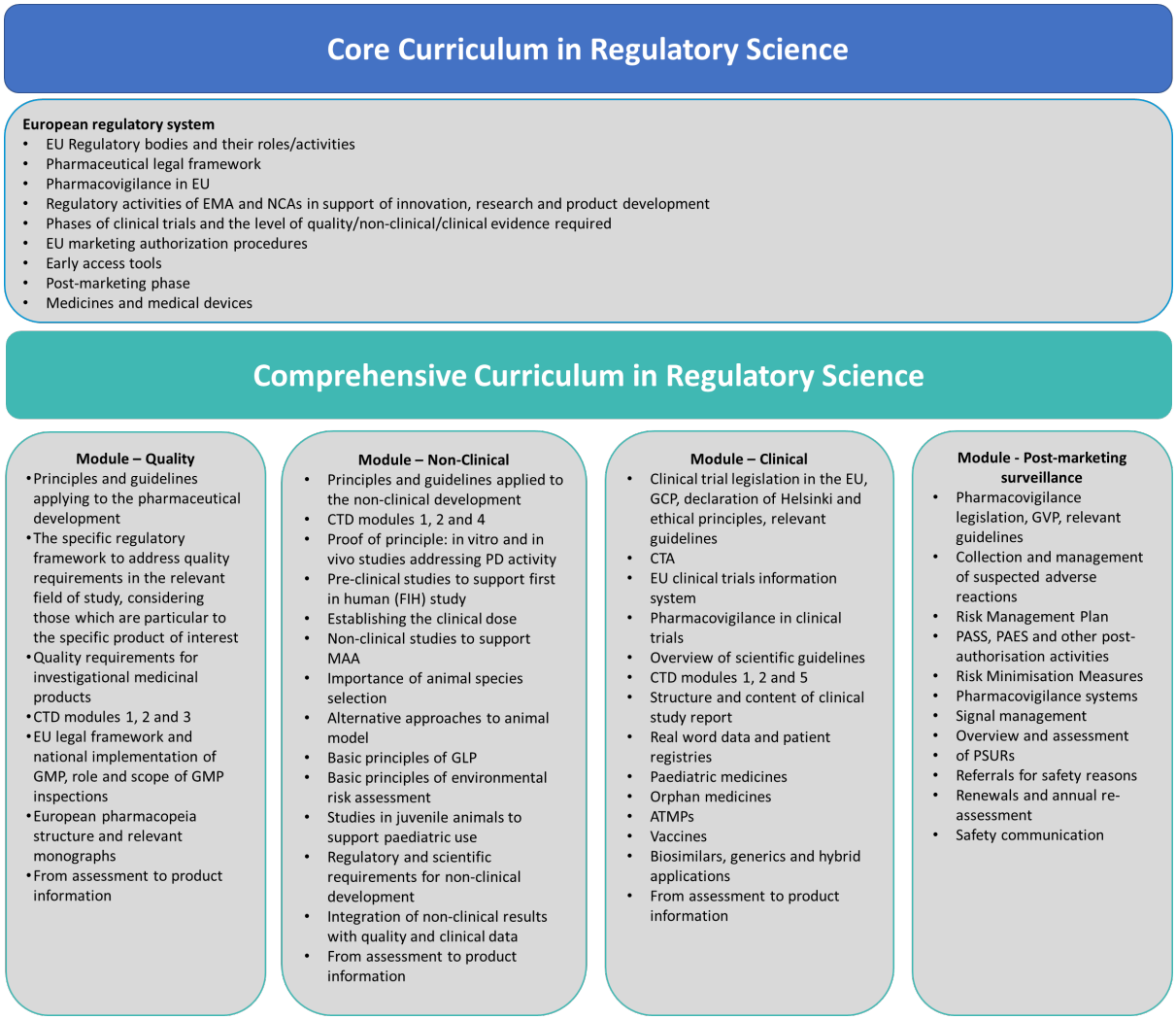

Figure 3: Overview and modules of the Comprehensive Curriculum.

Future perspectives of the curricula

As the pace of innovation is usually driven by academia, attention should be placed on the role of regulatory science in fostering and accelerating innovative processes, technologies and products. Academia should be offered support in enhancing the knowledge on regulation and legislation and enlightened on the tools that exist for them to be used as support to innovation from the very early phase of development. Moreover, dealing with innovation could implies the use of big data. In this perspective, the STARS consortium recommends that in the immediate future the curriculum could describe the big data landscape, in line with the HMA-EMA Big Data Steering Group work, in order to promote an understanding of the key concepts, pitfalls, tools and techniques involved in data management and use.

Finally, as innovation is a multidisciplinary activity, and given that disciplines next to (bio)medical science play an active role in innovation, the STARS consortium envisages that universities could offer relevant aspects of the curriculum to different disciplines such as engineering and computer science.

Recommendations for training of academia and curricula implementation

- The STARS consortiums consider the training of academia a crucial activity to be implemented in the NCAs as of highly benefit for regulatory system, academia and ultimately for patients. Increasing awareness and knowledge of the regulatory science in academia will increase the chances of a successful translation of academic health research into clinical benefit for patients. Fulfilling regulatory requirements from the beginnings of the development is crucial to assure a timely access to patients of efficacious and safe medicinal products and technologies. Implementation of training activities offered to academia will meet the needs and fill the gaps arisen through the STARS activities.
- EU Commission and HMA's endorsement to establishing, or continuing, NCAs activities of training to academia is recommended.
- Continuous and bidirectional dialogue between academia e NCAs should be promoted and established as the basis for any collaboration and activity.
- Clearly understand the needs of academia at different levels and within the different study courses, in terms of basic knowledge and of more in depth specialisation on topics of interest.
- Promote a continuous update of the Comprehensive Inventory to offer a mapping of the training courses offered by NCAs in Europe. Promote the one-stop shop in each NCAs for training purpose (e.g. training information and materials available on the NCA's website) and for a continuous discussion and collaboration with academia, including the issues regarding the training.
- Implement a "train the trainer" system to facilitate the dissemination of the curricula across Europe.
- Develop a system for timely informing academia about training events.
- Encourage NCAs participation to academic meetings and life science events, even organizing a booth in academia events as valuable occasions for an active exchange with academia.
- Create a networking of NCAs that could actively offer training activities and/or mutually support in training.
- Facilitate the exchange of training experts and materials among the network.
- Establish collaboration among the NCAs network, EMA, EU-NTC and EU-IN.
- Create a common repository of the existing materials for trainings.
- Adequate and periodic funding to NCAs and adequate allocation of human resources for implementing such activities is considered essential.
- Harmonisation of activities and networking across NCAs seems to be a key element for sharing tools and resources thus allowing capacity and sustainability in the future.