Implementing

"Good Lay Summary Practice"

REPORT

Virtual Workshop | 14, 15 & 21 February 2022

Table of Content

1. INTRODUCTION

2022 marks the start of a new era in clinical trials in Europe with the implementation of EU Clinical Trials Regulation (CTR) and Clinical Trials Information System (CTIS) going live on 31 January 2022. Significant new rules have come into effect alongside a series of non-legislative initiatives, bringing the hope of more efficient processes and greater patient benefit. Crucially, the new EU CTR has a focus on increasing transparency and creating new opportunities for patient engagement, notably in requiring trial sponsors to publish their results in lay summaries – documents purpose-built to be accessible to everyone. The challenge in making lay summaries available to patients and the public – with their simultaneous demands for readability and rigorous accuracy - was the subject of a multi-stakeholder workshop in February 2022, organised by EFPIA and EFGCP, and featuring input from patients, sponsors (industry and academia), and EU representatives (European Medicines Agency and European Commission).

Although many trial sponsors have been routinely producing reports aimed at non-professional audiences, this is the first time Europe has created a legal requirement – and associated rules - to inform patients and the public about each clinical trial in a manner which is easily understandable. As DG Santé put it at the meeting, "CTR is introducing stronger organisation and coordination across Europe for the assessment and oversight of clinical trials – with an increase in transparency." Representatives underlined how the policy environment in Europe is switching towards patient focus and engagement, and transparency.

The new requirement for lay summaries is much more than a long-overdue courtesy to trial participants, who obviously deserve clear information about how far their engagement has contributed to the advancement of science. It is also much more than an avenue for satisfying incidental curiosity about the development of a medicine or a treatment. What the systematic provision of these summaries amounts to is new and a necessary tool for developing and reinforcing the trust on which health research depends. Reliable and accessible information geared to a broad audience becomes a mechanism for dispelling public concerns that trials are part of an opaque black-box procedure. The impartiality implicit in these summaries offers the public and patients an unprecedented chance to understand what's going on in research, and gives researchers a channel to better communicate results. As DG Santé conveys, supporting public confidence in clinical trial processes has a positive effect in the overall EU regulatory system for medicines. More systematic public disclosure of the aims and outcomes of individual trials is breeding public confidence, contributing in turn to a more conducive environment for continued research.

While the concept is simple, its implementation is far less evident. The intrinsic challenges of combining readability and scientific rigour are undeniable, and the administrative aspects of planning, producing, translating and disseminating these reports are complex and potentially onerous. Inadequate compliance would be counterproductive insofar as it would risk destroying the very trust that the system is designed to consolidate. Inefficient compliance would make the processes so costly and time-consuming as to imperil diligent observance of the requirement. That is why a broad range of stakeholders have recognized the need for guidance on the implementation of GLSP, and are working towards refining it.

This workshop was a crucial link in that process, and a natural extension of the work that has preceded it. While the legislation lays down regulatory provisions for Lay Summaries (LS), and the guideline fills out many of the principles, effective implementation will require a clear understanding of each of the detailed tasks and processes necessary to attain the goal of improved understanding among patients and public. That is why, as the new legislation has come into effect in January 2022, a wide range of stakeholders – from authorities, sponsors (industry and academia), patients and civil society - are collaborating to explore how they can best deliver on this new responsibility, through a concept known as Good Lay Summary Practice.

2. The genesis of GLSP

The development of GLSP is a remarkable instance of intense cooperation between the European Commission and stakeholders, featuring official publication of a guideline developed with input from both sides.

The EU's 2014 Clinical Trial Regulation that came into full effect 31 Jan 2022 imposes a broad obligation on all trial sponsors, commercial and non-commercial, to create and disseminate lay summaries of their clinical trial results. In preparation, in a self-styled Roadmap Initiative to Good Lay Summary Practice, more than 60 participants from EU and US pharmaceutical companies, CROs, academic institutions, patient organisations and not-for-profit organisations had created a draft guideline offering more specific guidance on the new requirement. That was reviewed by the European Commission's Clinical Trials Expert Group (CTEG), revised accordingly, and subsequently adopted by CTEG. In a rare exception to EU rule-making procedures, this was published in late 2021 in EudraLex Volume 10 as the “Good Lay Summary Practice Guideline”. Link here.

The content of the guideline reflects and builds on earlier work – both from the European Commission ("Recommendations of the expert group on clinical trials for the implementation of Regulation (EU) No 536/2014 on clinical trials on medicinal products for human use. Version 2 (2017): Summaries of Clinical Trial Results for Laypersons”) and the experience of sponsors in Europe and beyond (MRCT, TransCelerate Biopharma). One of the key elements is the recommendation to include patient engagement throughout the process of development and dissemination of LS for adult and paediatric clinical studies.

This workshop was a follow-up by the Roadmap Initiative, to explore with a wider range of involved stakeholders how the new requirement can be most widely understood and most effectively implemented. It identified how hopes could be met and hurdles overcome.

The provision of summaries of trial results coincides with the shift towards greater patient engagement in international regulation (ICH-E8(R1)) and Europe's own evolution. DG Santé highlighted how the recent Accelerating Clinical Trials in Europe (ACT-EU) initiative, published in January 2022, aims to "engage all stakeholders to deliver inclusive patient-oriented medicines development and delivery across populations."

3. What stakeholders agree on

- A good lay summary is an ethical imperative and a good thing - for patients, for public, and ultimately for regulation and for research.
- Producing a good lay summary is very demanding, and requires skills, time and resources – and clear understanding of what GLSP really means in practical terms.
- Patient engagement will be critical throughout.
- There are still many unanswered questions about how the objective is to be fully and efficiently achieved.

4. The legal requirements

Clinical trial sponsors will need to prepare a summary of the results of each of their clinical trials in a format that is easy to access and to understand by anyone who would not have the necessary scientific background. This has to be submitted to the EU's central CTIS (Clinical Trial Information System) database at the same time as the scientific results summary – that is, no later than 12 months from the protocol-defined end of the clinical trial (but six months for paediatric trials, and up to 30 months for non-therapeutic Phase 1 trials). The lay summary must be in at least one of the languages of the member states concerned (trial participation), and it is recommended that it should also be in English, with the option to add additional versions later. Information about this legal requirement must be provided to all participants before entering a clinical trial.

The LS must contain:
Clinical trial identification (title, protocol number, EU trial number...);
Name and contact details of the sponsor;
General information (e.g. where and when the trial is conducted, main objectives, rationale);
Population of participants (e.g. number of participants/Member State concerned, age groups; inclusion and exclusion criteria);
Investigational medicinal products used;
Description of adverse reactions and their frequency;
Overall results of the clinical trial:
Comments on the outcome of the clinical trial;
Indication if follow up clinical trials are foreseen;
Indication where additional information could be found.

5. The challenges

Meeting the high ambitions of CTR and of GLSP is a challenge for all stakeholders – not just for sponsors for complying with the detailed requirements of the legislation, but for investigators and researchers who are expected to adopt reinforced roles in the process, and for organisations funding trials, who will be faced with increased demands for support. The challenge extends to patients whose input will be central to success, to the public at large who will be offered a new level of information about medicine development, and to the authorities who have to ensure that the legislation is followed.

One of the principal challenges as this new requirement comes into effect is the widespread **lack of awareness** of LS, among all stakeholders, and insufficient understanding of requirements among trial sponsors and trial funders. The lack of awareness of the guidance available on GLSP is consequently all the greater.

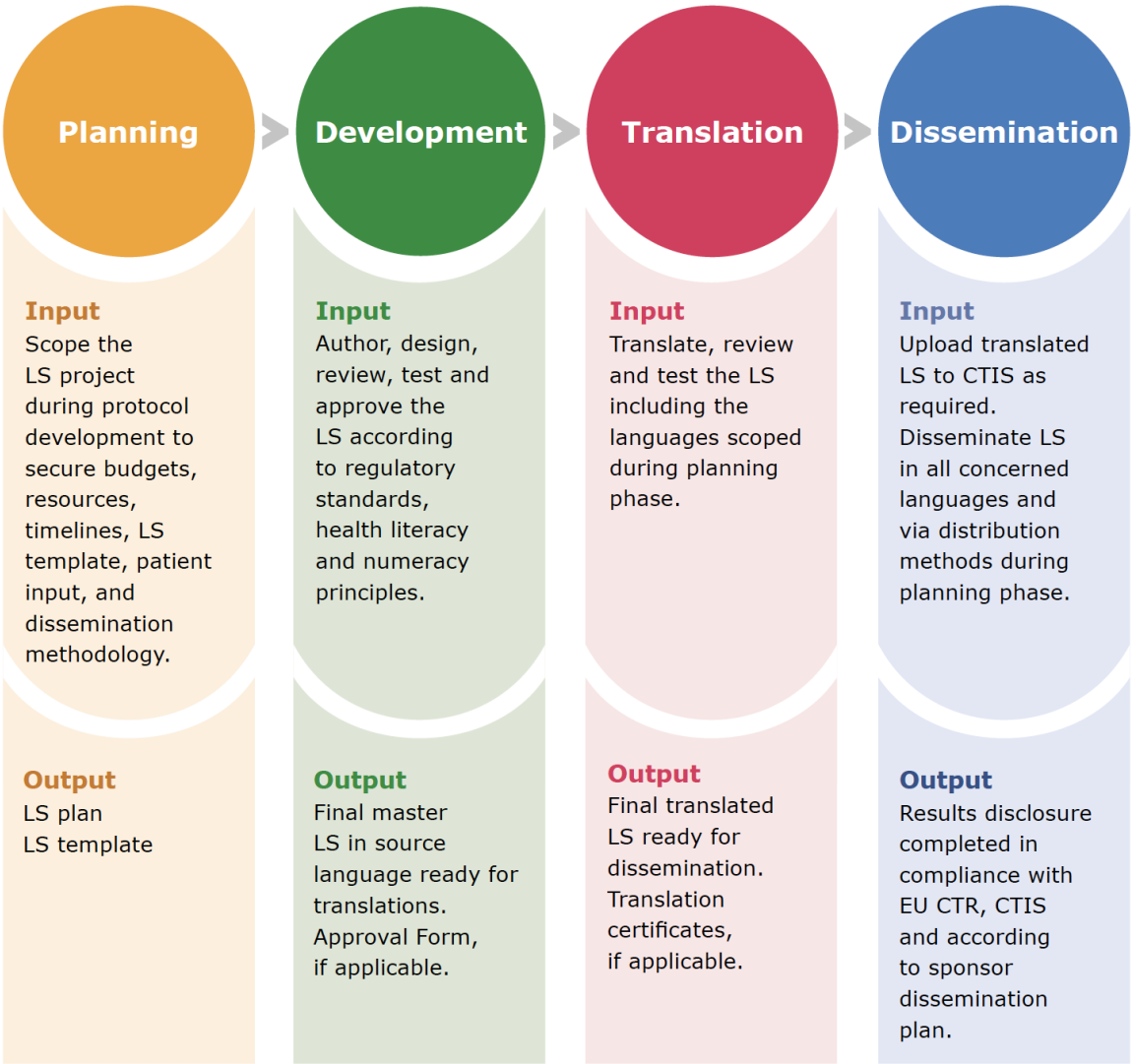
There is also widespread **uncertainty** among stakeholders on the definition of LS, with frequent confusion with the tabular summary results – the technical summary – that also has to be submitted to CTIS, grant application summaries, protocol summaries for ethics committees, plain language summaries of publication abstracts, with patient information leaflets, press releases, or with Patient Reported Outcomes (PROs) (which differ fundamentally since the focus of PROs is the patient experience, not the drug).

Uncertainties about the scope of LS also lead to questions about whether LS are required for observational, non-interventional studies, or whether an LS is required on interim results, such as in trials with extension studies without a defined study end.

Questions are frequently raised on **timing** – not only on producing individual LS, but also on implementation overall during the ongoing transition of trials from the previous legislation to the framework of the CTR.

Inevitably, the **withdrawal of the UK from the EU** also raises questions on multi-centre trials with a site in the UK.

More specifically, the challenges discussed in the workshop focused on the specific headings of the GLSP guideline**: planning, development, translation, and dissemination.**



This Section 5 "The challenges" outlines those key challenges and questions. Section 7 "Proposed solutions", on pages 9-12, contains recommendations voiced at the workshop for meeting these challenges and answering these questions. *(Issues specific to non-commercial trials are highlighted in italic)*

Planning

Planning the LS implies foreseeing clear **provision, timetabling and resources** for every aspect of LS delivery: template preparation, writing, review, patient engagement, translation, and dissemination – along with respective budgets. Estimated time for writing a LS is between 35 to 105 hours.

The planning phase should also – long before results are available -incorporate **decisions in principle** on the content of the lay summary, and the strategy for dissemination.

Development

Creating the LS is – as was stressed repeatedly at the workshop - "more than translating clinical words". Since the LS will be the first time that lay people see information about the trial outcome, it is even more important to make sure it is presented in a way that makes it **clear** for them. This challenge is matched by that of ensuring that the information reaches the **public at large**, who feature among the intended beneficiaries of the LS, and who cannot be assumed to have any knowledge of the disease or condition that is targeted by the trial.

The process has to take account of the reality that the **information priorities of trial participants**, patients and the public at large can be – and often are – very different from the perceptions and presumptions of industry and clinicians.

The production of the LS has to aim at a text that is comfortably within the **reading level** of the audience. That is not only a demanding task – and one that is equally demanding in terms of demonstrating that it is being achieved. It becomes even more demanding in the case of LS for paediatric trials.

Meeting the simultaneous requirements for **readability and scientific rigour** can raise questions over reconciling the two. And since ensuring readability for a non-scientific audience inevitably implies some extensive text to accommodate explanations of terms or concepts, there are questions over what the appropriate length of the LS is – and whether excessive length might be counterproductive by deterring lay audiences.

Since many elements of a trial results might not fit neatly into a yes/no format, there are likely to be areas where some i**nterpretation** of the data is appropriate. That raises questions over the legitimate or appropriate scope of interpretation.

While a "gold-standard" of neutrality, accuracy, impartiality and content balance is easily enunciated, there are likely to be issues of judgement over compliance. Even the relatively simple stricture of "strictly non-promotional" can be open to interpretation – and there is no provision in the legislation for **monitoring** of or ruling on compliance.

Since the legal requirement for a LS to report "main objectives" will naturally tend to a focus on primary endpoints, it may be considered appropriate in the case of some trials also to report on **secondary endpoints** – raising the question as to which, and the criteria for any selection. Even if the concept of "patient relevance" is to be a criterion, that still lacks – and possibly defies – a definition applicable in all cases.

The principle of patient engagement throughout the LS process presupposes a ready supply of patients ready and willing to engage. But there is widely uneven capacity of organised patient advocacy across the EU (and around world), and a correspondingly uneven supply of patients to engage. The risk and challenge is that **demand for patient input** can in some circumstances outstrip supply.

Translation

One of the most obvious challenges on translation is the decision on **how many language versions** should be created, and what criteria should govern the decision. Should translations be made into all languages of all countries where the trial was conducted? What attitude should be adopted to regional or national variations of languages? And what of minority populations in countries covered?

The **timing of translations** also raises questions, principally because they have to be ready within twelve months of the end of the trial (or six months for paediatric trials) so they can meet the legal deadline to be submitted along with the summary of results. This means early preparation (particularly to allow also for translation). And although the legal requirement is only that one version of the LS is to be submitted along with the technical summary, when translations appear in other languages raises issues of a more moral nature on fair access to information for all.

Ensuring **fidelity of translations** to the original is another evident challenge, as is the need for consistency across the full range of translations, which can be an issue in the face of demands for local variations to meet local linguistic or cultural sensitivities.

Dissemination

The task of dissemination bristles with challenges. How should the LS be disseminated, where, by whom, and to whom, in what languages, and for how long?

If investigators or other professionals linked to the trial itself are to be recruited to the task, will they require specific **training as communicators**?

Satisfying a "where" objective may not automatically achieve the desired result, since "findable" does not equate necessarily to **"accessible**" – in the case, for instance of an LS placed on a website rarely visited by – perhaps even unknown to - the public.

If an LS reports only **interim results (**where this is permitted because of the nature of the trial), should it be withdrawn/updated as and when subsequent data becomes available?

In some **multi-regional trials**, the study may finish in the EU before it does so in other regions, raising the question as to when the LS must be uploaded to CTIS. And where a study is global, with what additional measures (and with what timing) should dissemination of LS be pursued?

The provision at present under CTR is for LS to be uploaded only in **PDF** – but this medium may not always permit the most appropriate communication, particularly for **paediatric trials**, where "live" presentations or video might be more appropriate.

Whichever methods are chosen, dissemination should ensure the information is **accessible for all**: people with disabilities, elderly, people with low literacy.

Verification of the effectiveness of dissemination is another obvious challenge, raising questions of what constitute appropriate metrics? On a website, for instance, is it the number of clicks, time spent on the website, or number of downloads?

For non-commercial: trials:
In addition to the challenges facing all sponsors, there are particular difficulties for non-commercial trials – notably over funding, resources, capacity, and infrastructure. Research grants typically cover eligible "research costs" only, and funds can only be used while the project is "active" – while reporting falls mostly after a grant has been closed. Academic sponsor organisations have no central budget for experienced "medical writing" staff. There is anecdotal evidence of poor understanding and awareness among many research funding bodies of LS and its demands.

6. Opportunities

Despite the daunting list of challenges, the advent of LS brings with it some striking opportunities for sponsors and for the wider research and regulatory framework. In brief, those noted at the workshop included:

- wider implications for **collaboration** for such a joint work, and possibly with the EU authorities, as well as enhanced and more systematic collaboration between hospitals and academics, and a supportive role among clinical trial centres at hospitals for academic studies
- GLSP presents a unique opportunity as a role **model for patient engagement** all over the world, stirring culture change even beyond the CTR and beyond medicines regulation, with the recognition that patient involvement in the LS process brings added value and better results. Ultimately, GLSP could and should become the norm for everyone in clinical research
- revised understanding should be the result among **funding** bodies as bids for funding begin to routinely feature demands for covering the costs of LS
- LS is also useful for **researchers** to better communicate their results and focus on impact for patients - helping researchers to humanise the research
- the discussions have led to calls for the creation of a **paediatric** LS work group

7. The proposals for solutions

This section corresponds to the earlier Section 5 (on pages 7-8), of the key challenges and questions. It summarises proposed solutions and recommendations voiced at the workshop.

Some broad recommendations were made to ease some of the broader challenges.

- To remedy the current low level of awareness of LS and GLSP, dedicated **training** and workshops should be developed.
- To overcome the scale of the challenges and impart optimism, it should be recognised that **GLSP is evolving** and growing, in parallel to the three-year transition by the end of which all Clinical Trials (CTs) will be conducted under CTR. GLSP is "not something that we made once, put on a shelf and closed our eyes", as one participant observed. A pragmatic step-wise approach to implementation is advised, in line with available resource. As another participant said: "A little is better than nothing in patient engagement"
- To ease **funding** constraints, particularly for academic studies, it is essential to win changes to the current concept of eligible research costs in research grants, so that they allow for GLSP costs out of time.

More specific recommendations follow in line with the specific headings of the GLSP guideline: **planning, development, translation and dissemination.**

Planning

Planning should begin early, based on a Standard Operating Procedure (**SOP**) covering all the tasks involved in writing, review, and dissemination of LSs. Develop a general template of process flow that includes graphics and icons. Provide budget and resources for LS production, including cost of translation and dissemination. Develop a strategy for a comprehensive involvement of patients in LS production.

Develop a consistent strategy for **patient involvement**. A patients' panel review with a working minimum of three members should be set up at the earliest stage of planning each trial.

Where the trial is part of a global programme, the planning needs also to provide for **scalability**.

To ensure compliance with GLSP throughout the trial, **expertise** in producing LS should be developed and incorporated into the skill-set and reflexes of professionals in the clinical research settings or units.

For non-commercial trials:

A structured approach will be needed to improving awareness about the need for LS among all academic stakeholders and academic public funding bodies, including EU-supported funders such as under Innovative Health Initiatives (IHI) or Horizon Europe.

Development

Adopt the GLSP guidance to your specific approach to LS content.

As far as resources allow, establish **a team of writers and designers** with the appropriate skills, in terms of scientific knowledge and familiarity with clinical research, with specific communication skills in lay language writing and editing, visual and graphic design principles, bearing consistently in mind the linguistic differences between scientific and lay language. Establish practices on clear headings and subheadings, use of white space, simple and clear graphics.

Provide **Training** and **clear guidance** for internal reviewers.

Consider health **literacy and numeracy limitations** in the audience in the presentation of text and data.

Consider development of LSs for **children.**

The treatment of the trial data should ensure that the information is put in focus and in **context**, not only presenting the facts but also discussing what the trial is bringing to the knowledge of the product.

It should clearly explain the relevance of **side effects** described in the clinical trial.

The patient information sheet and informed consent form can be helpful **sources** for lay summaries.

The information should be presented to avoid any risk of **misleading** – such as undue prominence given to statistically insignificant figures inducing a false impression of the overall findings of the trial. This is particularly true for the treatment of secondary endpoint results, which are usually not statistically powered and therefore less reliable.

Each lay summary should make clear that the trial in question – and the LS itself - is just **one of a of a series of tests**, and that there are other documents that patients or the public should also take account of.

To avoid the risk of accusations of **cherry-picking** from the results as they emerge at the end of the trial, sponsors should state up-front a clear policy on the criteria to be employed for decision-making on content. The LS should in consequence be developed independently of the results outcome, and not adjusted in the course of its evolution.

There is no provision in the EU rules for ethics or regulatory review prior to loading or publication of the lay summaries, or for **monitoring**. The sponsor is fully responsible for the quality of the content.

Methods need to be found for **testing LS** for accuracy, readability and comprehensibility, and particularly to check them for whether they hit the appropriate reading level.

To ease **understanding** among non-scientific readers, the LS should include audio of "unpronounceable" drug names.

Panels of patients should be used to scrutinise the content for **impartiality**/neutrality.

Efforts are needed to generate collaboration and training among **patients as contributors** to the LS process.

Translation

Procure adequate **translation skills**.

Over and above the legal requirements, at least one language of the participants and English - to increase transparency and give access worldwide - are seen as the **minimum**.

In multinational trials, local sponsors should verify the fidelity of translations, and the appointment of a **responsible person** can ensure legitimacy of any changes and avoid translation-driven variance in the messaging output.

For non-commercial trials:

Sponsors of non-commercial trials may be able to recruit fellow academics from other disciplines in their institution (such as linguistics or communications) to support relevant training. They are also encouraged to engage with professional organisations for medical writers and EUPATI to support their work on LS.

Dissemination

Beside the publication of LS in the **publicly accessible part of CTIS** as requested by the Regulation, DG Santé advises that information on that availability of the LS should be provided through newsletters and similar published highlights, through liaison with patients and consumer organisations, through subscription services offering targeted dissemination, and through investigators and even trial participants (backed up by suitable training).

Direct dissemination can take place via e-mails from investigator to patients, or through printed documentation. **Indirect dissemination** on the sponsor's website is also permissible, on the strict understanding that the LS content and its presentation are non-promotional.

Investigators or site staff should be **trained** in how to present the lay summary, and suitably reimbursed.

DG Santé advises that notwithstanding the current guidance to submit LS in PDF format, the source data should be retained in a searchable format to permit subsequent use. The possibility of the use of other **formats** is currently under review within the Commission.

A large trial may have its own website engaging with patients and future study participants (with access codes for trial participants), and can showcase its activities in the trial world or the relevant area of diseases

(although it is recognised that this is **resource intensive**, and trial participants may lose or forget their access codes over time).

The **choice of dissemination method** will take account of trial size (number of patients and sites), characteristics of trial population, available budget and infrastructure, and local regulations.

A link to the lay summary should be included in relevant **scientific articles**.

Whichever method is chosen, it is recommended to **widely advertise the CTIS** portal to lay audiences and to patients.

The system allows the upload of LS along with **uploading interim results**, according to EMA, and not just with final results. But the release of interim results should be the consequence of advance planning that is communicated in the application and to trial participants.

It is permissible to **upload additional translations** after submission of the initial LS.

Feedback mechanisms should be created to **monitor the effectiveness** and aptness of the dissemination - perhaps through investigators and patients face-to-face, or via patient organisations.

Training and awareness-raising could be pursued via co-organised sessions with patients (e.g., EUPATI) and with EMA working parties who could act as channels to different medical societies, professional organisations, and scientific and medical organisations.

To overcome the risks of demand for patient input outstripping supply, efforts should be made to **boost patient representative bodies**, and to enhance connections among them.

The good offices of patient bodies can be sought to reach through their networks the **average patients** that are among the key audiences for LS.

There are options for **delayed upload**, e.g., in multi-regional trials when the study is finished in the EU but not yet in other regions.

For non-commercial trials:

Applicants for funding should plan for patient involvement and insist on including the demand in their applications to research organisations.

Smaller academic centres may need to devise their own methods for dissemination, depending on budget and infrastructure, or use third-party websites.

Research organisations should review their funding methodology to include provision for LS production and dissemination. They should also explicitly take account of patient engagement in their own operations.

Industry may be a potential source for support to academics for relevant expertise development.

8. Conclusion

The task is not easy, as the workshop demonstrated. The challenges are numerous, intrinsically complex and administratively demanding. The search for solutions is repeatedly exposing issues where interests diverge among stakeholders, and wide consensus is far from automatic. But the imperative of identifying the best procedures to meet the shared responsibilities has triggered a readiness to move forward together in a pragmatic fashion. The workshop was a further and crucial step in forging a pathway that will have to be followed by all stakeholders to achieve success – for individual trials, for individual treatments, for the credibility of the institutions that make decisions on treatments, and for the broad ecosystem within which new treatments can continue to be developed for the longer-term benefit of patients and European health. But the hope and expectation is that this process will lead to the definition of and agreement on good practices for LS evolving over time towards the ultimate objective of permitting patients - and Europe - to benefit from the very best practices in health. It is considered important to maintain the momentum developed over recent years and months, and the workshop participants shared an emphasis on the need to provide training to stakeholders to facilitate the process for planning, development, translations and dissemination of LS.

At the end of the workshop, the objectives of lay summaries are now clearer, the mechanics better understood, many of the challenges more precisely identified. The early stirrings among stakeholders of possible consensus have made themselves felt. Some tentative recommendations and proposals for action emerged and are now on the table. The immediate challenge is to refine them. The Roadmap Core Management Team will work on this list and develop a strategy for further steps in 2022. And because of the evident need to work together across many stakeholders, the ideal next step would be a joint workshop that would bring together a still wider group - sponsors (industry and academia), EMA, DG Santé, DG Research, IHI, other research organisations and patient organisations and even the European Parliament. Such a forum could generate a new degree of agreement about how best to increase the transparency that lay summaries can provide – and that the regulation requires. Through that, the real merit of this workshop will be confirmed.

9. Annex: Workshop Programme

Implementing

"Good Lay Summary Practice"

Virtual Workshop | 14, 15 & 21 February 2022

Faculty & Programme Committee

Programme Committee

Kerstin Breithaupt-Groegler	AGAH
Solange Corriol-Rohou	AstraZeneca
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Silvia Garcia	EFPIA
Debra Guerreiro	Janssen R&D
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Kaisa Immonen	EPF
Sabine Klager	ECRIN
Lotte Klim	Novo Nordisk
Ingrid Klingmann	EFGCP
Caragh Murray	Janssen R&D
Begonya Nafria Escalera	SJD Hospital
Margit Paul	Hepatitis Hilfe Austria
Outi Saramäki	Laurea University of Applied Sciences
Thomas Schindler	Formally Boehringer-Ingelheim, Lay & Regulatory Writing
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Debra Guerreiro	Janssen R&D
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Laura Hagan	Novartis
Kaisa Immonen	EPF
Ingrid Klingmann	EFGCP
Christine Kubiak	ECRIN
Sandrine Lavalle	LIH
John Linnell	US COPD Coalition
Souzi Makri	Cyprus League For People with Rheumatism (CYLPER)
Begonya Nafria Escalera	SJD Hospital
Margit Paul	Hepatitis Hilfe Austria
DK Theo Raynor	Professor Emeritus, University of Leeds
Maria Alexandra Ribeiro	CEIC, CTEG
Nicola Ruperto	PRINTO
Fergus Sweeney	EMA
Edit Szepessy	DG Santé
Thomas Schindler	formally Boehringer-Ingelheim, Lay & Regulatory Writing
Pia Windelov	LionBridge

AGENDA

Day 1

14 February 2022, 13:30 to 17:45 CET

13:30 Welcome and Introduction to the GLSP Development Process

- **Silvia Garcia**, EFPIA
- **Ingrid Klingmann**, EFGCP

Session 1
GLSP, the new standard to ensure information on clinical trial results that is understandable to patients and the public

13:40 The European Commission's strategy to enhance transparency on clinical trial results to patients and the public

- **Sylvain Giraud**, European Commission DG Santé

14:00 Good Lay Summary Practice:

- The new standard's principles
- The planning
- The development
- The translation
- The dissemination

- **Thomas Schindler**, formally Boehringer-Ingelheim, Lay & Regulatory Writing
- **Solange Corriol-Rohou**, AstraZeneca

15:30 Break

Session 2
Hopes and expected hurdles for implementation of GLSP
Chairs: **DK Theo Raynor**, Professor Emeritus, University of Leeds, and **Souzi Makri**, CYLPER

15:45 Lay Summaries in academia and publicly funded studies
Discussion

- **Christine Kubiak**, ECRIN

16:30 Patients' viewpoint
Discussion

- **Sandrine Lavalle,** LIH

17:15 Lay Summaries in global companies for global studies
Discussion

- **Julie Holtzople,** AstraZeneca

17:45 End of Day 1

AGENDA

Day 2

15 February 2022, 13:30 to 17:45 CET

13:30 Welcome and introduction to today's programme

- **Silvia Garcia**, EFPIA
- **Ingrid Klingmann**, EFGCP

13:40 Parallel Break-out Sessions (BOs) - Block 1

Break-out 1: How to make patient involvement in GLSP work in reality?

- **Margit Paul**, Hepatitis Hilfe Austria
- **Laura Hagan,** Novartis

Break-out 2: Lay Summary translations – Needs, complexity, and suitability

- **Pia Windelov**, LionBridge
- **John Linnell**, US COPD Coalition

15:30 Break

15:50 Parallel Break-out Sessions (BOs) - Block 2

Break-out 3: How to make Lay Summaries in paediatric studies the new norm?

- **Begonya Nafria Escalera**, San Joan de Déu
- **Solange Corriol-Rohou**, AstraZeneca
- **Nicola Ruperto,** PRINTO
- **Behtash Bahador,** CISCRP

Break-out 4: Approaches to the dissemination of Lay Summaries

- **Debra Guerreiro**, Janssen R&D
- **Thomas Schindler**, formally Boehringer-Ingelheim, Lay & Regulatory Writing

17:30 Feedback on highlights from the Break-out Sessions

- **Margit Paul,** Hepatitis Hilfe Austria
- **Pia Windelov,** LionBridge
- **Begonya Nafria Escalera,** San Joan de Déu
- **Debra Guerreiro,** Janssen R&D

17:45 End of Day 2

AGENDA

Day 3

21 February 2022, 13:30 to 17:45 CET

13:30 Welcome and introduction to today's programme
- **Silvia Garcia**, EFPIA
- **Ingrid Klingmann**, EFGCP

13:40 Feedback from Break-out Sessions 1,2,3, and 4
Chair: **Kerstin Breithaupt-Grögler**, AGAH, and **Maria Dutarte**, EUPATI
- **Margit Paul**, Hepatitis Hilfe Austria
- **Pia Windelov**, LionBridge
- **Begonya Nafria Escalera**, San Joan de Déu
- **Debra Guerreiro,** Janssen R&D

15:40 Break

15:55 How will EMA and CTIS fulfil the need for fair access to lay summaries in Europe and beyond?
Discussion
- **Fergus Sweeney,** EMA

16:25 Panel and plenary discussion
Increasing trust: Priority activities for successful implementation of GLSP
Chairs: **Ingrid Klingmann**, EFGCP, and **Silvia Garcia**, EFPIA
- **Maria Alexandra Ribeiro,** CEIC, CTEG
- **Edit Szepessy**, DG Santé
- **Nicola Ruperto**, PRINTO
- **Kaisa Immonen**, EPF
- **Laura Hagan**, Novartis
- **Thomas Schindler**, formally Boehringer-Ingelheim, Lay & Regulatory Writing
- **Pia Windelov**, LionBridge
- **Solange Corriol-Rohou**, AstraZeneca

17:45 Conclusions and next steps
- **Silvia Garcia**, EFPIA
- **Ingrid Klingmann**, EFGCP

Implementing

Good Lay Summary Practice

14, 15 & 21 Feb. 2022 | 13.30 – 17.45 PM CET

Virtual Event - Report

More Information: glsp@efgcp.eu

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