D|A|CH Symposium
Deutschland|Österreich|Schweiz
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Good Lay Summary Practice (GLSP) – Übersicht zu den Empfehlungen

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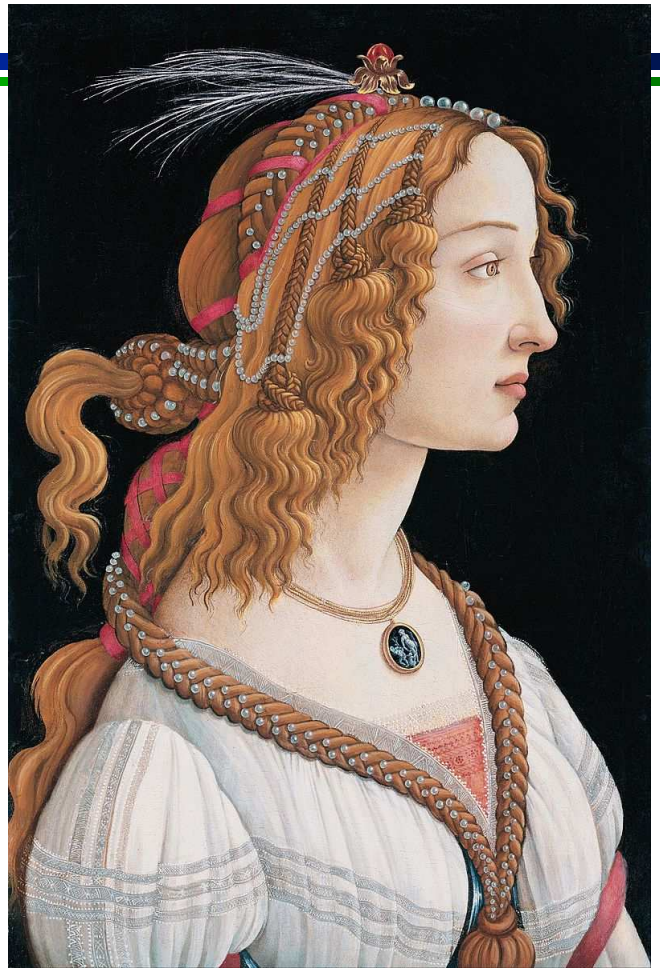
An wen richten sich Lay Summaries?

Der bittere Trank
Adriaen Brouwer (1605-1638)
Städel Museum, Frankfurt/M

- Generelle Öffentlichkeit
- Patient:innen
- Studienteilnehmer:innen
- Personen ohne Vorkenntnisse zu medizinischer Terminologie oder klinischer Forschung

Lay Summaries – ‚nice to have' oder ‚must have'?

- EU Clinical Trials Regulation 536/2014 fordert ‚summary of clinical trials results in a format understandable for laypersons'
- EU CTR Annex V legt 10 Elemente fest, die abgedeckt sein müssen
- Für alle klinischen Prüfungen, die nach der EU-CTR genehmigt werden, d.h. ab dem 31.1.2023 verpflichtend



Simonetta Vespucci
Sandro Boticelli (1445-1510)
Städel Museum, Frankfurt/M

1. *VERORDNUNG (EU) Nr. 536/2014 DES EUROPÄISCHEN PARLAMENTS UND DES RATES vom 16. April 2014 über klinische Prüfungen mit Humanarzneimitteln und zur Aufhebung der Richtlinie 2001/20/EG*
   https://eur-lex.europa.eu/legal-content/DE/TXT/PDF/?uri=CELEX:32014R0536

Lay Summary - Was muss berichtet werden? (1)

Element 1: Clinical trial identification (study name)

Element 2: Name and contact details of the sponsor (Who sponsored this study?)

Element 3: General information about the clinical trial (When and where was this study done? What was the main objective?)

Element 4: Population of subjects (What patients/people were included in this study)

Lay Summary - Was muss berichtet werden? (2)

Element 5: Investigational medicinal products used (Which medicines were studied?)

Element 6: Description of adverse reactions and their frequency (What were the side effects?)

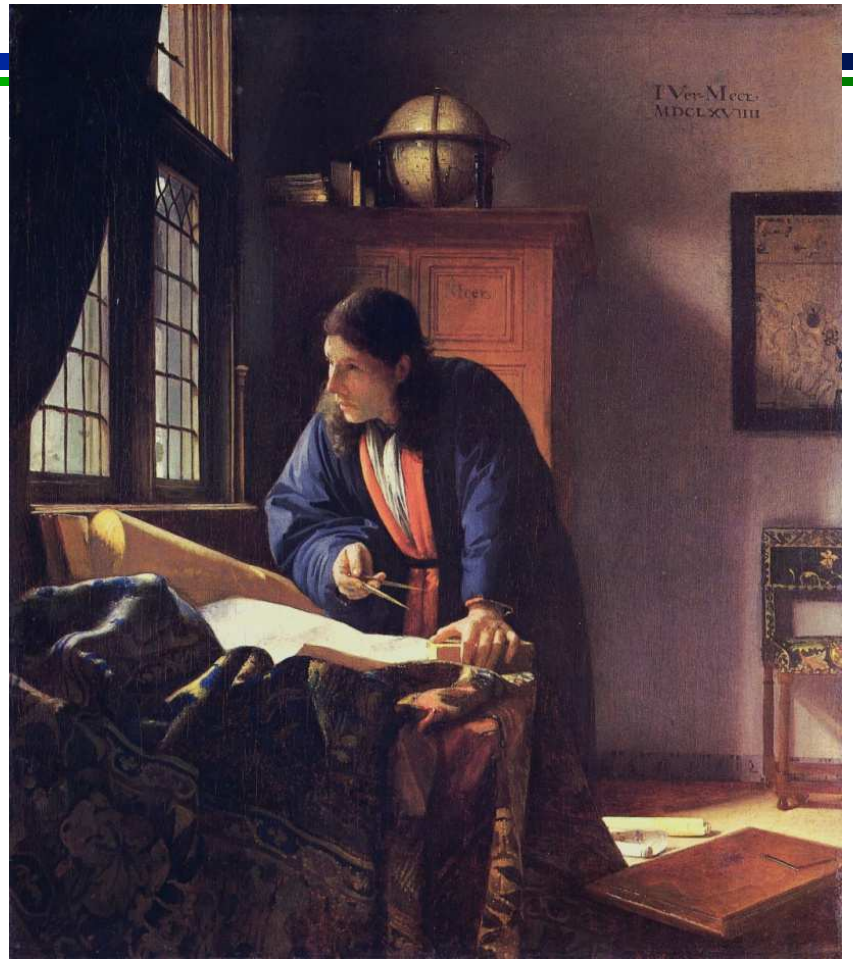
Element 7: Overall results of the clinical trial (What were the overall results of the study?)

Element 8: Comments on the outcome of the clinical trial (How has this study helped patients and researchers?)

Lay Summary - Was muss berichtet werden? (3)

Element 9: Indication if follow up clinical trials are foreseen (Are there plans for further studies?)

Element 10: Indication where additional information could be found (Where can I find more information?)



Der Geograph
Jan Vermeer (1632-1675)
Städel Museum, Frankfurt/M

Wie erstellt man Lay Summaries?

- EU Expert Group erstellt 2018 erste Empfehlungen zur Umsetzung der 10 Elemente[1]
- Questions & Answers document zur EU CTR 536/2014
- Good Lay Summary Practice Roadmap Initiative entwickelt 2021 darüber hinausgehende praktische Handlungsempfehlungen[3]

1. *Summary of Clinical Trial Results for Laypersons. 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 February 2018*. https://www.eu-patient.eu/contentassets/43803699d1884ff0b3dca3b7e0f6cf0b/gl_3_consult.pdf
2. *EU CTR 536/2014 Questions and Answers - Version 6. April 2022.* https://ec.europa.eu/health/system/files/2022-04/regulation5362014_qa_en.pdf
3. *Good Lay Summary Practice. 2021*. https://ec.europa.eu/health/system/files/2021-10/glsp_en_0.pdf

Good Lay Summary Practice

This guidance was developed in cooperation with the Roadmap Initiative to Good Lay Summary Practice and adopted by the Clinical Trials Expert Group (CTEG, a working group of the European Commission representing Ethics Committees and National Competent Authorities (NCA)).

Version 1

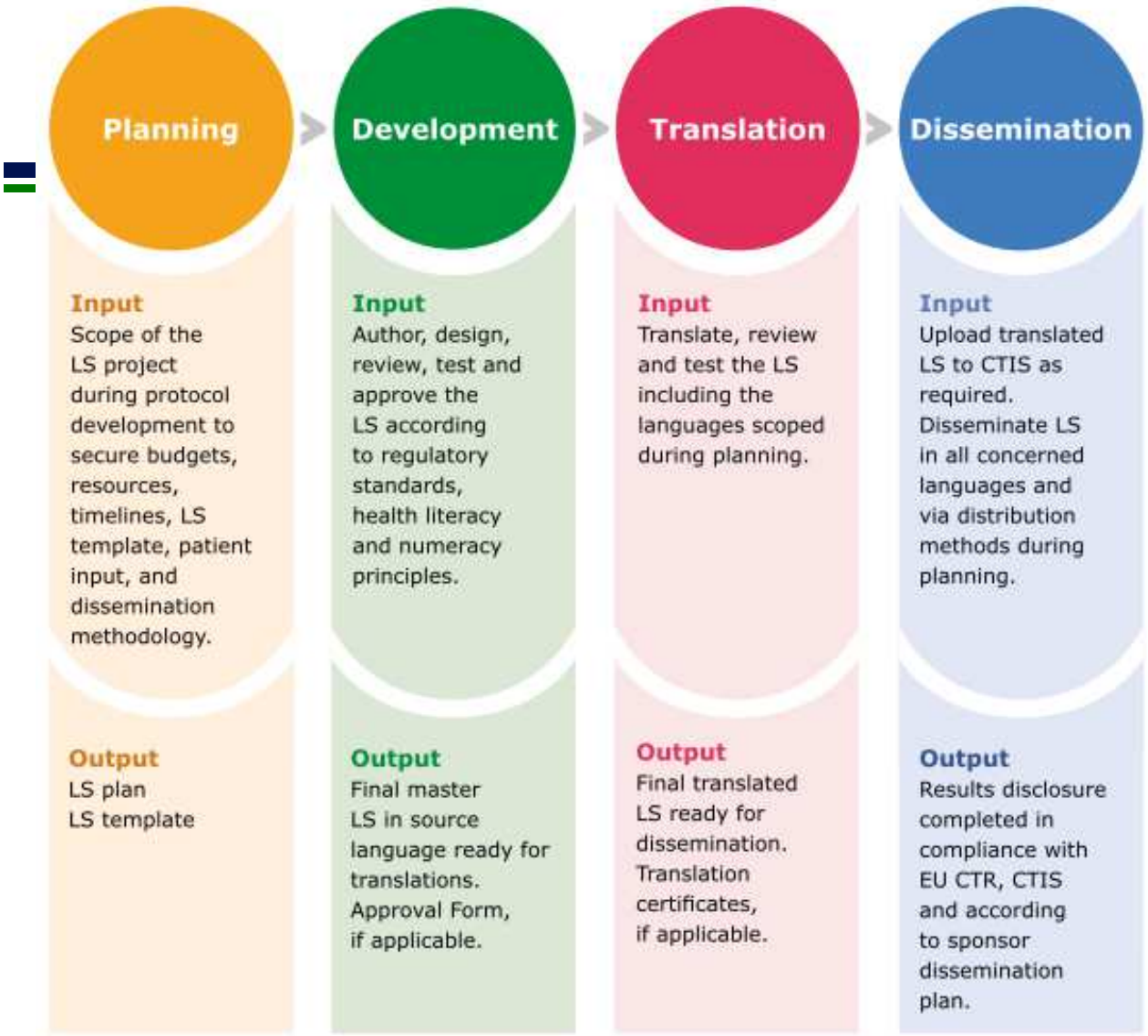
Document history:	
Date of adoption by the expert group on Clinical Trials	9 July 2021
Date of publication	4 October 2021

Good Lay Summary Practice

This "Good Lay Summary Practice" ("GLSP") provides recommendations on how to prepare, write, translate, and disseminate summaries of clinical trial results in lay language. This is a mandatory requirement laid out in Regulation (EU) No. 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use[1] ("EU CTR") and a transparency obligation to all trial participants and the interested public.

How to use this document

The GLSP is organised in two parts. Part 1 is a GLSP Quick Guide and Part 2 is the full GLSP Handbook. The GLSP Quick Guide contains core extracts from the GLSP Handbook and may serve as an overview of the recommendations offered in the Handbook. Since the intention of the GLSP is to provide practical recommendations and strive for good lay summary practices, professionals directly involved in lay summary projects are encouraged to read the full handbook to benefit from the detailed recommendations.



Lay Summaries benötigen einen Planungsprozess

Was muss die Planung beinhalten?

- Finanzierung: was wird wann benötigt für welche Punkte ?
- Personelle Resourcen: wer schreibt ?, wer prüft den Inhalt ?
- In welche Aspekte werden Laien wie eingebunden ? Welche Personen ? Patienten, Patient Experts, Patientenorganisationen ?
- Wie werden die Endpunkte der klinischen Prüfung festgelegt ? Welche Endpunkte sind patientenrelevant ?
- Welche Endpunkte erscheinen für die Lay Summary wichtig ?
- Wie wird Transparenz erreicht ohne die Lay Summary zu überfrachten ?
- Wie ist Konsistenz mit dem Clinical Trial Report sicherzustellen ?
- Welche anderen Verteilungswege über CTIS (Clinical Trial information System, EMA Platform) hinaus sind gangbar ?
- In welche weiteren Sprachen soll die Lay Summary übersetzt werden ?

Die Zeit ist knapp …

- Lay summaries müssen 12 Monate nach Ende der klinischen Prüfung vorliegen, d.h. zum gleichen Zeitpunkt wie der Clinical Trial Report und die Sientific Results Summary
- Bei pädiatrischen klinischen Prüfungen nach 6 Monaten
- Bei nicht-therapeutischen klinischen Prüfungen der Phase I kann eine Verlängerung um 30 Monate beantragt werden

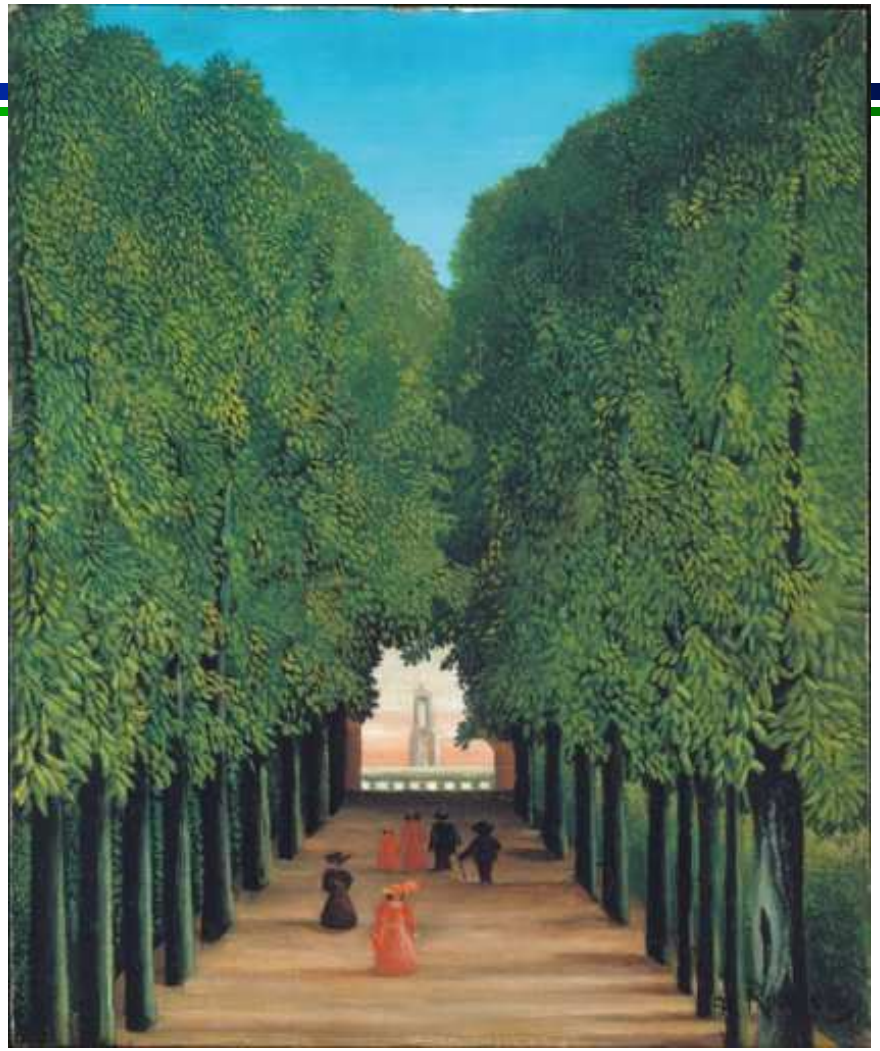
  - Was ist ‚end of trial'?
  - Last patient - last visit - last finding?
  - Data base lock? Möglich, wenn dafür eine Rationale vorgelegt wird (z.B. komplexe Bioanalytik von parent compound und metabolites oder pharmakodynamischen Markern)

Erforderliche Kompetenzen

- Scientific knowledge regarding e.g. clinical research methodology, disease, trial population
- Familiarity with source documents (informed consent, clinical trial report, summary of results, statistical evaluation)
- Familiarity with terminology and judgement of safety results
- Statistical knowledge
- Legal and regulatory knowledge
- Lay language communication skills
- Skills for quality control and accuracy checks
- Visual and design skills
- Skills to integrate stakeholder validation
- Willingness to work in a team and dedication to lay communication

Prinzipien laienverständlicher Sprache

- Use short words, sentences, and paragraphs
- Use active rather than passive voice
- Do not use technical or scientific language
- Present medical terms in brackets
- Use neutral, non-promotional language
- Do not use statistical terms
- Apply numeracy principles
- Use words and terms consistently
- Be respectful in your language and apply cultural sensitivity
- Do not use Latin expressions



Avenue im Park St. Cloud
Henri Rousseau (1844-1910)
Städel Museum, Frankfurt/M

Element 7: Results of the clinical trial

- Lay summaries report primary endpoint(s) and potentially patient-relevant secondary endpoints[1]
- Option 1: Limit results to the primary endpoint(s)
- Option 2: Include relevant secondary endpoint BUT NO CHERRY PICKING
  - Develop an overarching framework for selection of secondary endpoints to be reported in lay summaries and apply consistently to all trials
  - Preferably define patient-relevant endpoints already in trial protocol, in the latest prior to availability of interim results, but not after database lock
  - As secondary endpoints may lack statistical power, avoid placing undue emphasis on these results
  - Provide link to the Scientific Summary of the Clinical Trial Results in the EU Database

1. *EU CTR 536/2014 Questions and Answers - Version 6. April 2022.*

Element 6: Adverse reactions

- Adverse reactions must be clearly defined and presented with their frequency
- Serious adverse reactions listed first, followed by common adverse reactions
- Provide frequency in numerical terms and percentages [1]
- Lay summary presents results of a single clinical trial
  - Kategorien der klinischen Prüfung und geforderte Kategorien der Lay Summary sind nicht identisch?
  - AE = non-serious plus serious, SAE ist immer auch AE, important AE nach ICH E3, AE resulting in discontinuation, SUSAR, ….
  - Wie ist kausaler Bezug zur Prüfmedikation definiert?
  - Wie ist ‘common’ definiert?
  - Matching zur Scientific Summary of Results?

1. *Summary of Clinical Trial Results for Laypersons. Recommendations of the expert group. 2018.*

Layout and design

- Layout and design are as important as the wording
- Appearance and attractiveness have a strong impact on whether it may be read at all
  - Headings and descriptive sub-headings
  - Adequate white space
  - Columns, page breaks, colours
  - Reduction of e.g. logos
- Attractive structure helps lay summary to appear reader-friendly and accessible

‚Paradiesgärtlein'
Upper Rhenish Master (1410)
Städel Museum, Frankfurt/M, Germany

Review and User Testing

- Review by different stakeholders involved in the clinical trial (patients, medical monitor, statistician, …) is recommended
- Ensure completeness and accuracy in all aspects
- This review process should at least be envisaged for the lay summary template
- Good practice to user test the lay summary with individuals who are not involved in the trial and unfamiliar with clinical research methodology
- Clear instructions on tasks expected from the test persons and feedback process are essential

Translation

- Patients' native language is an important element of fair access to information
- As a minimum, the lay summary should be provided in the languages of the countries where the trial took place[1], matching the languages used in the Informed Consent Form
- Sponsors should consider preparing an English version to allow greater accessibility across the EU and globally
- Thorough review before translation, well-managed translation process, use of glossaries and pre-defined terminology are helpful for achieving successful translation
- Proactive planning and management will facilitate the quality, timeliness, and adequacy of lay summaries to the target audience

Dissemination

- EU CTR[1]: Sponsors must upload the lay summary to the EU Database via the EU Portal
- Additional option[2]: Direct dissemination to trial participants (e.g. printed lay summary provided by the investigator)
- Delivery of the lay summary (outside of EU mandate) needs to be done in compliance with local laws, restrictions, and standards
- Sponsor should ensure dissemination in a non-promotional manner (caveat: Is Sponsor's website non-promotional?)
- Sponsor should describe principles, planning, strategies, and communication of dissemination and apply to all trials, regardless of outcome
- Sponsors should weigh benefits against risks of various dissemination methods and consider partnering with the investigator to ensure proper results communication

1. *EU-CTR 536/2014*
2. *Summary of Clinical Trial Results for Laypersons. Recommendations of the expert group. 2018.*

Sign In

The Roadmap Initiative to Good Lay Summary Practice

Over 60 participants from EU and US pharmaceutical companies, CROs, academic institutions, patient organisations, and not-for-profit organisations have formed the "Roadmap Initiative to Good Lay Summary Practice" with the aim to develop and implement a pragmatic, broadly accepted framework for Lay Summary planning, development, translation, and dissemination.

https://glsp.network/

Roadmap Initiative Updates

Get our updates by email now, register to our Newsletter.

Newsletter Registration

[Upcoming Workshop] GLSP Translation Workshop

Date: 27 June 2022 | 14:00 - 18:00 CEST

by GLSP Core Team Team | 23 May 2022

› View

Take home messages

- Lay Summaries sind aufgrund der Anforderungen der EU-CTR zukünftig für alle klinischen Prüfungen erforderlich
- Lay Summaries erhöhen die Sichtbarkeit der eigenen Forschung in der breiten Öffentlichkeit
- GSLP und EU-Expert Group Recommendations geben wichtige Empfehlungen zur Umsetzung
- GSLP dient als Guidance Document, den Lay Summary Prozess für die eigene Institution und die eigenen Forschungsprojekte anzupassen
- Die Vorbereitung darauf muss JETZT starten

Lay Summaries - Wissenschaft verstehbar machen

Goethe in der Römischen Campagna
Johann Heinrich Wilhelm Tischbein (1751-1829)
Städel Museum, Frankfurt/M, Germany

Enable users to understand plain language
the first time they read or hear it

https://health.gov/communication/literacy/quickguide/factsbasic.htm