Patient Engagement Open Forum: Roadmap Initiative to Good Lay Summary Practice (GLSP)

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Author: Ingrid Klingmann, EFGCP and Silvia Garcia, EFPIA

Communicating trial results to the general public – How patient engagement can work

The upcoming Clinical Trial Regulation EU No 536/2014, to be implemented beginning of 2022, requires the development and dissemination of **Lay Summaries of clinical study results from commercial and non-commercial sponsors.**

Several large companies have already generated experience with creation of Lay Summaries and in the USA guidance on Lay Summary content have already been developed for pharma companies by TransCelerate Biopharma Inc and as a proposal to FDA for a guidance by MRCT, the Multi-Regional Clinical Trial Center at Harvard. Also, the European Commission's Clinical Trial Expert Group (CTEG) has released Recommendations on the content of Lay Summaries*[1]. However, there is no proposal for a best practice framework that ensures the engagement of patients in the whole Lay Summary process from planning through production, review and dissemination that is suitable for commercial and academic sponsors and that optimises the chance that the ultimate goals can be achieved: increase of clinical research transparency, patients' and public's understanding of clinical research, as well as feedback to study participants about the overall results of their study.

To create such a suitable, mutually acceptable framework for Lay Summaries a consorted effort of all involved stakeholders is required. To that goal over 60 participants from EU and US pharmaceutical companies, CROs, academic institutions, patient organisations, and not-for-profit organisations have created the "**Roadmap Initiative to Good Lay Summary Practice (GLSP)"**. This initiative, lead by EFGCP and EFPIA, is building on the CTEG Recommendations, on experience and documents that are already available. This Roadmap Initiative created "Good Lay Summary Practice" (GLSP) recommendations that underwent broad public consultation over the summer period of 2020 including review by the CTEG.

Currently, the comments from the public consultation and CTEG will be integrated to achieve a final version by end of the year that has good chances to also become Recommendations adopted by CTEG. This GLSP will pave the way for an important role of patients in the clinical trial result communication process for patients and the public at large.

*1: https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-10/2017_01_26_summaries_of_ct_results_for_laypersons.pdf