



STARS

STRENGTHENING
REGULATORY
SCIENCE

Strengthening Training for Academia in Regulatory Science (STARS) Project: The road so far

Dr. Viktoriia Starokozhko

MEB Science Day 2022
February 17th 2022

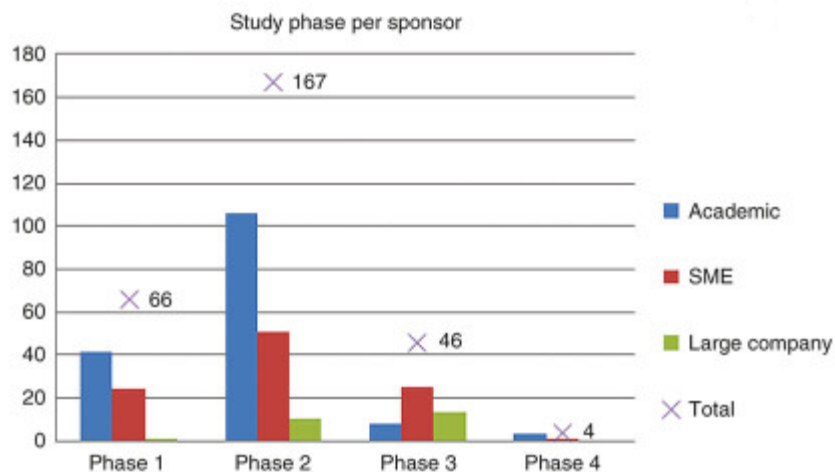
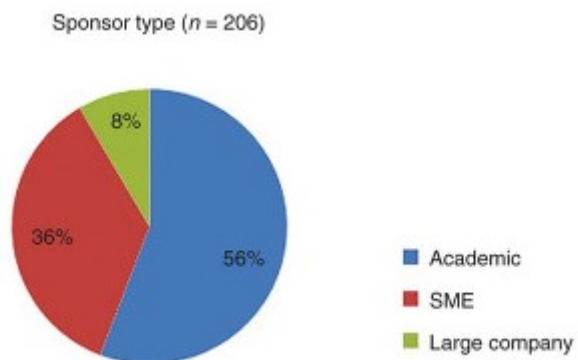


This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No. 825881

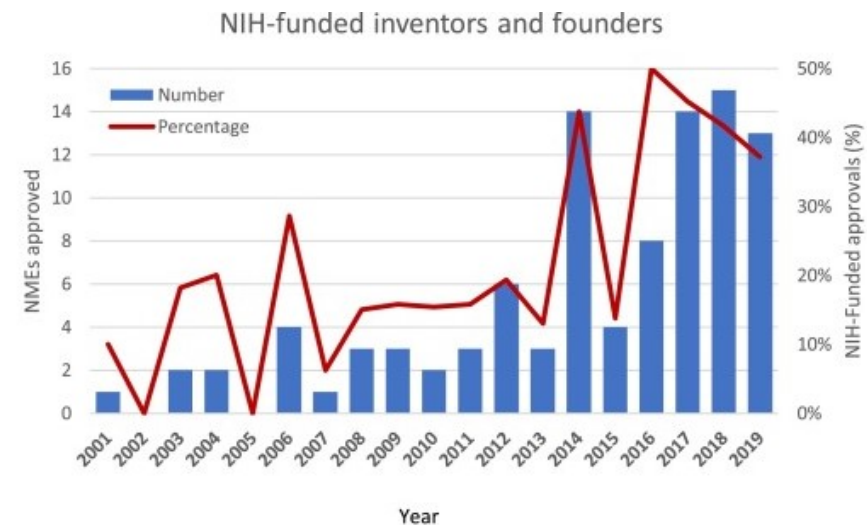
Academic Drug Development

- Contribution of academia in drug discovery & development is increasing
- Especially in the field of advanced therapies
- No EU academic drug marketing authorization holder till now

Sponsor variations in clinical gene- and cell-based therapy development



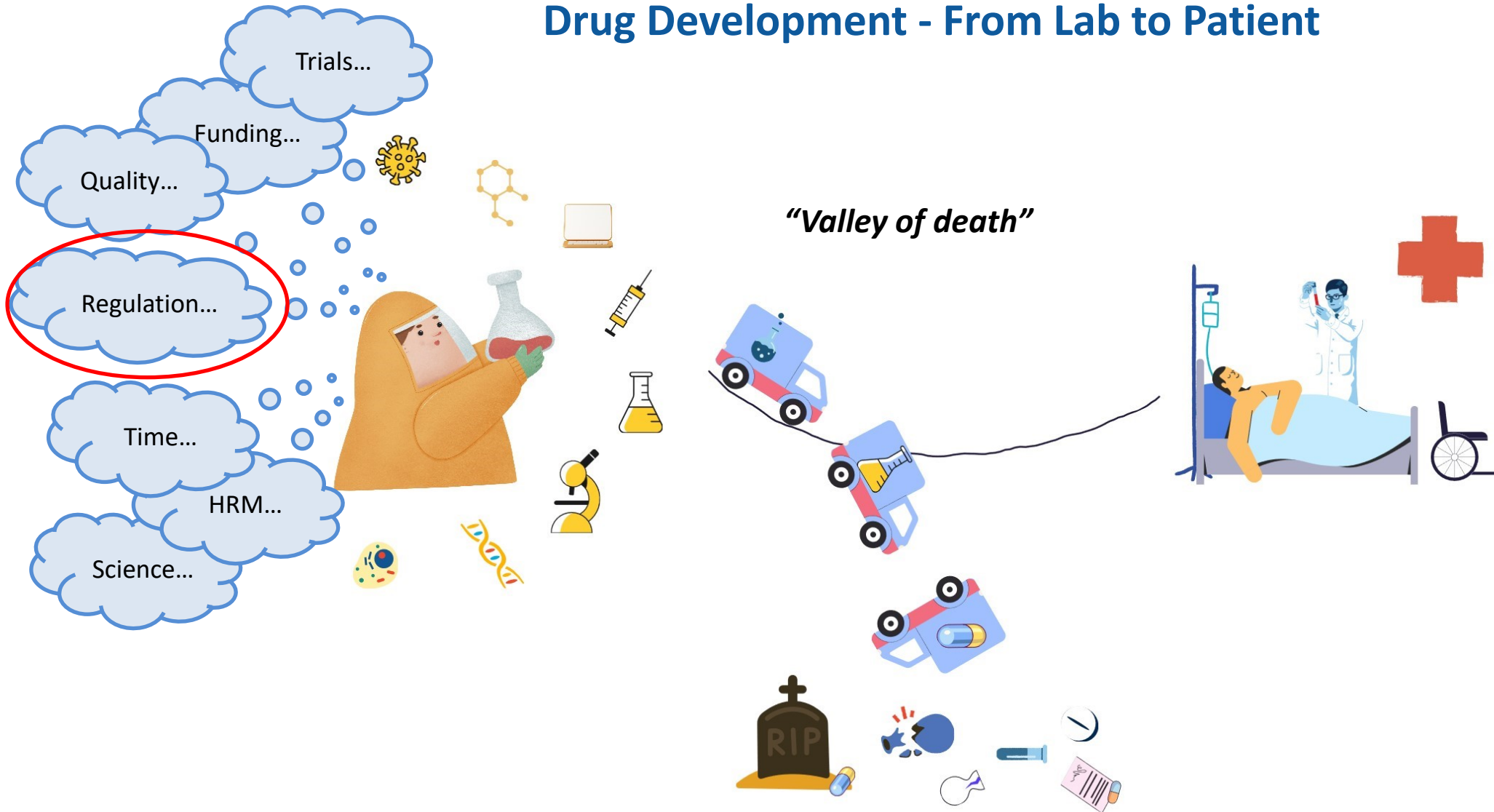
De Wilde et al, 2016



Drug Discovery Today

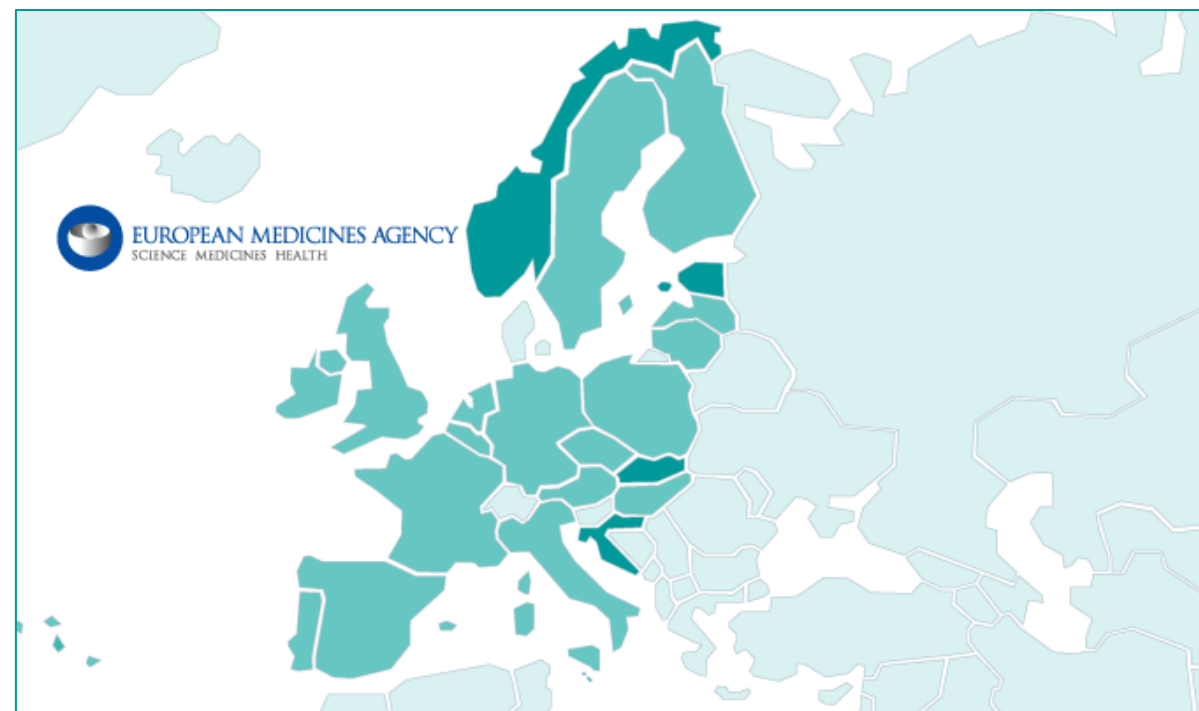
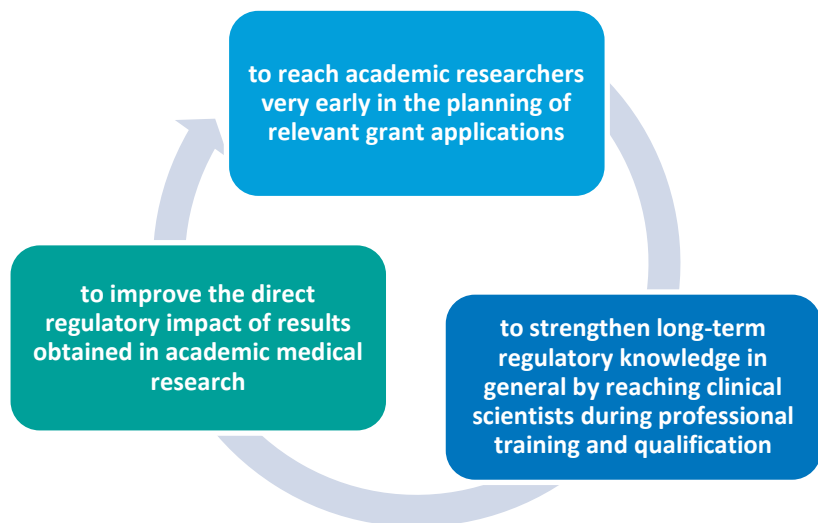
Kinch et al, 2020

Drug Development - From Lab to Patient

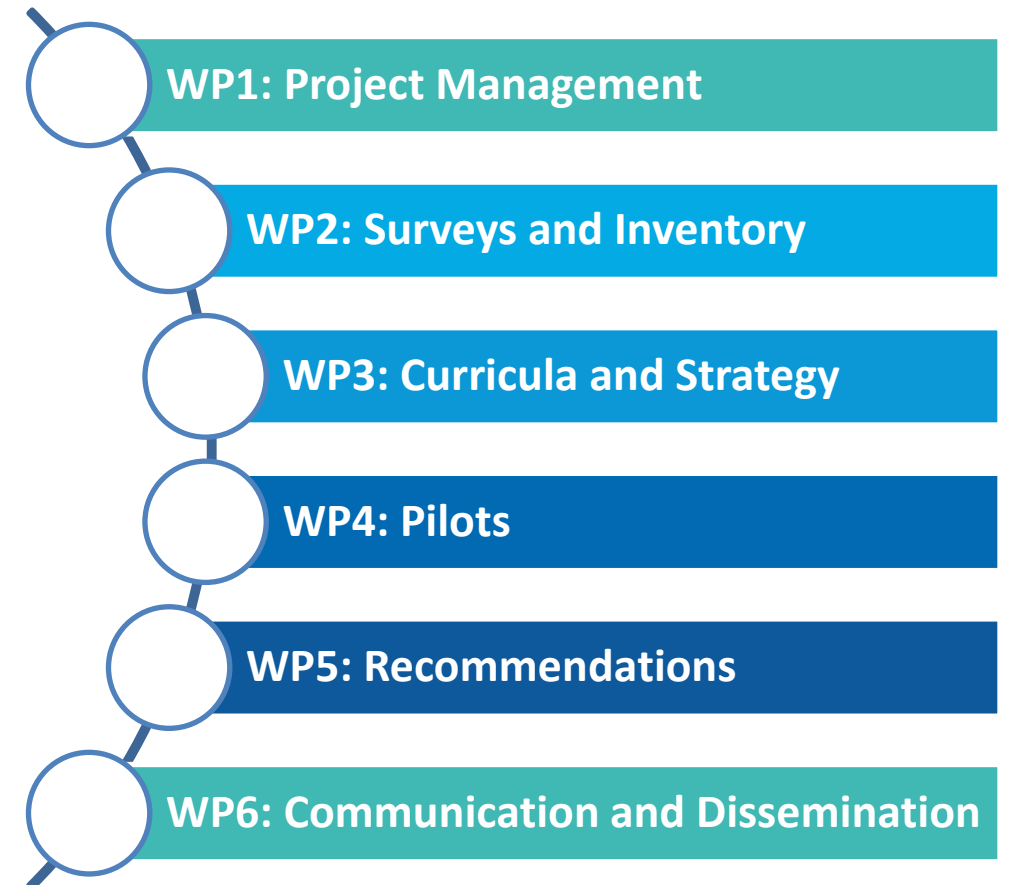
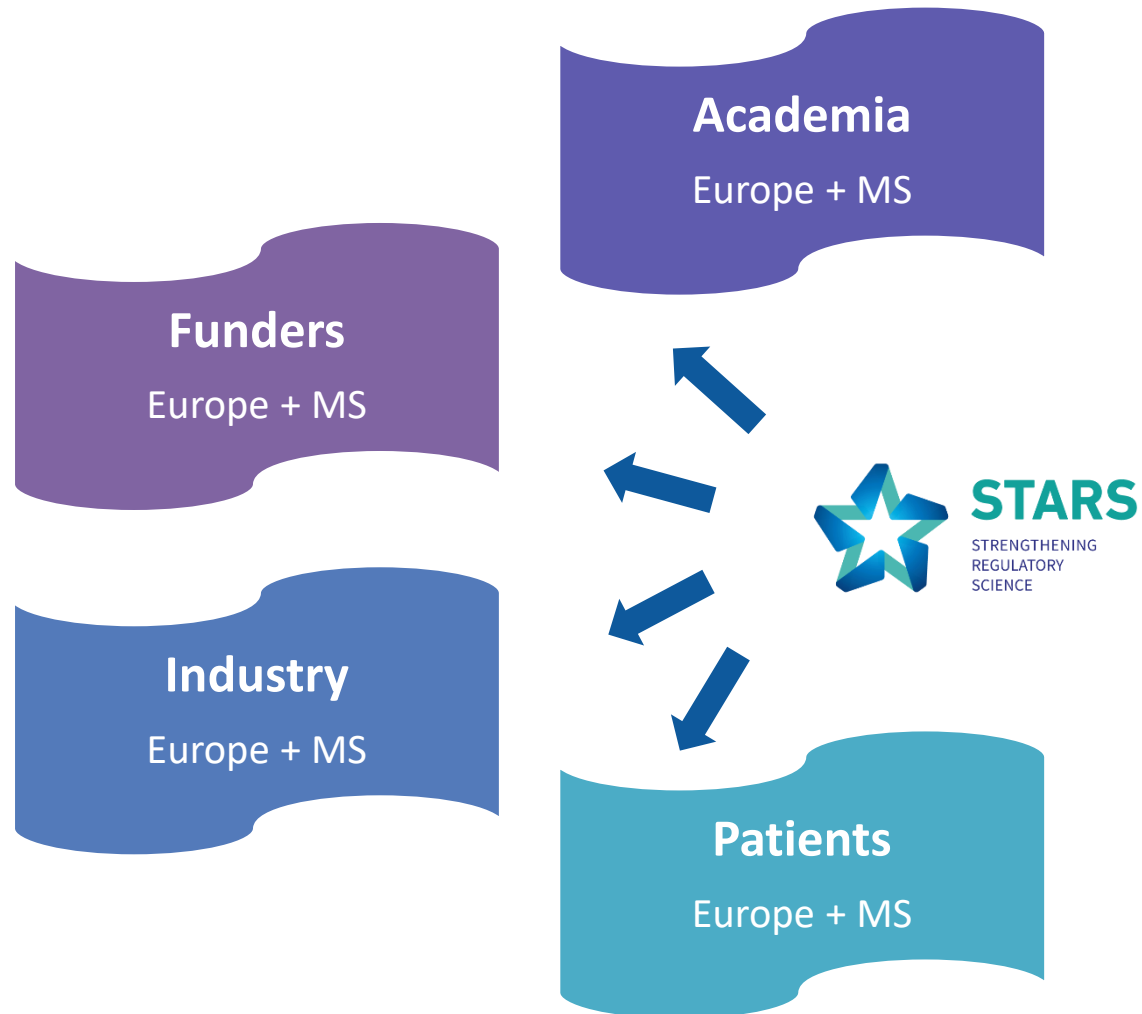


CSA-STARS: Strengthening Training of Academia in Regulatory Sciences & Supporting Regulatory Scientific Advice

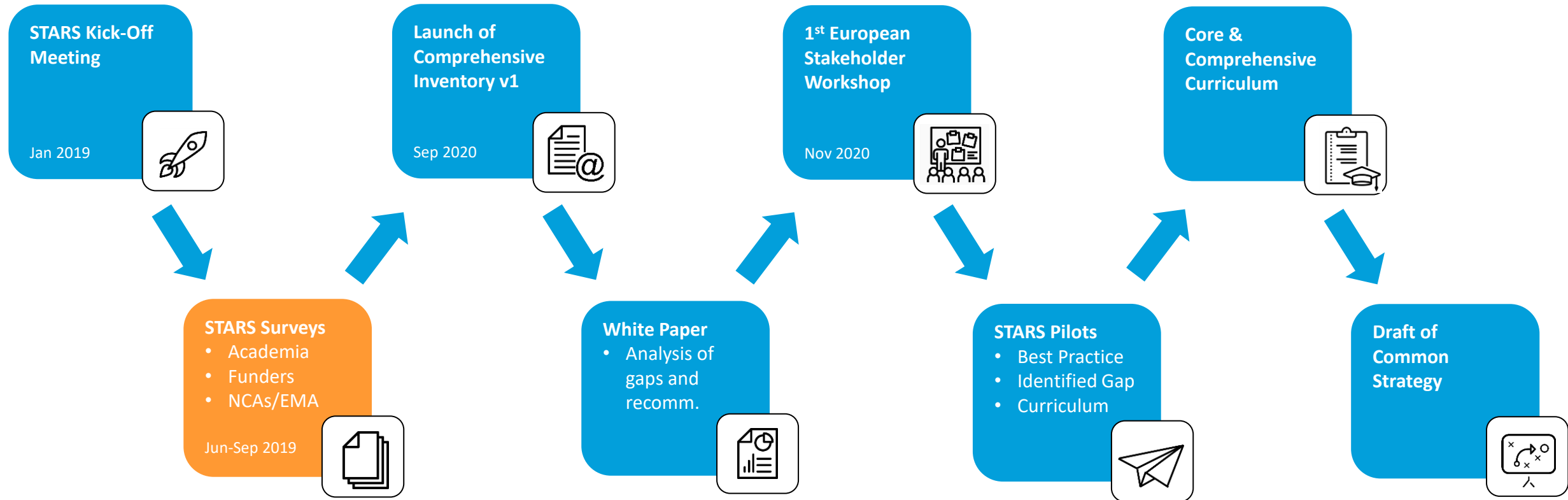
- Consortium of 21 partners from 18 European countries represented via their NCA & EMA (plus 4 associated partners) and DLR-PT
- Funding by European Commission
- Project period: January 2019 – June 2022



Interactions with Stakeholders –Communication is Key!



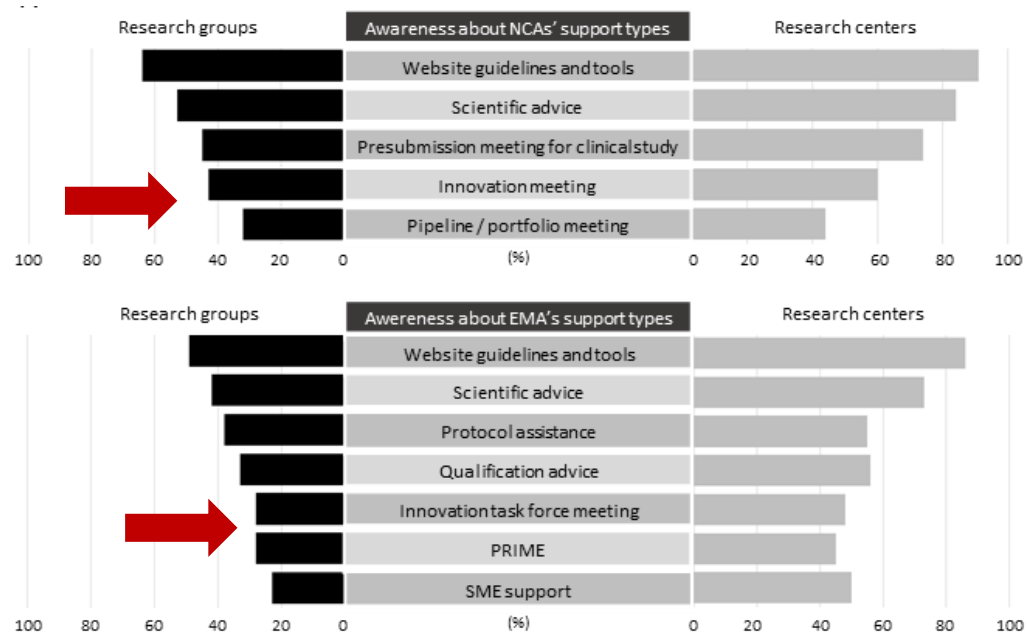
The STARS Road so far...



Mind the (Knowledge) Gap

A lot of support activities already exist:

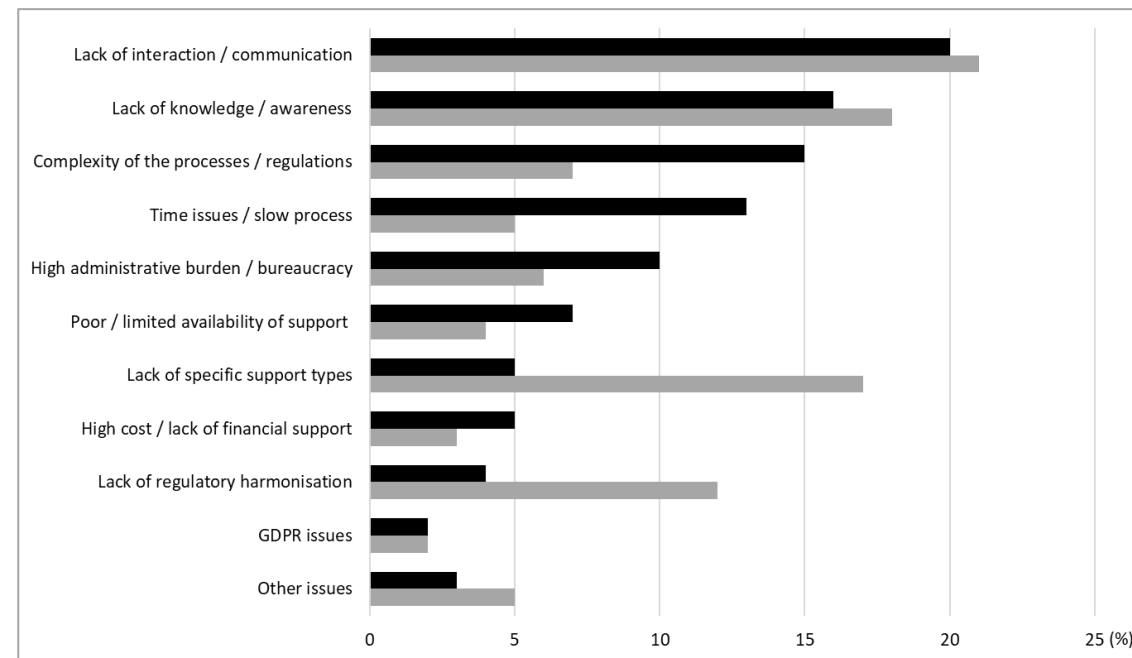
- National level: Scientific Advice, Innovation Offices
- EU level: EMA's early development and advice services (Innovation Task Force, PRIME scheme, Scientific Advice, etc.)
- EU Innovation Network



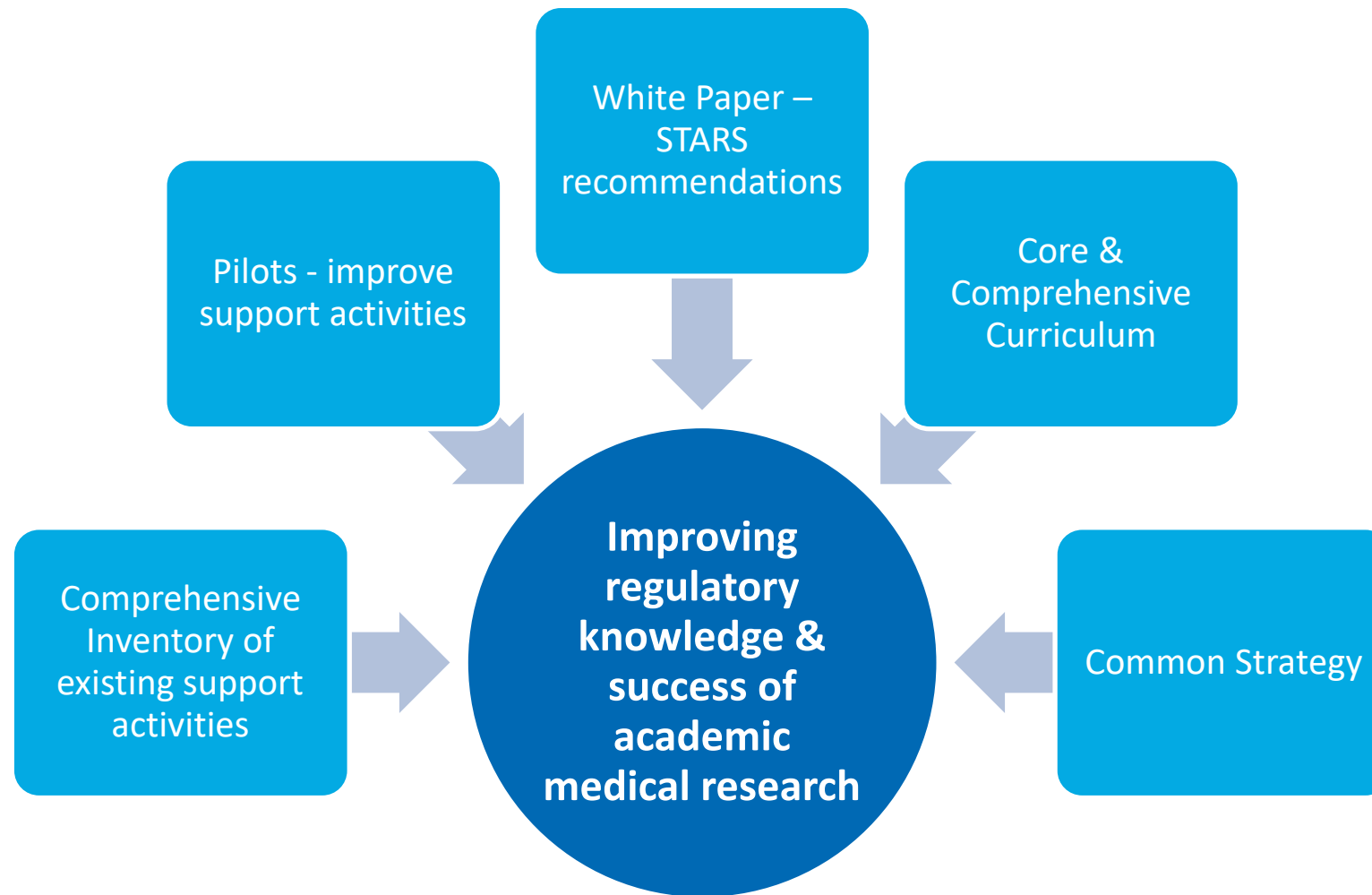
Kallio et al., manuscript in preparation

Challenges in academia

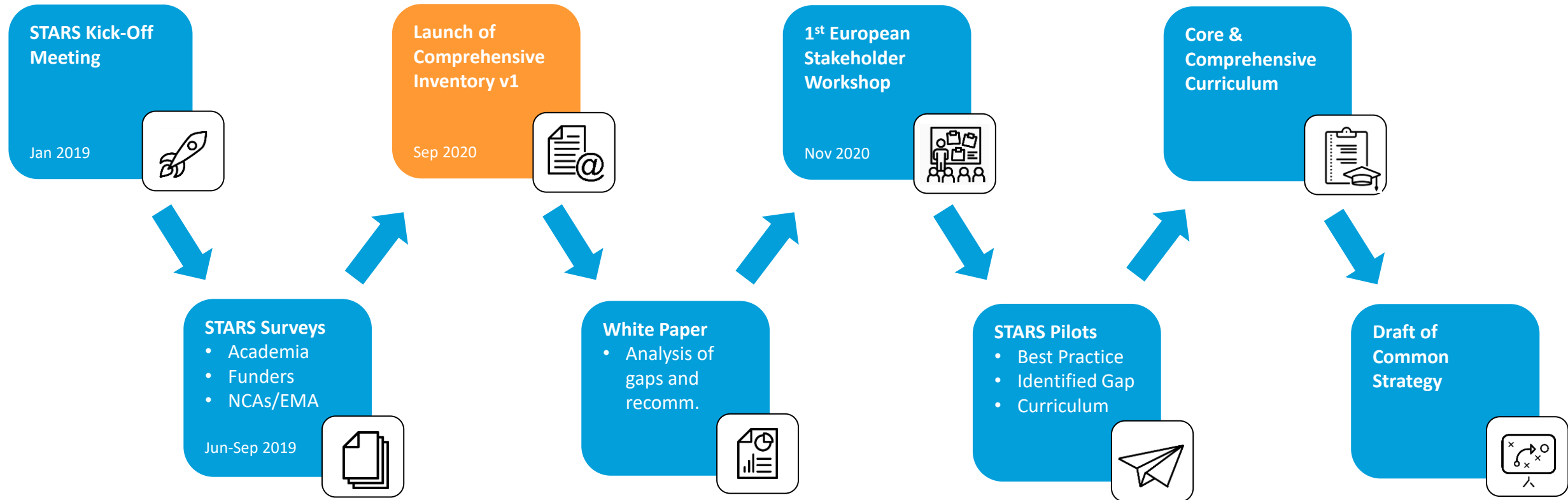
- **Communication** with regulators: poor, high-bar, different “language”
- Poor **awareness** of regulatory guidance and support
- Lack of general regulatory **knowledge**
- Lack of **knowledge** on development & methodology in academia (e.g. Clinical Trial Application)
- **Time**: difficulties to ask the right questions at the right time
- **Complexity** of the regulatory process



Working Programme, Project Outcomes and Impact



The STARS Road so far...



Comprehensive Inventory (CI)

Comprehensive overview of support services for regulatory activities

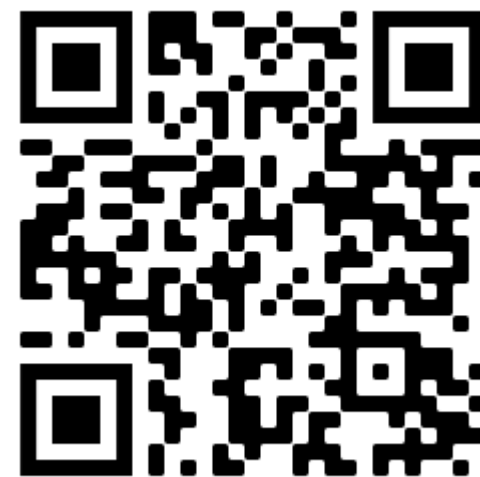
Listing by Expertise Area

Country	Provider Type	Expertise	Provider Details
Spain	National Competent Authority	ATMPs	AEMPS
Belgium	Public Actor	ATMPs	Antwerp University Hospital
France	Public Actor	ATMPs	AP-HP
Germany	Public Actor	ATMPs	Association for Applied Human Pharmacology
Austria	National Competent Authority	ATMPs	BASG / AGES
France	Public Actor	ATMPs	CHU Amiens Picardie
Spain	Public Actor	ATMPs	CIBER
Switzerland	Public Actor	ATMPs	Clinical Trials Center Zurich
Germany	Public Actor	ATMPs	Clinical Trial Centre Leipzig
Europe	Public Actor	ATMPs	Coordination Centre for Clinical Trials (KKS) Heidelberg
Germany	Public Actor	ATMPs	Coordination Centre for Clinical Trials (KKS) Heidelberg
Czech Republic	Public Actor	ATMPs	Czech Clinical Research Infrastructure Network
Europe	Public Actor	ATMPs	EATRIS

Listing by Support Scope

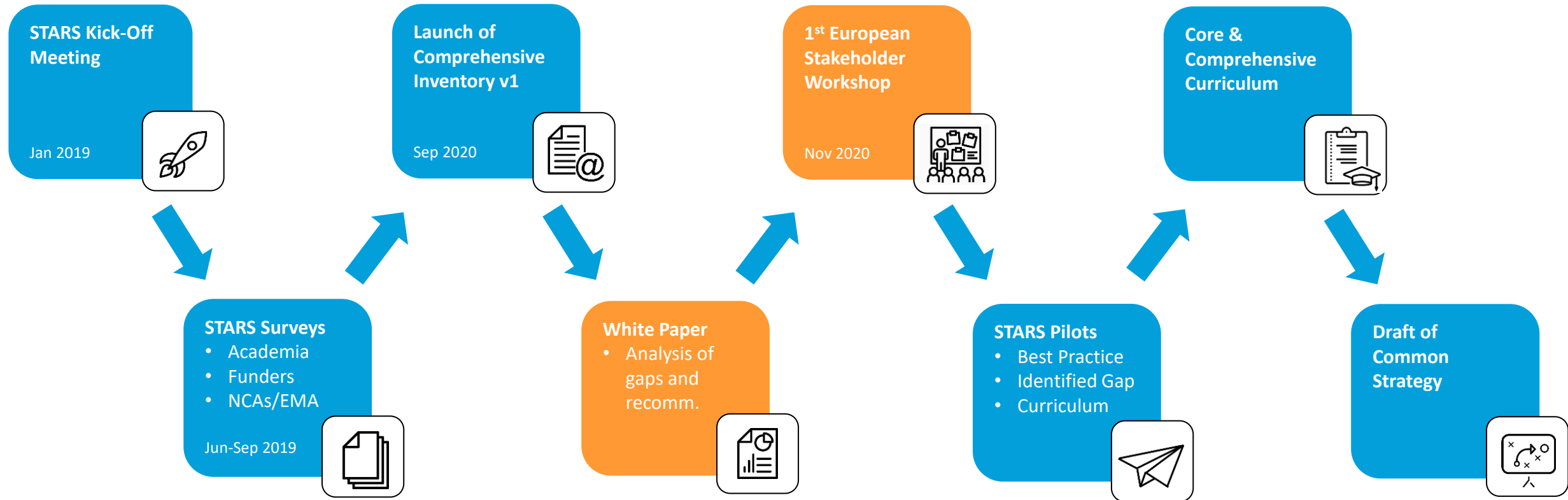
Country	Provider Type	Support Activity	Provider Details
Portugal	Public Actor	Assistance in clinical trial application	2CA-Braga
Spain	National Competent Authority	Assistance in clinical trial application	AEMPS
Belgium	Public Actor	Assistance in clinical trial application	Antwerp University Hospital
France	Public Actor	Assistance in clinical trial application	AP-HP
Germany	Public Actor	Assistance in clinical trial application	Association for Applied Human Pharmacology
Austria	National Competent Authority	Assistance in clinical trial application	BASG / AGES
Germany	National Competent Authority	Assistance in clinical trial application	BfArM
Ireland	Public Actor	Assistance in clinical trial application	Cancer Trials Ireland
Germany	Public Actor	Assistance in clinical trial application	Center for Clinical Trials Tuebingen
France	Public Actor	Assistance in	CHU Amiens Picardie

Direct support for clinical researcher!
Visit our website:
<https://www.csa-stars.eu/Inventory-1721.html>



Comprehensive Inventory

The STARS Road so far...



STARS White Paper & 1st Stakeholder Workshop

Communication & Interaction Framework and its Gaps



Drug Discovery Today
Volume 26, Issue 2, February 2021, Pages 283-288

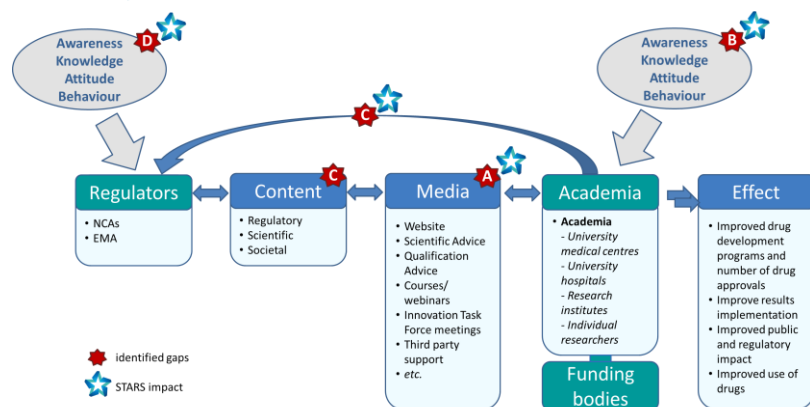


Feature

Strengthening regulatory science in academia: STARS, an EU initiative to bridge the translational gap

Viktoriia Starokozhko^{1, 2}, Marko Kallio³, Åsa Kumlin Howell⁴, Anna Mäkinen Salmi⁴, Gunilla Andrew-Nielsen⁴, M. Goldammer⁵, Manja Burggraf⁶, Wiebke Löbker⁷, Anne Böhmer⁷, Eleonora Agricola⁸, Corinne S. de Vries⁹, Anna M.G. Pasmooij¹, Peter G.M. Mol^{1, 2}✉, on behalf of the STARS consortium

Show more ▾



Groups:

- Academia
- Funding Bodies
- Regulators
- Industry
- Patients

Aim:

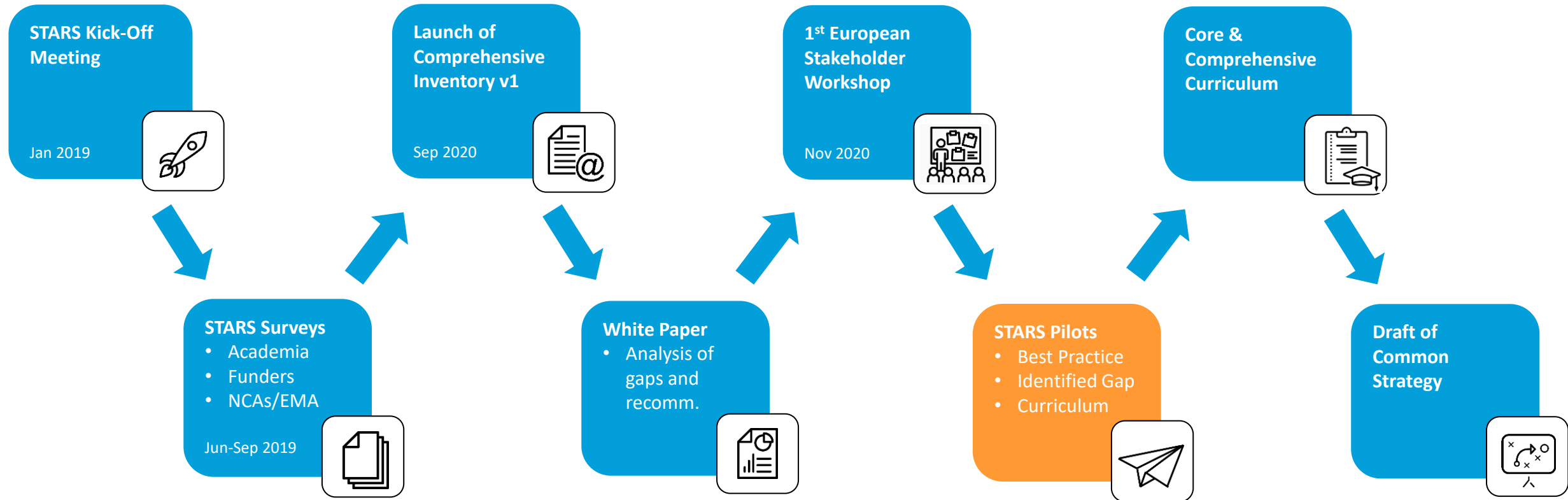
Exchange with the research community and important stakeholders on how to change the mindset



Major outcomes:

- Bridging the language gap
- Bidirectional communication
- Continuous regulatory training

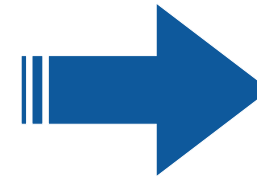
The STARS Road so far...



STARS Pilots



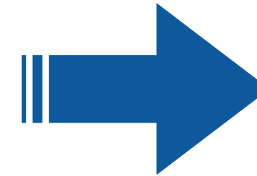
Pilot I: Transfer of an identified **best practice example** to (an) other EEA member states



Transfer basic
regulatory
knowledge



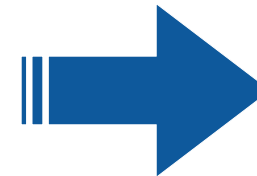
Pilot II: Addressing gaps – initiation of a **novel support activity** for improving success on regulatory Scientific Advice



Improve
communication



Pilot III: Implementing the Comprehensive Curriculum



Sustainable
level of
regulatory
knowledge

Pilot I

Transfer of an identified best practice example

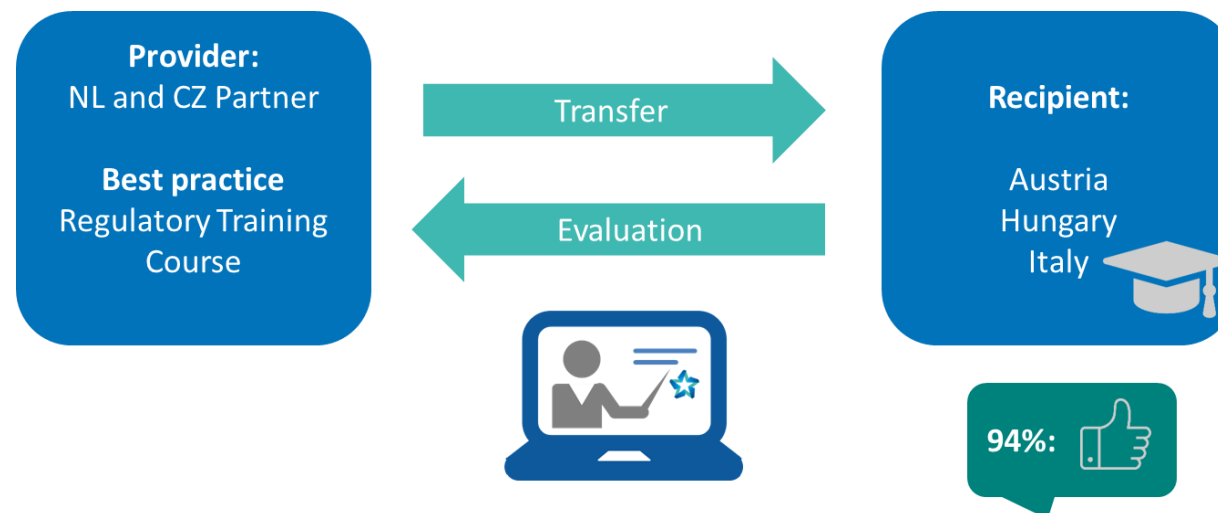


STARS survey data:

- Poor awareness of regulatory support tools
- Difficulty in reaching sufficient level of regulatory knowledge (with attention to CTA)

Topics of the online course:

- Regulatory system and framework
- Essential regulatory knowledge in drug development
- Specific Regulatory Knowledge for Advanced Therapy Medicinal Products (ATMPs)



Pilot II

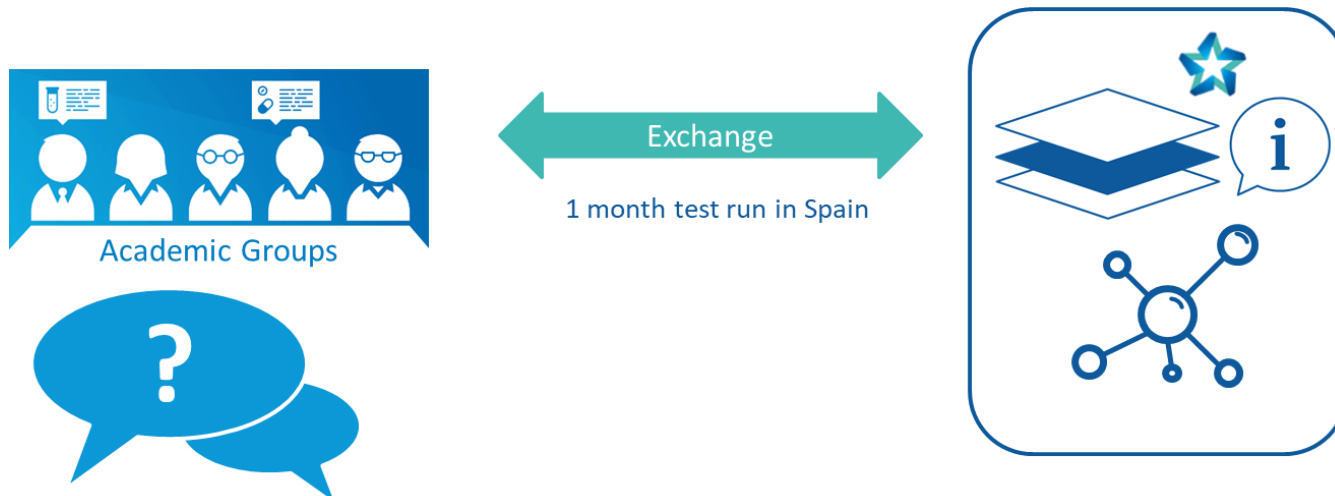
Initiation of a Novel Support Activity



STARS Survey data:









- Tool/s to improve the communication between regulators and academia
- Timely response is probably the most remarkable need

Concept: **one-stop-shop platform** for Spanish academia (September 2021)

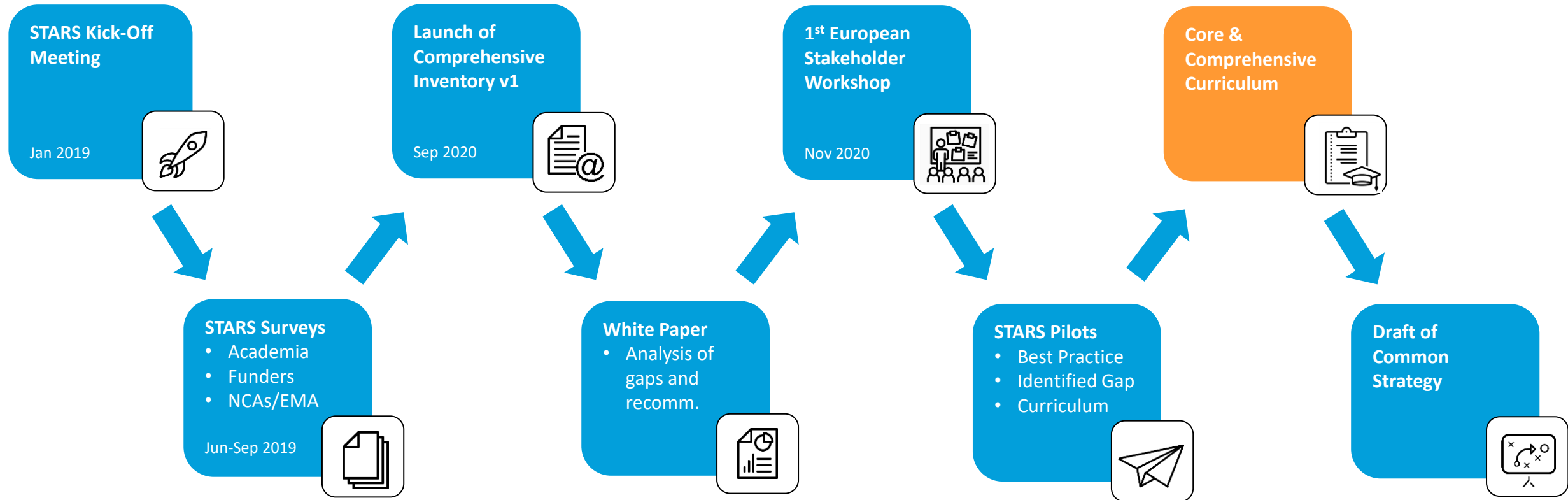


Pilot Project II

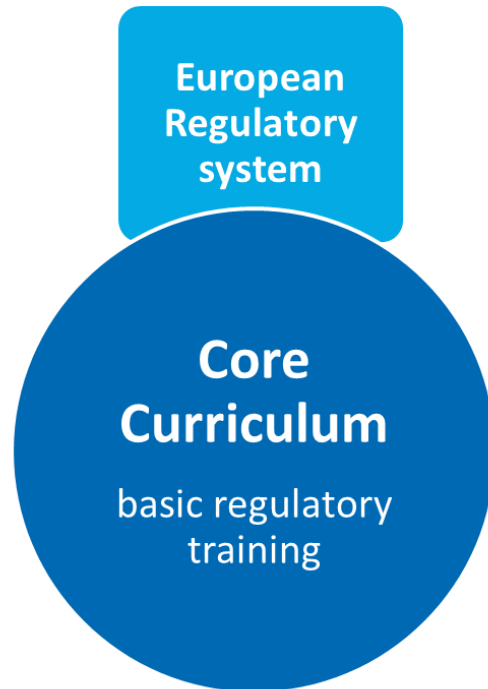
Initiation of a novel support activity for improving success on regulatory Scientific Advice.

	Explanation Board	
	Information Board	
	Communication Board	
	Feedback Board	

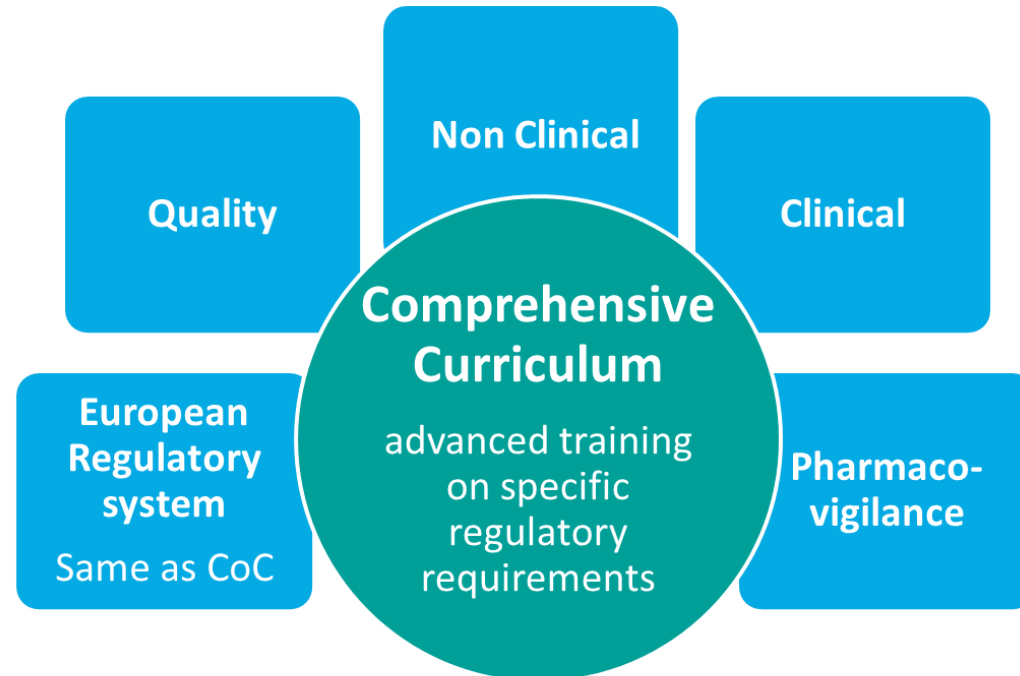
The STARS Road so far...



STARS Curricula

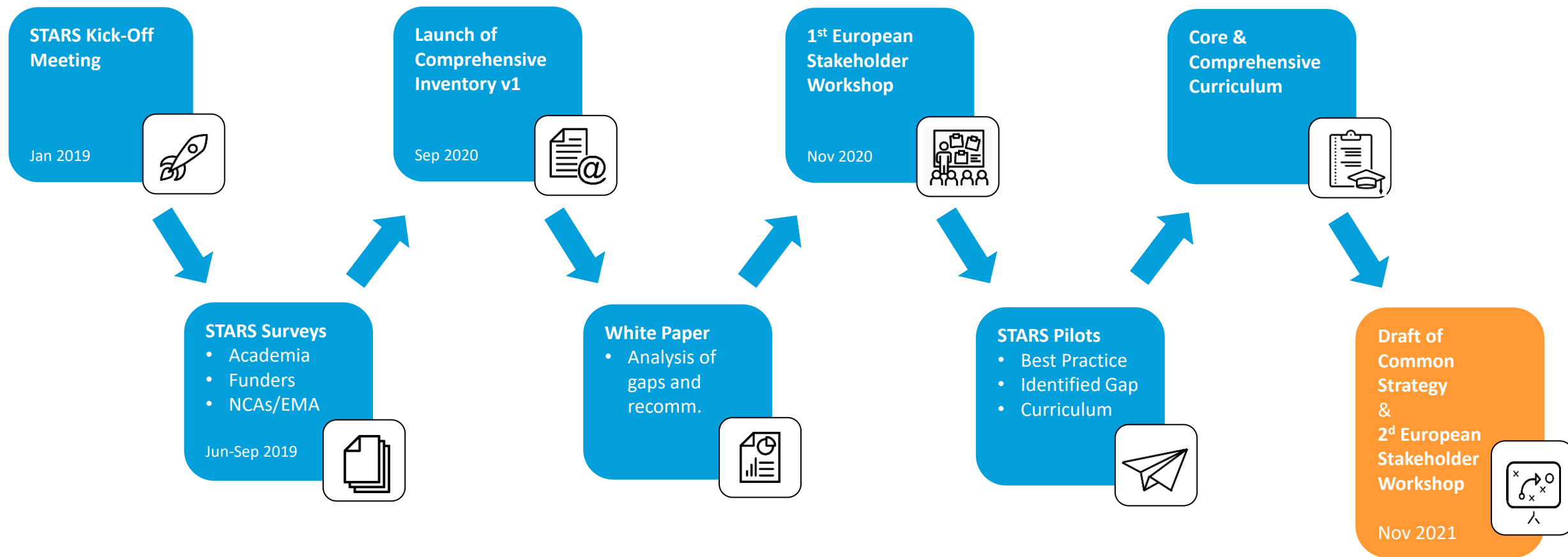


**Bachelor and Master's
students**

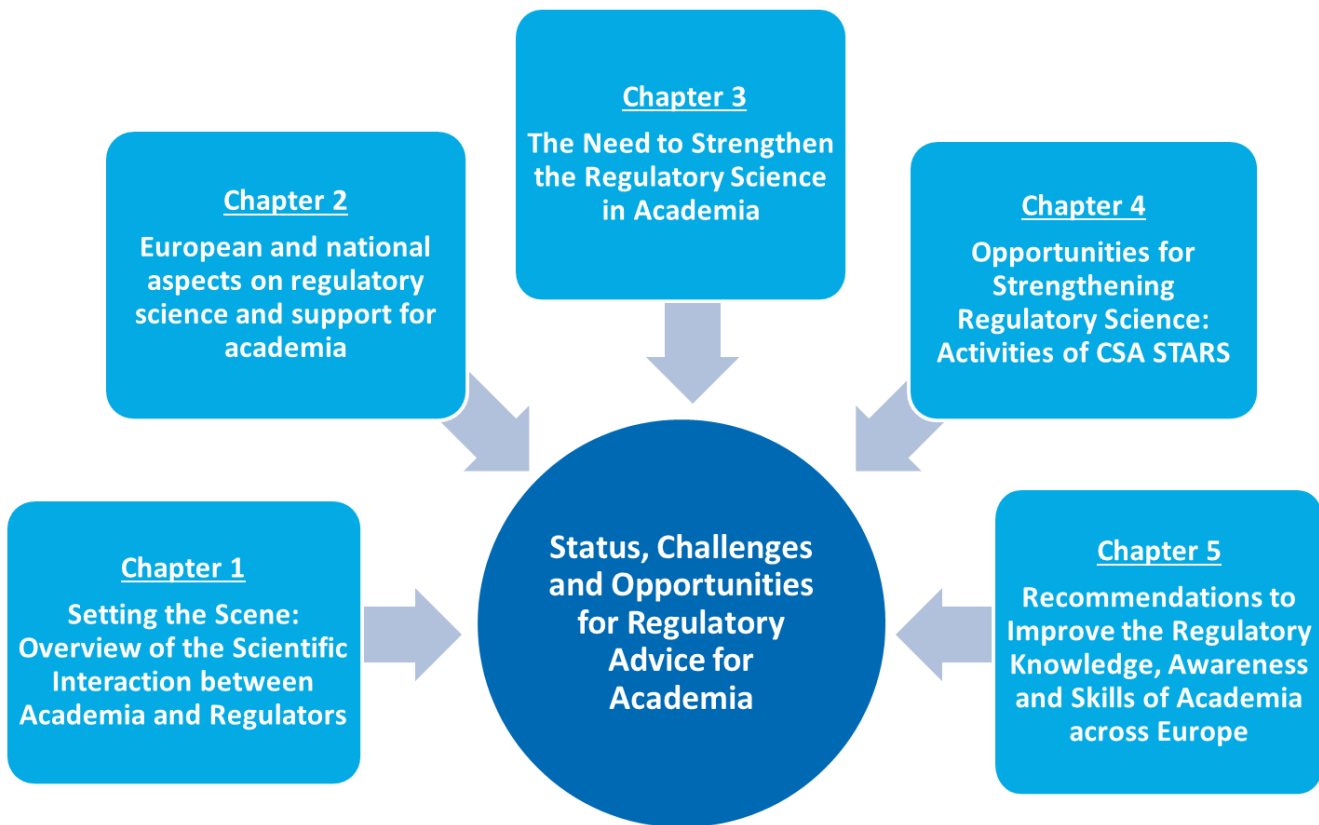


**Healthcare
professionals**

The STARS Road so far...



The STARS Common Strategy & 2^d Stakeholder Workshop



What is the Common Strategy?

Strategic document with recommendations to improve the regulatory knowledge, awareness and skills of academia

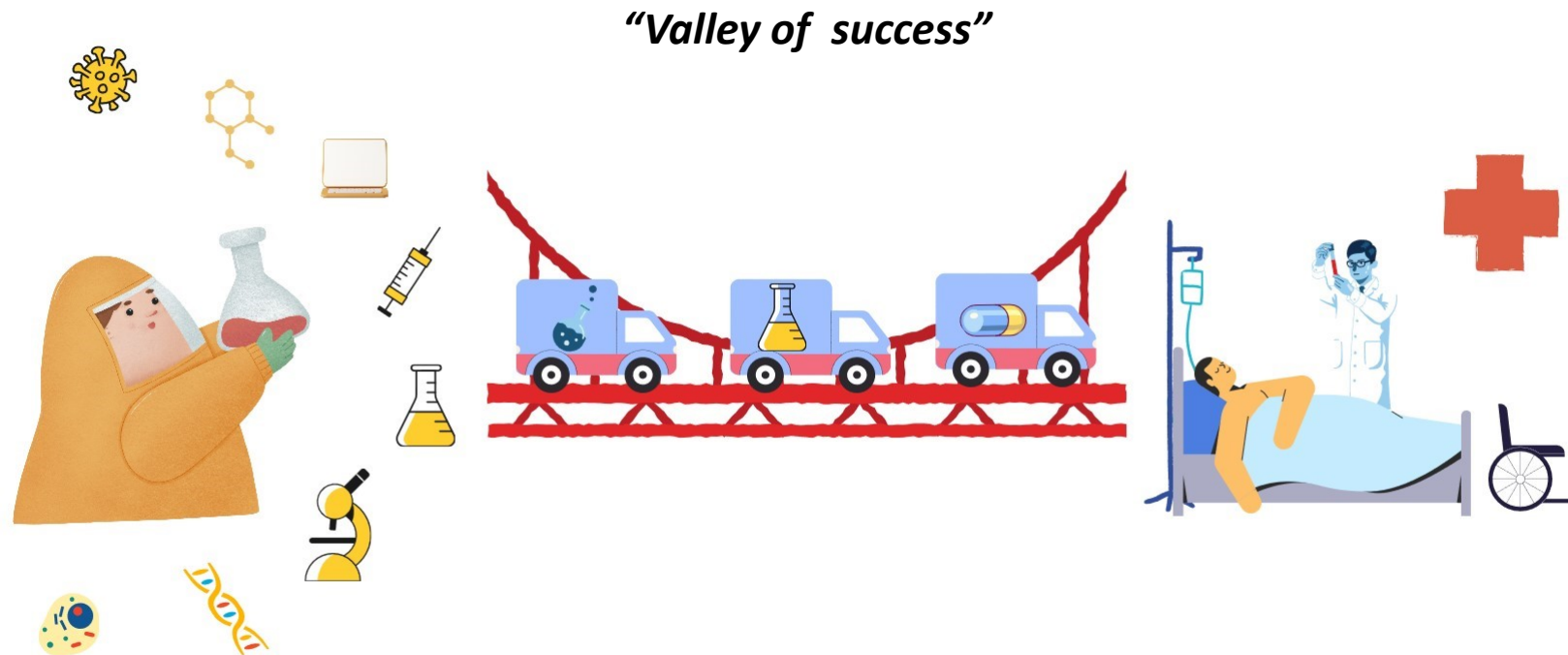
What does it include?

Recommendations based on survey data, evaluation of pilots, input from stakeholders

To whom addressed?

European Commission, stakeholder in Europe and member states, e.g. ministries, policy maker, funders, academia, NCAs and public

Drug Development - From Lab to Patient



Acknowledgement



This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No. 825881

<https://www.csa-stars.eu/index.html>