STARS
STRENGTHENING
REGULATORY
SCIENCE

Aim and Background of the Workshop – Setting the Stage

Dr. Wiebke Löbker and Dr. Anne Heß
(BfArM)

Second European Stakeholder Workshop
November 17th/18th,2021

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

Aim of the Workshop

2nd European Stakeholder Workshop

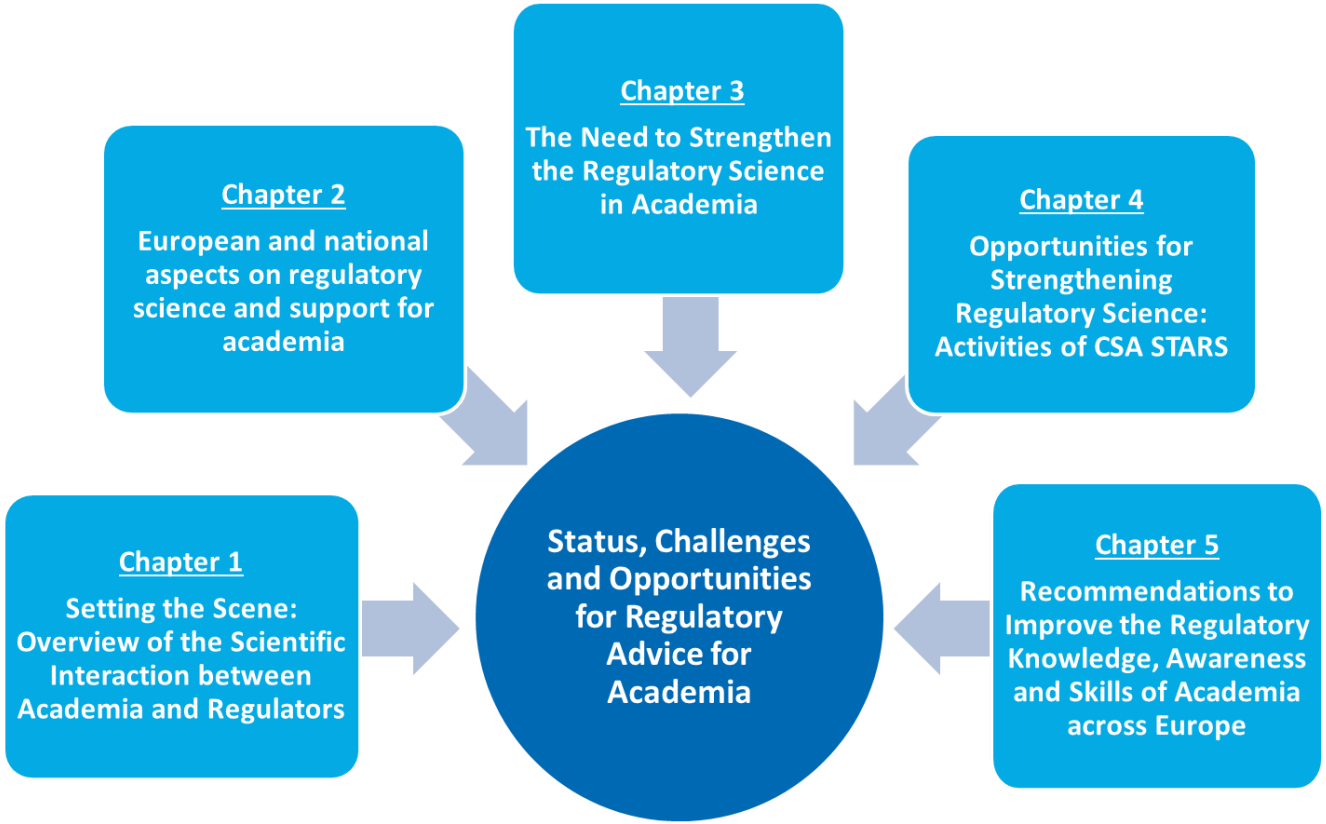
Nov 2021

To present the **STARS activities** and draft of the STARS **Common Strategy**

To discuss the **recommendations** that have been developed so far based STARS activities with the stakeholders' expertise and to further elaborate the recommendations

Dialogue between clinical researchers and experts from the innovation and health care environment to further improve the knowledge and success of academic driven health research

The STARS Common Strategy



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

"Status, Challenges and Opportunities for Regulatory Advice for Academia"

Analysis and Recommendations by the STARS consortium

Table of contents

STARS Common Strategy Confidential Stakeholder Draft - pre workshop

(1) Regulatory authorities in Europe (EMA & NCAs)

#1 Provision and regular update of targeted information material about the regulatory framework and legal approval procedures in place

#2 Use of appropriate media channels to reach out to academia

#3 Communication and networking events

#4 Low threshold access to regulatory authorities

#5 Increase of awareness and use of regulatory support tools

#6 Support in the preparation of scientific advice for academia

#7 Low threshold to apply for regulatory advice

#8 Expanding and promoting existing structures within NCAs

#9 Harmonisation of the regulatory processes between the member states is expected to be beneficial for all stakeholders, including the academics. The harmonisation should include adapted and standardised forms and processes as well as mutual online service platforms.

(2) Academic Researchers and Institutions (e.g. Universities & Research Institutes)

#10 Optimize engagement and collaboration of academia

#11 Encouraging compliance with clinical trial results reporting requirements on EudraCT

#12 Early communication with regulators and HTA before starting research project.

(3) European Commission, Ministries and Funders (e.g. RTD & Research and Health Ministries as well as other funders)

#13 Introduction and implementation of regulatory needs and aspects for funded biomedical research projects

#14 Monitoring compliance with regulatory affairs during the project

#15 Sustainability of the STARS achievements and tools

#16 Support of research of regulatory processes by specific funding measures

#17 Implementation of a pre-grant advice

(4) Industry (e.g. Pharmaceutical & Biomedical)

#18 The early contact and dialogue between academic researchers/institutions and start-ups, small medium enterprises and industry should be fostered reciprocal

(5) Education (e.g. Universities & Regulatory Authorities)

#19 Continuous education and training of regulators

#20 Continuous regulatory training of the academia

(6) Cross-cutting Recommendations

#21 Consideration of lessons learned in regulatory science, procedures and guidelines beyond Europe, e.g. along with the STARS global conference in 2022

→ **Currently 21 recommendations (page 29-34)**

→ **Six strategic areas**

Common Strategy – Timeline

January – March 2021
- Kick-off initial writing phase with core writing group (agreement on structure, chapter leads, responsiblities and partner contributions, with endorsement of consortium)

March – August 2021:
- V1 (core writing group plus partner contribution)
- Input consortium and advisory board

August – October 2021:
- Further progress in writing v2
- Review of comments from consortium and advisory board

October 2021:
- Circulation of stakeholder‘s version = clean draft for workshop participants

2nd EU stakeholder workshop

November 2021– February 2022:
- Evaluation of stakeholder‘s input at workshop
- Debriefing with STARS Consortium (Dec 6th)

Your further written input is welcome until mid of December to CoordinationSTARS@bfarm.de

March/April 2022:
- Professional editing/layout

May 2022:
- Launch of Common Strategy at STARS global conference

Version 0 | Version 1 | Version 2 | Version 3 = stakeholder‘s version | Version 4 | prefinal | final

Breakout Sessions in the Afternoon

- **Each group: discussion of 5 recommendations**
- Use of Slido polls
- You will be automatically assigned into the breakout room
- Click “join now” to be placed into the Breakout session that you are automatically assigned to

Block 2	
13:15 - 14:15	**Panel Discussion** on STARS Recommendations from the Common Strategy draft Moderated by Peter Mol (MEB, STARS partner) **Panelists** Sabine Klager (ECRIN) Teun van Gelder (Leiden University) Delphie Coppens (Dutch Cancer Society) Nils Lilienthal (BfArM) Maren von Fritschen (addonpharma, EUCOPE representative)
14:15 - 14:30	Short break
14:30 - open end (around 16:30)	**4 Breakout Sessions** with polls (max. 25-30 participants per group), Aim: to discuss the recommendations of the Common Strategy draft and the strategic recommendations (cf. chapter 5) developed by STARS Breakout Session are moderated by STARS partners (Laurence O’Dwyer (HPRA), Viktoriia Starokozhko (MEB), Wiebke Löbker (BfArM), Juan Garcia Burgos (EMA) Rapporteur: stakeholders (tbd) Note-Taker: STARS members Assignment into the breakout groups will be done by workshop organization team.
	End of Day 1

Agenda Tomorrow

Thursday, November 18th, 2021

Block 3	
10:00 - 13:00 With short break inbetween	– Presentation of results and polls from breakout session by rapporteurs of each breakout session Speaker: Rapporteurs – Plenary discussion on recommendations in the Common Strategy Wolfgang Ballensiefen (DLR-PT, STARS partner) – Summary, outlook and conclusion by STARS coordination Moderated by Wiebke Löbker (BfArM, STARS coordination) – **End of workshop**

Acknowledgement

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

Back up slides

STARS Surveys

Data Basis for STARS Activities

	Academic Research Groups	Clinical Research Centres	Funding Bodies	NCAs
Invited	795	110	52	23
No reponse	2%	5%	2%	5%
Partial response	335 (42%)	16 (15%)	11 (21%)	0
Full response	**449 (56%)**	**88 (80%)**	**40 (77%)**	**21 (95%)**

Kallio et al., manuscript in preparation

STARS Surveys

Data Basis for STARS Activities

I) Clinical research centres & academic research groups

- Awareness/knowledge about sources of regulatory guidance and support and their usage
- Challenges in regulatory matters for academic researchers
- Training needs

II) Funding bodies

- Requirements for project submission, consideration of regulatory aspects
- Contact with regulatory authorities
- Characterization of advice sought and funding organization experiences, coverage of costs for Scientific Advice
- Enablers and barriers in the linkage between academia and regulators

III) Regulatory Agencies in EU

- Preparedness of academic and non-industry researchers requesting Scientific Advice
- Experience with academic and non-industry developers and theirs problems when applying for Scientific Advice
- Regulatory training and regulatory support in the different EU member states.

STARS Surveys

Example 1 – Topics why reaching out to regulatory guidance/support

Clinical Centres Survey:

In which of the following topics the health researchers of your organization have contacted your unit and inquired about regulatory guidance/support, and how often this has happened?

	Never		Occasionally		Fairly often		Often		Very often		Not applicable		Total	Weighted Average
General matters (e.g. where to find information, document templates)	4,55 %	4	11,36 %	10	2,27 %	2	14,77 %	13	65,91 %	58	1,14 %	1	88	3,28
Preclinical R&D matters	20,45 %	18	39,77 %	35	6,82 %	6	7,95 %	7	9,09 %	8	15,91 %	14	88	1,35
Clinical study/trial design	9,09 %	8	18,18 %	16	9,09 %	8	11,36 %	10	52,27 %	46	0,00 %	0	88	2,8
Manufacturing, characterisation and/or control of medicinal products	28,41 %	25	32,95 %	29	12,50 %	11	6,82 %	6	7,95 %	7	11,36 %	10	88	1,24
Product classification	30,68 %	27	18,18 %	16	20,45 %	18	10,23 %	9	10,23 %	9	10,23 %	9	88	1,46
Preclinical safety/toxicology/biodistribution	35,23 %	31	35,23 %	31	7,95 %	7	4,55 %	4	1,14 %	1	15,91 %	14	88	0,82
Clinical pharmacokinetics	29,55 %	26	42,05 %	37	10,23 %	9	6,82 %	6	5,68 %	5	5,68 %	5	88	1,12
Biom														
Diag														
Medi														
Digit														
Patient recruitment/selection	14,77 %	13	11,36 %	10	23,86 %	21	13,64 %	12	34,09 %	30	2,27 %	2	88	2,42
Clinical first-in-man study	26,14 %	23	37,50 %	33	7,95 %	7	13,64 %	12	7,95 %	7	6,82 %	6	88	1,35
Data reporting (e.g. posting at EU trial database)	18,18 %	16	17,05 %	15	15,91 %	14	11,36 %	10	34,09 %	30	3,41 %	3	88	2,27
Clinical safety reporting	17,05 %	15	19,32 %	17	9,09 %	8	15,91 %	14	36,36 %	32	2,27 %	2	88	2,36
Clinical study statistics	12,50 %	11	21,59 %	19	13,64 %	12	19,32 %	17	29,55 %	26	3,41 %	3	88	2,33
Pharmaco-economical matters	29,55 %	26	28,41 %	25	10,23 %	9	6,82 %	6	11,36 %	10	13,64 %	12	88	1,33
Public health research and/or health technology assessment matters	27,27 %	24	28,41 %	25	17,05 %	15	5,68 %	5	13,64 %	12	7,95 %	7	88	1,46
Advanced Therapy Medicinal Product classification matters	28,41 %	25	30,68 %	27	17,05 %	15	7,95 %	7	6,82 %	6	9,09 %	8	88	1,27
ATMP certification matters	44,32 %	39	26,14 %	23	9,09 %	8	4,55 %	4	4,55 %	4	11,36 %	10	88	0,86
Orphan designation matters	42,05 %	37	25,00 %	22	11,36 %	10	3,41 %	3	4,55 %	4	13,64 %	12	88	0,88
Preparation of a Paediatric Investigation Plan (PIP)	47,73 %	42	18,18 %	16	3,41 %	3	6,82 %	6	5,68 %	5	18,18 %	16	88	0,83
Other reason (please specify the topic and frequency).													4	

Conclusion

- **“General matters” is one of the major topics for a researcher to contact the on-site clinical center**

STARS Surveys

Example 2

Academic Research Groups Survey

Which of the following procedures and support offerings typically provided by the National Regulatory Agency you and/or your research group is aware of, and how many times has the group has used them during 2014-2018?

	We are not aware of this procedure /offering		We are aware of this procedure/ offering but have not used it		We have used this procedure/offering 1 time		2 times		3 times		4 times		5-10 times		+10times		Not relevant for the group		Total
Scientific advice	43,21 %	194	22,94 %	103	8,24 %	37	5,12 %	23	3,79 %	17	0,89 %	4	3,79 %	17	3,79 %	17	8,24 %	37	449
Innovation meeting	51,22 %	230	21,60 %	97	6,68 %	30	4,23 %	19	2,23 %	10	0,89 %	4	1,34 %	6	1,56 %	7	10,24 %	46	449
Pipeline / portfolio meeting	59,69 %	268	21,83 %	98	3,12 %	14	0,89 %	4	0,89 %	4	0,22 %	1	0,45 %	2	0,45 %	2	12,47 %	56	449
Pre-submission meetings for clinical studies	49,22 %	221	23,16 %	104	7,57 %	34	4,23 %	19	2,23 %	10	0,67 %	3	2,23 %	10	1,11 %	5	9,58 %	43	449
National Agency's website guidelines and tools	33,41 %	150	21,83 %	98	6,46 %	29	3,34 %	15	4,45 %	20	2,23 %	10	5,12 %	23	15,37 %	69	7,80 %	35	449

7

Conclusion

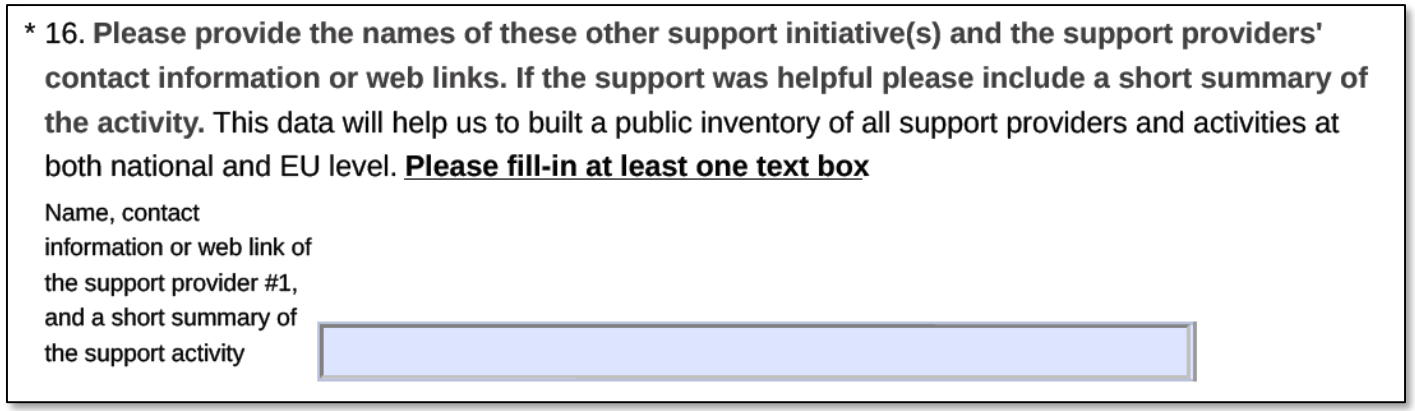
- Frist column: no awareness (e.g. 51,22% are not aware of innovation meeting)
- Second column: aware of the procedure, but are not aware of the added value
- 10 % do not consider innovation meetings as relevant - although that would be the right format

Comprehensive Inventory (CI)

How we got there

Aim of the Comprehensive Inventory

- To provide a list of various support services provided by national competent authorities, public actors and private entities
- To assist European academic drug developers in finding support on regulatory affairs
- The CI is a living document



* 16. **Please provide the names of these other support initiative(s) and the support providers' contact information or web links. If the support was helpful please include a short summary of the activity.** This data will help us to built a public inventory of all support providers and activities at both national and EU level. **Please fill-in at least one text box**

Name, contact information or web link of the support provider #1, and a short summary of the support activity

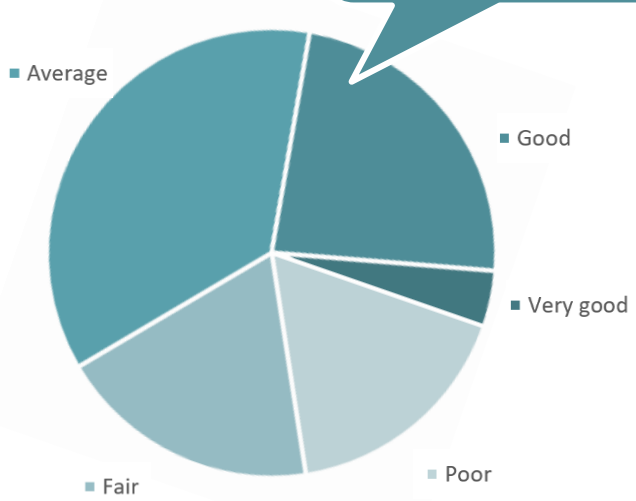
Pilot I - Evaluation

Pre-course and after-course surveys

Have you ever contacted your national authority or EMA?

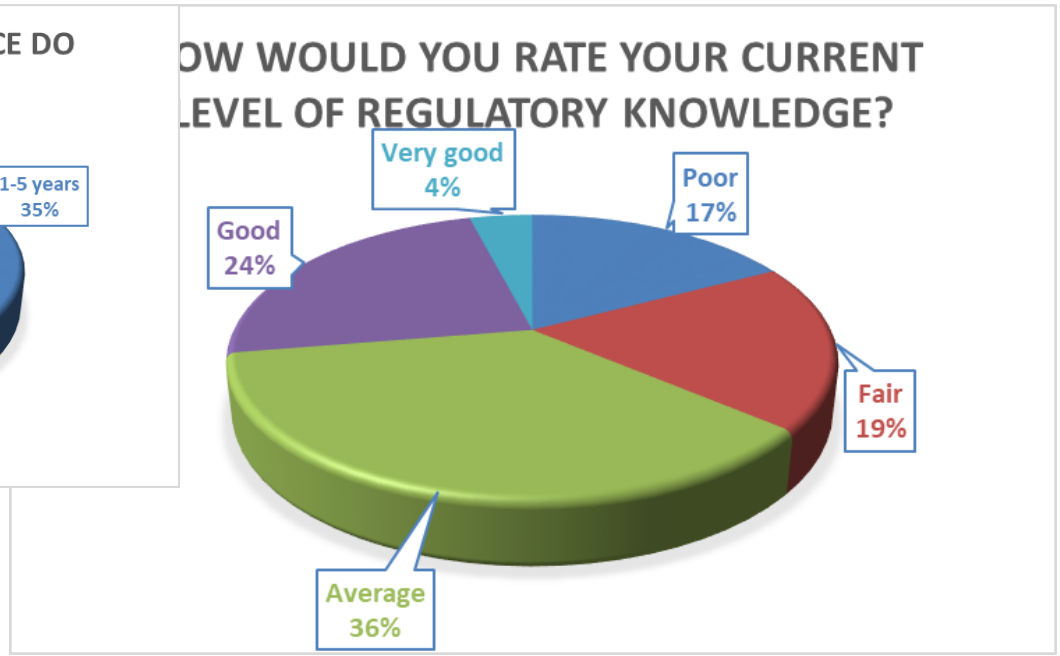
Yes: 40%
No: 60%

How would you rate your current level of regulatory knowledge?



Pilot I - Evaluation

Pre-course and after-course surveys



Pilot I - Evaluation

Pre-course and **after-course** surveys