Joint EFGCP-EFPIA Multi-Stakeholder Workshop on

Communicating Clinical Trial Results to Meet Public Needs

-Working towards Implementation of Lay Summaries-

FINAL REPORT

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ECRIN European Clinical Research Infrastructure Network

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Summary of presentations, discussions and conclusions.

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Introduction

Today the results from clinical trials are usually discussed within the scientific community only and are seldom spread to the general public. With the release of the EU Clinical Trials Regulation 536/2014 in 2014 [1], informing the public about clinical trial results will become mandatory in Europe. Lay language summaries intend to improve the transparency of clinical research in general and may help to return results of clinical trials to the patients concerned.

Once the EU Regulation 536/2014 [1] will enter into application, Lay Language Summaries will need to be released within 1 year after operational completion of a clinical trial (last-patient-last-visit). Thus, sponsors as well as clinical researchers need to get prepared. Consequently, EFGCP and EFPIA joined forces, prepared a workshop programme together with large patient organisations and organised a workshop on 02 May 2017 with stakeholders from patient and consumer health organisations, regulatory authorities, pharmaceutical industry and academia to discuss and develop best practices for implementation of Lay Summaries.

This second joint EFGCP-EFPIA Workshop aimed at presenting the upcoming European Commission Guideline on Lay Summary development and other initiatives having taken place since the first joint workshop in 2015 [2]. The following sessions were dedicated to introductory statements and discussions about what should be considered a suitable Lay Summary, how to implement the Lay Summary production process into an organisation and how to prepare the European audience for awareness and optimal use of Lay Summaries. In lively debates on each presented topic creative suggestions were made triggering expressions of support and concern. They were discussed from different view-points and concrete solutions were proposed. While the upcoming guideline will certainly help to write Lay Summaries, their contents, production infrastructure and dissemination processes need much more joint preparatory work between sponsors responsible for trial reports, treating physicians, patients, scientific societies and communication experts. Consensus was achieved that “Good Lay Summary Practices” will have to be developed.

Presentations and discussions

Guidance documents and recommendations on Lay Summary development

On behalf of the EU Commission, a multi-stakeholder task force had been established in 2015 to draft a European Guideline on Summaries of Clinical Trial Results for Lay Persons [3]. The UK Health Research Authority (HRA) led and coordinated this task force (Chairman: Sir Nick Partridge OBE, UK), bringing together 18 members from patient organisations, pharmaceutical industry, academia, scientific societies and other organisations (EMA, HRA, Involve/NHS, MRCT). The resulting draft guidance builds upon Annex V of the EU regulation 536/2014 [1] defining the mandatory content of a Lay Summary and takes respective state-of-the-art publications into account (e.g. MRCT [4], Sroka-Saidi et al. [5]).

Amanda Hunn (Manager of the HRA Task Force, UK) addressed crucial aspects of the draft guidance that had been debated by the task force members in detail:

- Acceptable literacy levels (recommendation: suitable for low to average literacy, medical jargon and technical language should be avoided, language-specific tests should be performed to ensure easy readability)
- Readability (recommendation: clear lay-out with adequate white space, use of carefully selected visuals may be helpful);
- Use of language (recommendation: an English version is mandatory plus translations into the languages of those countries where the trial had been performed and trial participants had been recruited)
- Reporting of safety results (recommendation: only adverse reactions, thus events with at least possible causal relationship to trial medication as judged by the investigator)
- Reporting of trial medication / co-medication (recommendation: generic names only as there might be large numbers of brand names for the same generic in multi-national trials). *Frans Corthals* (Glaxo Smith Kline, Italy) stressed the fact that generic names might be difficult to provide for vaccines and called for adequate flexibility in the guideline under development.
- Reporting of outcomes (recommendation: only the primary outcome should be reported to avoid "cherry-picking" among secondary outcomes; secondary outcomes should be fully accessible via a link to the technical/scientific summary).
- Inclusion of patients / patient organisation representatives in the Lay Summary writing and review process (recommendation: seek patient advice regarding readability testing, reporting of patient-oriented outcome measures, usefulness of information provided).
- Development of 10 patient-friendly headings structuring the Lay Summary content that may be used to address the 10 mandatory topics predefined in Annex V of the EU Regulation 536/2014.

Angelika Joos (EFPIA and MSD, Belgium) reported on other initiatives working on how best to share trial results with research participants (EFPIA Reflection Paper on Lay Summaries [6], TransCelerate initiatives [7, 8], MCRT [4]). Europe-US alignment initiatives emphasize that Lay Summaries need to convey fair and balanced messages using strictly non-promotional language.

The TransCelerate guidances comprise recommendations for non-promotional language [7] and most recently also on the process of implementing Lay Summaries [8]. Lay Summaries need to make clear that they refer to results of single trials only and are not intended to convey an overall assessment for a new medicine under development. Superlatives and citation of marketing experiences must be avoided; infographics should be used with care to avoid commercial allegations. Accordingly, therapeutic changes must not be based on the information presented in a Lay Summary and references to the approval status of a compound should not be made.

Essential topics in the MCRT guidance document [4] cover recommendations with examples for neutral language and suggestions how to phrase endpoint results as well as specific templates for presenting results from Phase 1 to 3 trials. They also cover logistics and how to establish a successful process for results sharing. Both, the EU guidance document under development [3] and the EFPIA reflection paper [6] have incorporated several recommendations from MRCT. As the ideas and expectations for Lay Summaries are much aligned between Europe and US, EFPIA supports a global format for Lay Summaries with focus on the primary endpoint and references to the technical summary for secondary endpoints to avoid promotional selection of reported trial results.

Involvement of patient organisations

In further discussions throughout the workshop on content, preparation and dissemination of Lay Summaries, the role and responsibilities of patients and patient organisations were the underlying theme. There was no disagreement in the audience that patients should be involved. The discussion focused on the type of patients to be involved and in which aspects patients should be consulted. Which aspects depend on successful patient involvement and how can patients and patient organisations organise their own infrastructure to maximise the effect of Lay Summaries?

While *Angelika Joos* pointed out that the sponsor needs to decide how to involve patients in the preparation of Lay Summaries, Giulio Maria Corbelli (European AIDS Treatment Group [EATG], Italy) stated that Lay Summaries should be written by patients and be more patient-owned than just be patient-friendly. He referred to examples from the AIDS community that may serve to guide Lay Summary preparation. The AIDS advocacy started in 1983 using the motto 'nothing about us without us', expressing a strong patient involvement in medical progress ever since. Accordingly, Lay Summaries are a way to empower the patient community to get more involved into medicines development. He considered it a useless waste of time and efforts, if Lay summaries are just regarded as a legal requirement. As lay persons are more competent in choosing the information really important to their patient population, Lay Summaries should be written by patients living with the disease or at least in collaboration with them. Among examples from the AIDS community, the i-Base guidelines [9] provide practical instructions for lay summaries. *Nele Caeyers* (Patient Expert, Brussels) and *Marleen Katee* (PSC Patients Europe, The Netherlands) called for trained patients to be involved in the Lay Summary process and pointed out that patient organisations can help finding patient experts. However, industry representatives argued that currently not enough trained patients can be identified who could actually write Lay Summaries. *Robert Johnstone* (EFGCP, Belgium) agreed that a lot of support can be provided by patient organisations, yet this needs appropriate funding. *Marleen Kaatee* added that patients contributing to the Lay Summary process need to receive proper compensation like every other contributor. *Kaisa Immonen* (European Patients Forum, Belgium) pointed out that patient organisations are dedicated to help increasing the general level of health literacy and specific knowledge about medicines development. Thus, patient organisations need to work on preparatory activities in their own organisations to be better prepared for their intended involvement in the process of producing Lay Summaries in the EU. EPF will advocate for structured patient engagement and collaboration with commercial and academic sponsors in this process and can help to channel input as well as work with EMA on the glossary and the user-friendliness of the portal, thus constantly improving the process. The impact of Lay Summaries on the patient community and the general public needs to be assessed regularly.

Juan Garcia Burgos (EMA – Public Engagement) emphasised the increasing focus of regulators on patients and healthcare professionals. EMA tends to engage the civil society into the review of documents aiming at a public audience. Taking up experiences with EPARs (European Public Assessment Reports developed in the context of marketing approval submissions), also Lay Summaries need to get better and to more transparently communicate information on medicines to the general public, overcoming obstacles caused by low levels of health literacy. Patients may give very important input to these documents, thus helping to avoid useless 'data dumps'.

Lay Summary content

Headlines

Several elements of the proposed Lay Summaries content triggered controversial discussions. This started with the discussion about the suitability of the headlines as suggested by the Clinical Trial Regulation: *Angelika Joos* reported that based on EFPIA [6] members' experience on consumer testing of lay summaries the use of the 10 content elements defined by the EU Regulation as 'text headings' is not feasible. She feels more comfortable with the reader-friendly alternative wording suggested by the HRA Task Force. The level of liberty allowed by the Clinical Trial Regulation to use different headings was discussed. Another important element of Lay Summaries will be the terminology used: The HRA task force recommended the EU portal should provide a glossary on clinical research terms, however, this might be postponed until more experience has been gained with Lay Summaries. *Marleen Kaatee* informed the audience that a number of patient organisations, including PSC, have developed / are about to develop glossaries in several European languages. Also the EUPATI Toolbox [10] might be helpful to the general public / trial participants looking for explanations on terms commonly used in clinical trials. But how to ensure correctness and consistency between the different glossaries? Suggestions were made to make the Lay Summaries fully searchable for key words to help finding the appropriate information. A multi-layer approach might be needed, starting with more general information and being able to dig into more details if that is of interest.

Reporting of endpoints

Very different positions were held concerning the industry's proposal to limit reporting to the primary objective's outcome: *Marleen Kaatee* emphasised that as long as there is no established cure for, e.g., rare diseases, the information on secondary objectives available in Lay Summaries is extremely important. *Solange Corriol-Rohou* (AstraZeneca, France) questioned the clinical value of such information; results from a single clinical trial cannot be more than a snapshot and may miss the big picture. She pointed out that we should not forget the role of the treating physician in the context of dissemination and explanation of information on new medicines. However, several contributors suggested that patient organisations should be asked to give advice on patient-orientated endpoints to be reported in a Lay Summary. *Jessica Scott* (GlaxoSmithKline (GSK), USA) recommended a consultation with patient organisations as early as protocol writing to help deciding on endpoints reporting that really matter to the patients concerned. *Ingrid Klingmann* (EFGCP, Belgium) supported the proposal to refer to secondary outcomes in the technical summary for those interested to keep the Lay Summary short and concise.

Reporting of safety results

An intense discussion was raised when *Angelika Joos* presented industry's suggestion for a suitable way of reporting safety results in Lay Summaries. EFPIA [6] sees the reporting of adverse reactions = side effects (and not the full set of adverse events) as a good compromise to present trial results in a transparent and concise manner.

Giulio Maria Corbelli expressed concerns about this recommendation presented in both, the EFPIA [6] as well as the EU guidance [2] documents, since determining if an adverse event is related to the medicine can be difficult. *Amanda Hunn* stressed the need of limiting the information presented in the Lay Summaries to that most important for patients. *Jessica Scott* suggested that the term 'side effect' is easier to understand for lay persons but the regulatory concept of 'adverse reactions' needs explanation. *Sini Escola* (EFPIA, Belgium) proposed that referencing to a respective glossary might be a helpful tool to avoid lengthy and repetitive explanations in each Lay Summary. *Kerstin Breithaupt* (kbr, Germany) warned that numbers presented in the technical and Lay Summaries will refer to differing Adverse Event (AE) / Adverse Drug Reaction (ADR) categories and thus numbers; e.g. in the technical summary usually the total frequency of ADRs and the number of serious ADRs is presented, while the frequency of non-serious ADRs is not addressed. According to the EU guidance document [2], the Lay Summary is to separately state serious and non-serious ADRs but not the total number of ADRs. Lay Summaries would need to explain how the categorisation of ADRs was done: in blinded trials the investigator judges the relatedness of AEs during trial conduct, not knowing the patient's treatment at that time. *Esteban Herrero-Martinez* (ABBVIE, UK) strengthened that aggregate safety and tolerability assessments prior to submission might convey other messages than ADR information presented in a Lay Summary on a single trial. This should also be made clear to the lay audience. *Amanda Hunn* concluded this discussion by stating that the European Commission will clarify the ADR reporting conditions in the final guidance version.

Despite the different needs and expectations on Lay Summary content *Jessica Scott* recommended that there should only be ONE Lay Summary per study. In her experience the most important challenges for a suitable Lay Summary are (i) the use of a common template, (II) the choice of endpoints and adverse reactions to be considered for reporting, (iii) how to appropriately restrict the amount of information, and (iv) how to ensure factual and non-promotional language, enabling easy perception by the public. Lay Summaries should be regarded as one tool only to report results back to trial participants, but other means of communication should not be neglected.

Production process and implementation of Lay Summaries

As important as agreement on the content of the Lay Summaries will be, it will also be important to implement their production into the commercial and academic sponsor infrastructures and to share best practices on production options.

Julie Holtzople (AstraZeneca, USA) presented the following recommendations, based on her experience with Lay Summary projects in her company:

- Perform a kick-off meeting to inform the trial team about the need for returning trial results to patients and the concept of Lay Summaries, convince them that Lay Summaries are part of the entire project and thus part of their responsibilities. Get an SOP and process agreed.

- Prepare a distribution plan and review it (e.g., 'thank you card' to be approved by the ethics committee). Supervise the trial team to take care of all processes regarding final communication to patients and the Lay Summary.
- Send out 'thank you card' as soon as patient completes the trial.
- Prepare the trial team for the requirement to finalise the clinical trial within 10 months after last-patient-last visit to enable the preparation of the Lay Summary within 12 months, as requested by the Clinical Trial Regulation.
- Define a vendor/central group or part of the medical writing group as authors for Lay Summaries and provide them with the clinical trial report as early as available. Develop an agreed template for Lay Summaries. Consider how to get patients involved according to the company's patient engagement policy.
- Define the internal review process and ensure that no complex language creeps in during review.
- Finalise the Lay Summary content by defining the number and types of reviews and the final authority for approval. Define where to store the Lay Summary (e.g. Trial Master File, regional submission file, Investigator Site File)
- Ensure that the sites send out the Lay Summary to all patients (this might be a long time after the individual patients had completed the trial). An external vendor could drive this via a website, alarming the trial participants when the Lay Summary is available. This process might be introduced by the thank you card; patients can then decide to sign up for getting alarmed.
- The vendor translates the Lay Summary into the additionally required languages and puts it on the website.
- Define how and where to post the Lay Summary.

Julie Holtzople commented that overseeing the sites to actually distribute the Lay Summaries was the biggest hurdle within her Lay Summary projects. Taken together, it took about 2 years to get the described process working. Julie advised to collaborate between companies and institutions to systematically evaluate lessons learned, e.g., through TransCelerate.

David Leventhal (Pfizer, USA), reported that at Pfizer Lay Summaries are written by the medical writing group, yet patients' perspectives are included in the entire process from protocol design to informed consent and thereafter. Patients' feedback on their needs is most important. Furthermore, the treating physicians should be integrated into the Lay Summary preparation process.

Theo Raynor (University of Leeds, UK) recommended that experts in writing for lay people should be involved to make Lay Summaries work, for example writers used to writing package inserts. He suggested that the length of a Lay Summary is less important than the design and layout – a longer document may work better if it is easy for the reader to navigate around it. He pointed out that, as with package leaflets and other lay documents, user testing can work well to improve the readability of Lay summaries and could be considered when first drafting such summaries in a company. Involving senior staff in the user testing process can be an eye opener and significantly help to change the general attitude towards Lay Summaries. He reported that he applied his experience from user testing EPAR and Risk Management Plan summaries to the Lay Summary implementation process. The user testing group included 31 lay persons to test whether a lay summary was readable and understandable and met people's needs. Participants included people with various levels of health literacy and also a higher education group. Writing clearly and simply was found to be acceptable for readers on all levels of literacy. Feedback revealed that long sentences should rather be split into two sentences and that shorter line length worked best. Infographics could be difficult to decipher for readers not used to such methods of presentation. Other suggestions: structure the document well, to make sure people actually find the information they are looking for. Breaking the text in two columns as well as separation of paragraphs/contents by headings on coloured lines will increase legibility. Main headings should be numbered (1, 2 etc) but sub-headings should not (lay people are not familiar with 1.1, 1.2 etc). A key information or headline section at the start appears helpful. Research-specific terms like 'primary', 'in-vitro' or composite medical terms (e.g. 'patient's global evaluation of seasonal allergy symptoms') should not be used.

Jessica Scott (GSK, USA) reported from the feedbacks on a 6 pages Lay Summary (a less and a more complicated version) provided via the CONNECT GSK Plain Language Summary Portal. This portal provides links to several Lay Summary examples, internal articles and external guidances. Crowdsourcing feedback was received through Amazon Turk, about 500 000 US-based people with an Amazon account were approached. People were paid via this account for reviewing the Lay Summary versions and answering survey questions. Entry questions on people's background helped to ensure choosing a representative group. Six populations could be identified who tested the Lay Summary versions as a real case in COPD. The test offered a fast way to see if specific parts of a Lay Summary were understandable and could be used to assess specific issues (e.g. 'are more graphics preferable?'). Based on these and other feedbacks from participating patients, a detailed internal Lay Summary production and review process was prepared. Sponsor employees needed to be trained in different functions.

Amanda Hunn commented that Lay Summaries need to be read and understood by all type of patients and the public, not only by knowledgeable patients. In her experience, communication is more straightforward with smaller patient communities (like in rare diseases) than with larger groups in more common indications.

Kerstin Breithaupt summarised that different target populations for Lay Summaries have different needs and we should try to find ways to cover the various needs. *Juan Garcia Burgos* felt that it is important to find the balance between needed and wished information; links between Lay and technical Summaries as well as to additional documents may provide good solutions.

Petra Evenaes (Leo Pharma, Denmark) asked for any experience with Lay Summaries on paediatric trials. It will be especially demanding to have technical and Lay Summaries ready within only 6 months which is the time frame to adhere to in paediatric trials. However, none of the industry representatives in the room had experience with paediatric trial Lay Summaries. *Jacques Demotes-Mainard* (European Clinical Research Infrastructure Network (ECRIN), France) stressed that Lay Summaries will also have to be prepared by investigators in investigator-initiated trials and publicly funded clinical trials. This community is not yet broadly aware of this upcoming need and has hardly considered involvement of patients in preparing Lay Summaries for their trials. ECRIN, however, will take-up this topic and help preparing academia in Europe for this new requirement.

Before dissemination of the Lay Summary to the public, there needs to be a review process. The workshop audience discussed whether Lay Summaries generally should undergo an ethical review. Feasibility (e.g. time constraints, organisational process and funding) seems to preclude involvement of an ethics committee in the disclosure of a Lay Summary after trial completion and when patients are no longer on investigational treatment. Nikos Dedes (Positive Voice & NEAT, Greece) suggested a formal review and the implementation of an EMA adjudication committee to resolve discussions about potentially inaccurate statements. Amanda Hunn pointed out that the sponsor is responsible for the content of a Lay Summary and it will be the sponsor's decision whether to provide updated versions. Nikos Dedes recommended that formal feedback mechanisms on Lay Summaries should be foreseen in the EU portal to be easily used by patients and the general public.

Marina Chavet (Norgine, Italy) raised the question whether Lay Summaries from pharma companies should not go through an EFPIA review process and be subject to the EFPIA Healthcare Professional Code [11]. Sini Escola confirmed that the latter suggestion is currently under review in EFPIA.

Lay Summaries will be publicly released but will this have to be considered as pre-publication? *Angelika Joos* and *Amanda Hunn* denied this, yet discussions are ongoing. *Jessica Scott* emphasised that discussions with journal editors need to get done quickly to avoid pre-publication concerns in pharmaceutical industry and academic research.

<u>Potential legal considerations in Lay Summaries</u>

As a last point, the audience discussed potential legal considerations implied in the Lay Summary preparation process, e.g., vendor contracts may require specific agreements regarding data protection and handling of patient-related data. *David Leventhal* advised to do upfront work on potential contractual/legal issues to be prepared. *Robert Johnstone* suggested to provide lawyers with valid examples of Lay Summaries. *Ingrid Klingmann* agreed that we need to work on learning broadly from existing experiences. Legal departments may in future play a bigger role in the Lay Summary process than nowadays but legal considerations should not play the leading role when phrasing the Lay Summaries.

Angelika Joos concluded that overall producing meaningful Lay Summaries will cause additional work at the end of a trial and it will need various efforts to sort out best approaches. More resources will be required to produce Lay Summaries, while in parallel a process has to be established to investigate whether the available Lay Summaries are really helpful and of distinct value to patients and public. Sharing practical experiences with production of Lay Summaries will help to see if the intended concepts work out well or may have to be adapted over time. As communicated in 2016, FDA is not comfortable with the current Lay Summary concepts and will delay its respective regulations until better solutions will be available.

Dissemination of Lay Summaries

The final session focussed on dissemination and optimal use of Lay Summaries. *Jacques Demotes* referred to the transparency process started in 2004 with the requirement to publish trial reports that is now continued into Lay Summaries to promote trustworthiness in clinical research and to empower patients. Yet, science does not always provide 'the' truth; it rather reports the current status of knowledge. He reminded the audience that we have to respect that results are based on statistical grounds, meaning that the 'real' effect of a drug may still be different. The solutions we have to find regarding Lay Summaries are neither black nor white and many questions remain. We need to define the right level of information in a Lay Summary, how many details do patients need to understand the results correctly?

Ilaria Passarani (European Consumer Organisation Food and Health (BEUC), Belgium) reported that BEUC was a driving force for including lay summaries as topic into the EU Regulation 536/2014 [1]. This should serve as a major step to increase transparency and public trust in medicines development. BEUC members conveyed high interest in Lay Summaries; these should be short and easy to understand, translations into local languages seemed a key factor for success. Accessibility should not depend on IT literacy and also people without internet access should be able to receive the information, e.g. via mobile phone. Therapeutic recommendations should not be given in a Lay Summary and it should be made entirely clear that investigational compounds are not yet on the market. *Theo Raynor* pointed out that most people will not know about the existence of Lay Summaries and patient organisations would be very well suited to spread this information. *Kaisa Immonen* (EPF, Belgium) agreed that patient organisations can help in many ways to ensure that Lay Summaries reach the community and are well understood. The quality of the public interface will be crucial; it needs to be attractive and user-friendly. The involvement of patient organisations should improve user-friendliness. *Marleen Katee* suggested that dissemination of information could also include social media. She advised not to place Lay Summaries on company websites as this might raise doubts about the objectivity of the information. *David Leventhal* (Pfizer, US) reported that Pfizer is posting Lay Summaries on their website as part of their 'Broader Clinical Trial Transparency' initiative and gives access to investigators through the 'Pfizer Investigator Platform'.

Juan Garcia Burgos (EMA), stressed the public has to be made aware that already now EMA provides important information on new medicines. However, until the first Lay Summaries will actually be accessible via the EU portal in 2020/2021 we should use this time slot wisely. Currently, no clear processes have been established regarding the handling of Lay Summaries by EMA / on the EU portal. Who will own the documents, EMA, the sponsors, or who else? Clear production and control processes will have to be established in due course. EMA is about to develop an awareness campaign and in the meantime will prepare the portal's suitability. Juan strengthened the importance of an appropriate life-cycle alignment for new medicines, this means information on approved medicines has to be properly linked to the clinical trial portal. A multi-stakeholder approach will be needed to measure the impact of Lay Summaries on the public, to find out who is accessing them and if the users find the information provided helpful. Search keys will have to be implemented in the EU portal to obtain statistical information about the use of Lay Summary pages. These evaluations, however, have to respect data protection issues.

Another very important source of information on the availability and content of Lay Summaries will be the investigators and treating physicians. *Amanda Hunn* commented that investigators should already notify trial participants about the availability of Lay Summaries when seeking informed consent, but equally point out that results will only be accessible with considerable delay via the EU portal (i.e. not earlier than 1 year after the entire trial has been completed). Sponsors should involve investigators in the distribution of Lay Summaries in addition to the mandatory postings on the EU portal. *Jessica Scott* suggested that we should find systematic ways to inform the treating physicians about the availability of Lay Summaries for their patients as one element of information about new treatments. *Angelika Joos* recommended identifying best logistic options and pro-active organisations, institutions, infrastructure for dissemination of Lay Summaries on a country by country basis to maximise dissemination efficiency. *David Leventhal*

saw great advantages in co-ordinating initiatives, like TransCelerate, to increase consistency in Lay Summary dissemination across pharmaceutical companies. The guidelines developed by TransCelerate are open access and can be used by all sponsors.

Conclusions and next steps

At the end of a full day of discussions, *Ingrid Klingmann* (EFGCP) expressed what everybody in the room felt: we are only at the beginning of a journey.
The soon available guidelines on Lay Summaries will be a starting point for the implementation process that lies ahead of commercial and academic sponsors and authorities. Content definition and the entire production and dissemination process needs to be oriented towards the target audience: the patients who have been involved in the clinical trial as well as the general public. Patient organisations will be part of the production and dissemination processes and their interaction with the sponsors will need to occur within a clearly defined framework of transparency, fairness and defined roles and responsibilities. While several but not all pharmaceutical companies have made progress with defining and even implementing the production process in their infrastructure, academia has not yet been sufficiently made aware of this upcoming change in requirements. As it is an ethical requirement that patients all over the world get access to the same information on their treatments, it will be mandatory to work hard on aligning the requirements for content and dissemination of Lay Summaries amongst sponsors on a global basis. “Good Lay Summary Practices” should be developed. As a next step, both EFGCP and EFPIA agreed to establish a joint task force to work with all stakeholders involved towards creation of such best practices, to make Lay Summaries meaningful in order to meet the needs of the public and to enhance the understanding of clinical research in general.

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