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Second European Stakeholder Workshop: Summary, conclusion and outlook

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Second European Stakeholder Workshop
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#STARS-Day2

(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 (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

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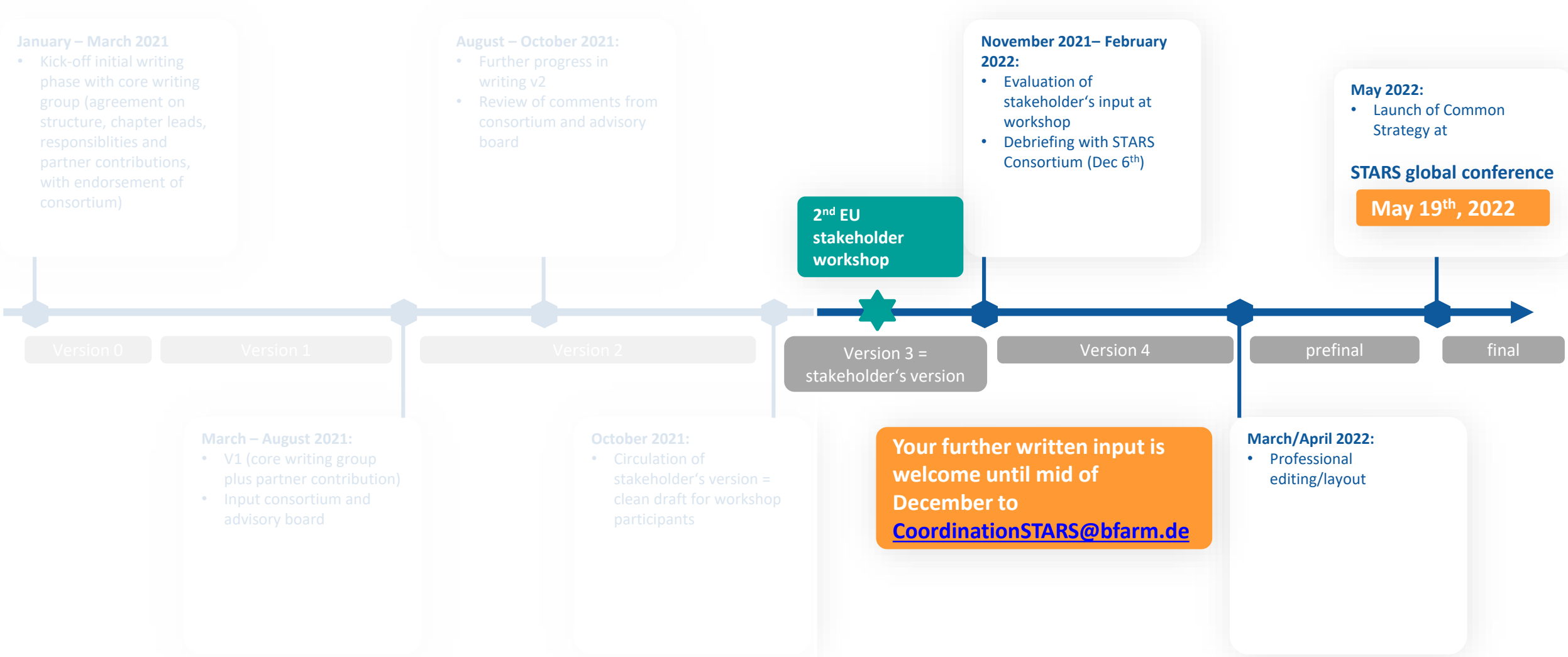
Slido result 18 November

Outlook


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)
August – October 2021:
• Further progress in writing v2
• Review of comments from consortium and advisory board
November 2021– February 2022:
• Evaluation of stakeholder's input at workshop
• Debriefing with STARS Consortium (Dec 6th)
May 2022:
• Launch of Common Strategy at
STARS global conference
May 19th, 2022
2nd EU stakeholder workshop
Version 0
Version 1
Version 2
Version 3 = stakeholder's version
Version 4
prefinal
final
March – August 2021:
• V1 (core writing group plus partner contribution)
• Input consortium and advisory board
October 2021:
• Circulation of stakeholder's version = clean draft for workshop participants
Your further written input is welcome until mid of December to CoordinationSTARS@bfarm.de
March/April 2022:
• Professional editing/layout

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Thank you!

… to all participants, panelists, moderators, notetakers, rapporteurs, supporters, impulse givers, …

…and especially to Anne Heß (BfArM/STARS coordination)
&
Hanneke Parkinson & EMA team for preparing this event!

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