PPI (+E) in practice

PD Dr. med Marie Méan
Division of Internal medicine, CHUV
&
Cindy Allenbach, PhD
Clinical research Center, CHUV

PPI (+E) in practice, experiences from

Cindy Allenbach, PhD

Head of the research consent unit of the clinical research center and investigators' advisor, CHUV

PD Dr med. Marie Méan

Senior house staff physician

Lausanne University Hospital

Director of LUCID national data stream

Question

When could PPI contributors be involved in a clinical study (check all possible choices)?

- ❑ In the preparatory phase
- ❑ During the study
- ❑ After the study

PPIE in Helsinki Declaration

Art.6:

Medical research involving human participants is subject to ethical standards that promote and ensure respect for all participants and protect their health and rights.

Since medical research takes place in the context of various structural inequities, researchers should carefully consider how the benefits, risks, and burdens are distributed.

Meaningful engagement with potential and enrolled participants and their communities should occur before, during, and following medical research. Researchers should enable potential and enrolled participants and their communities to share their priorities and values; to participate in research design, implementation, and other relevant activities; and to engage in understanding and disseminating results.

When could PPI contributors be involved?

PPI contributors can make valuable contributions at every stage of research

Identifying research question

→ research priorities are aligned with those of patients and citizens

Designing research project

→ research outcomes and design are relevant for patients

Research conduct

→ another perspective based on experience is provided

Results dissemination

→ communication is accessible to the public

Implementation

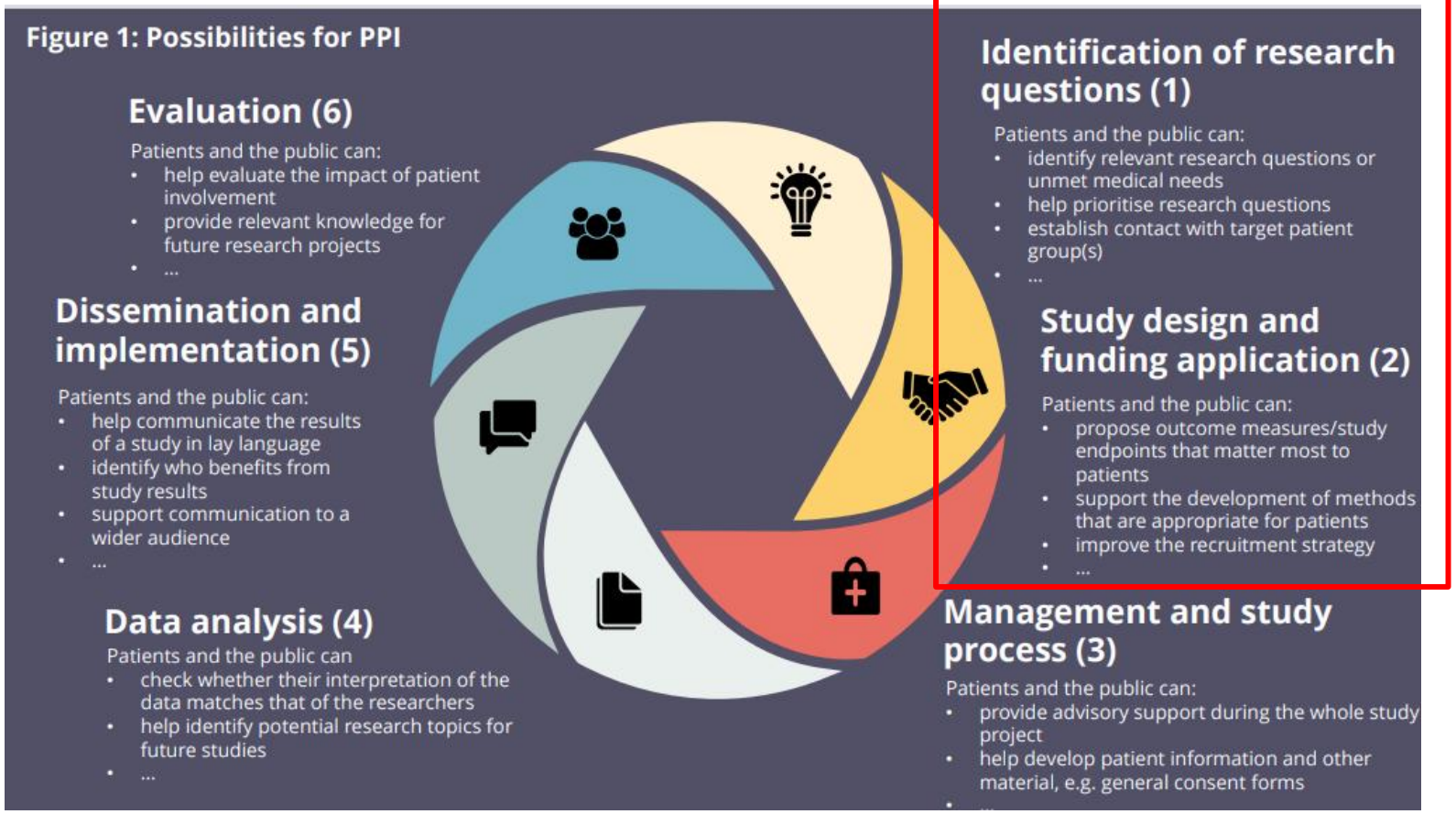
→ research leads to action

Evaluating PPI impact

→ PPI practice can be optimized in future studies

When and how PPI contributors could be involved?

Preparatory phase



PPI contributors can get involved to:

- Share perspectives about the study through individual interviews, focus groups, working groups, surveys, …
- Write/review the lay summary for general public
- …

[Guide for researchers to address patient and public involvement (PPI) in clinical trials]

In the letter of intent

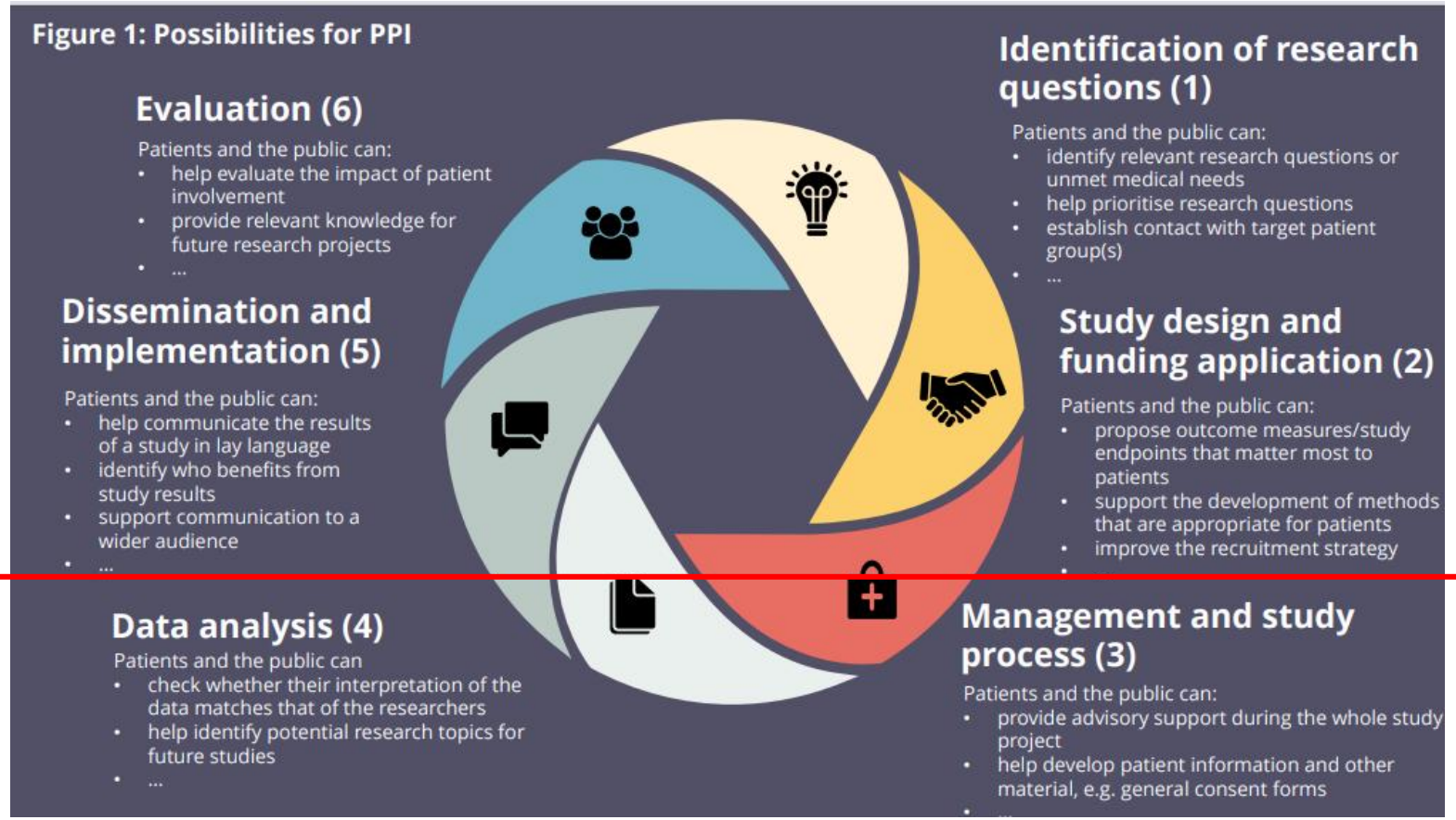
Patient engagement plan

- Explain the PPI planned until the proposal submission
- Add the associated budget requested : up to 5000 CHF allocated by SNF

Activity	***What is the role of the PPI contributor(s)?***	***What is the objective of the activity?***	***Budget*** *_Compensation (hourly/half-day/day)* *_Reimbursement (travel/accommodation/ meals)*
Total Sum			*Total Cost*

When and how PPI contributors could be implicated?

During the trial



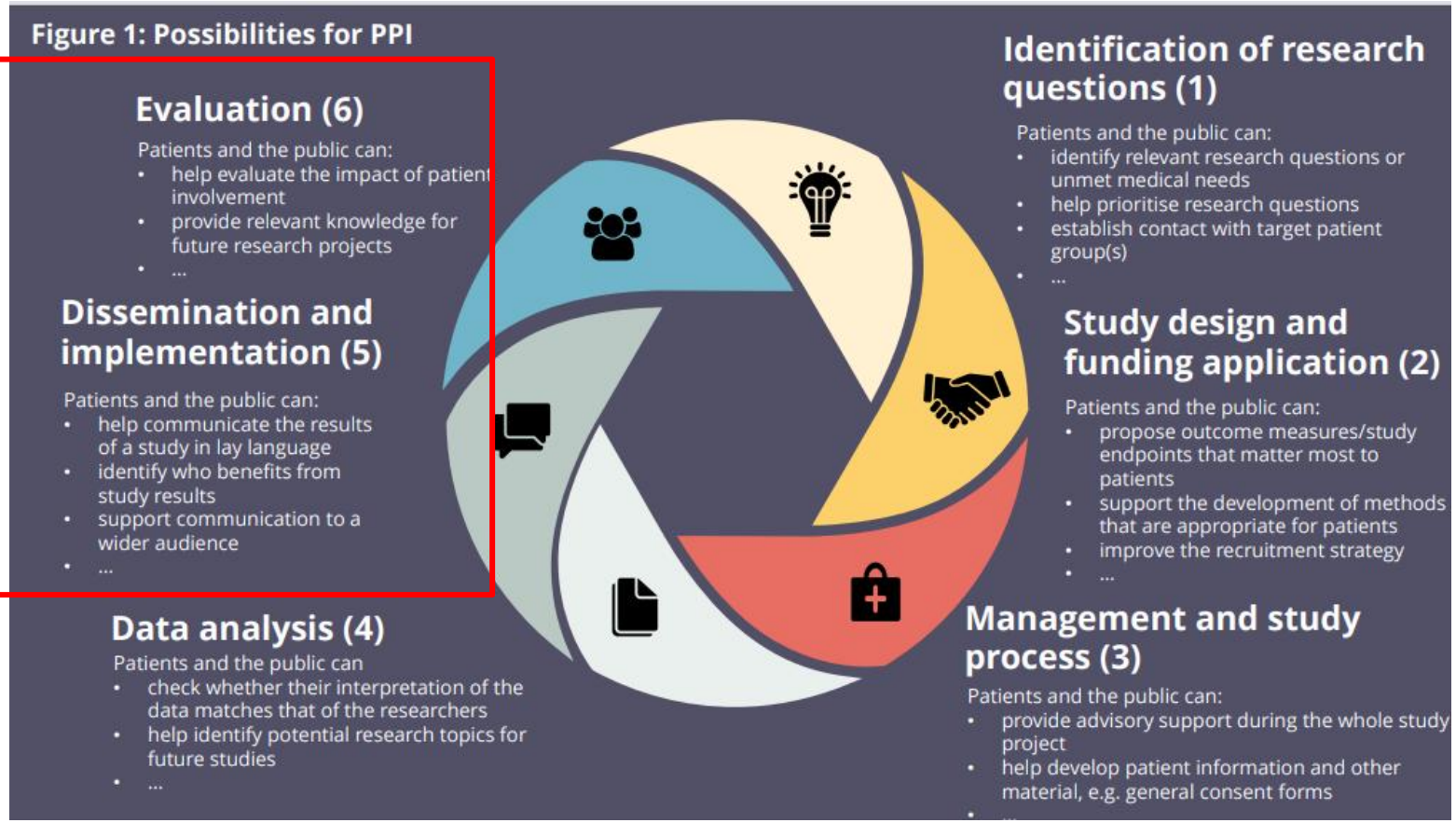
PPI contributors can get involved to:

- Review documents dedicated to participants
- Become members of an advisory board
- Support communication with study participants
- Provide input on data analysis and highlight results that are relevant for the public
- ...

[Guide for researchers to address patient and public involvement (PPI) in clinical trials]

When and how PPI contributors could be implicated?

After the trial



PPI contributors can get involved to:

- Summarize study results in lay language
- Support study results communication to participants and public
- Participate in article writing
- Give feedbacks about PPI actions and impacts
- ...

[Guide for researchers to address patient and public involvement (PPI) in clinical trials]

In the proposal

Patient and public involvement

- Describe patient engagement activities that have taken place during the proposal preparation and the effect of PPI on planning and designing the trial.
- Describe the PPI planned during and after the project.

A) Activities that have already taken place **BEFORE** the proposal submission:

Activity	What was the role of the PPI contributor(s)?	What was the objective?	How did it influence the study submitted? Please describe the benefit of the involvement.

B) Activities planned **DURING** and **AFTER** the trial conduct:

Phase	Activity	What is the role of the PPI contributor(s)?	What is the objective?
Management and study process			
Data analysis			
Dissemination and implementation			
Evaluation			

PPI: Who, how and when?

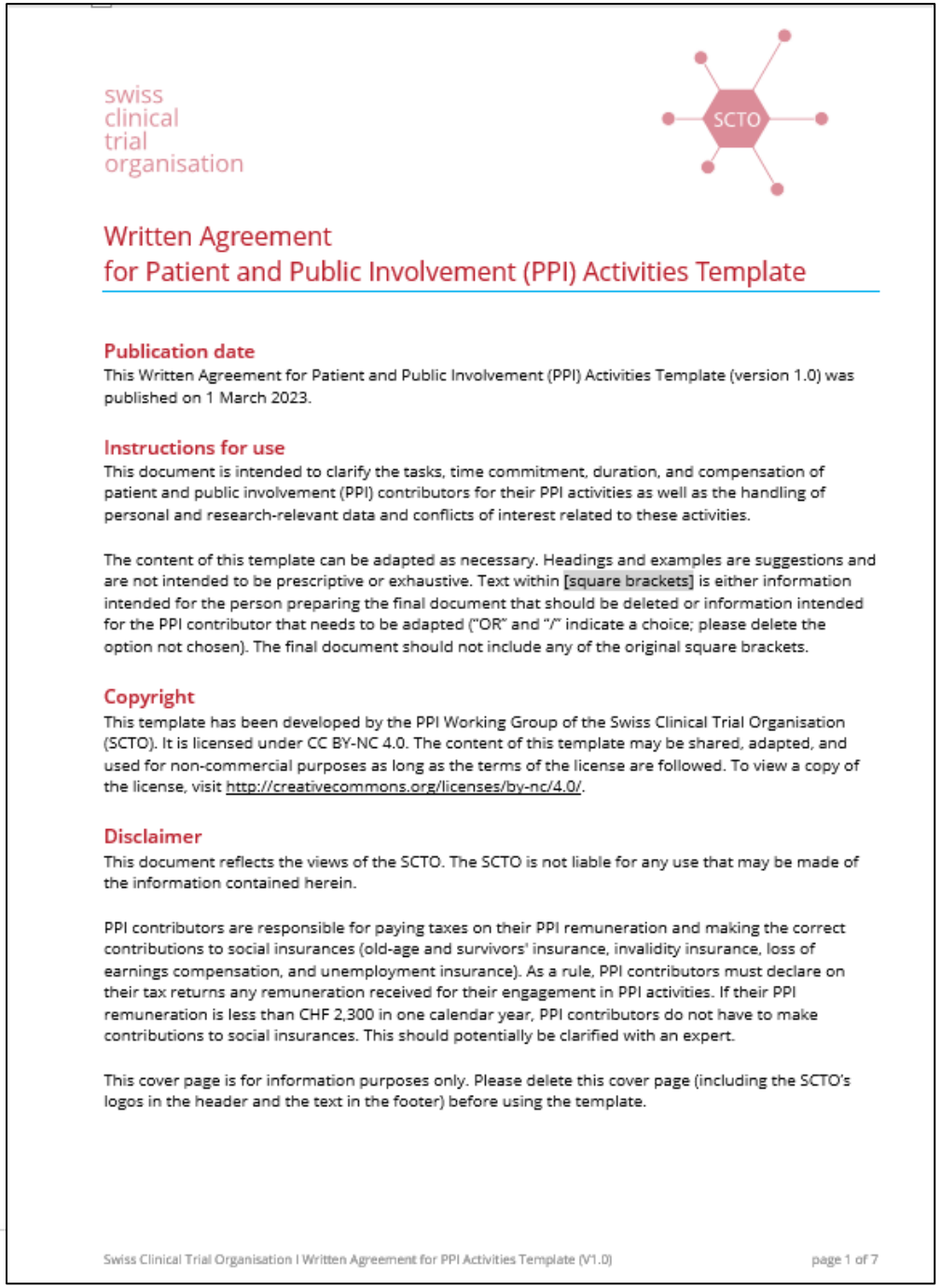
- The level of engagement, profile, expertise and numbers of PPI contributors change depending on PPI activity.

- PPI activities have to be tailored according to:
  - Research team ressources (human and financial)
  - Research team experience
  - Available time

	Level of engagement			
	Information *Provide information*	**Advice** *Give advice on specific questions*	**Joint decision-making** *Contribute at a decision-making level*	**Leadership** *Lead specific parts of a project*
Identification of research questions				
Study design and funding application				
Management and study process				
Data analysis				
Dissemination and implementation				
PPI Evaluation				

PPI: Who, how and when?

- In multicentric studies, include PPI contributors from the different regions
- Involve people with different profiles and expertises. Diversity makes the insights richer and more relevant.
- For each PPI contributor, precise:
  - The role and missions
  - The necessary expertise
  - The period of involvement and the frequency of requests
  - Remuneration modalities
- SCTO templates:
  - *For PPI recruitment*: Participation Request for PPI Activities Template
  - *To formalise the collaboration*: Written agreement for PPI activities Template



swiss clinical trial organisation

SCTO

Written Agreement for Patient and Public Involvement (PPI) Activities Template

Publication date

This Written Agreement for Patient and Public Involvement (PPI) Activities Template (version 1.0) was published on 1 March 2023.

Instructions for use

This document is intended to clarify the tasks, time commitment, duration, and compensation of patient and public involvement (PPI) contributors for their PPI activities as well as the handling of personal and research-relevant data and conflicts of interest related to these activities.

The content of this template can be adapted as necessary. Headings and examples are suggestions and are not intended to be prescriptive or exhaustive. Text within [square brackets] is either information intended for the person preparing the final document that should be deleted or information intended for the PPI contributor that needs to be adapted ("OR" and "/" indicate a choice; please delete the option not chosen). The final document should not include any of the original square brackets.

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Disclaimer

This document reflects the views of the SCTO. The SCTO is not liable for any use that may be made of the information contained herein.

PPI contributors are responsible for paying taxes on their PPI remuneration and making the correct contributions to social insurances (old-age and survivors' insurance, invalidity insurance, loss of earnings compensation, and unemployment insurance). As a rule, PPI contributors must declare on their tax returns any remuneration received for their engagement in PPI activities. If their PPI remuneration is less than CHF 2,300 in one calendar year, PPI contributors do not have to make contributions to social insurances. This should potentially be clarified with an expert.

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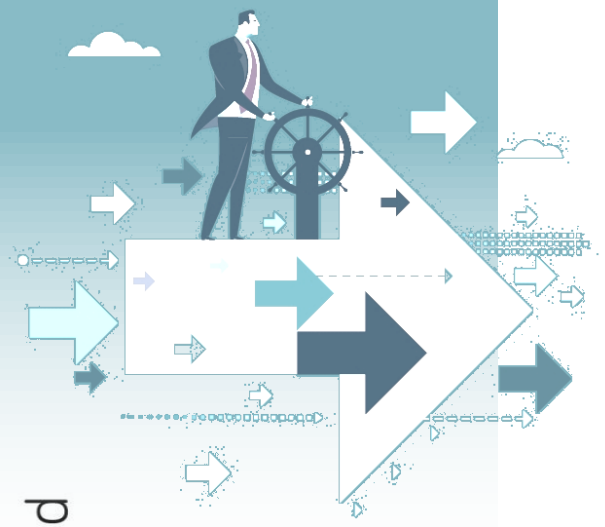
Swiss Clinical Trial Organisation I Written Agreement for PPI Activities Template (V1.0) page 1 of 7

NATIONAL DATA STREAM : DIVING INTO HOSPITALS OVERUSE

Monitor and study quality of care of medical patients hospitalized in Swiss University hospitals

more specifically, identifying Low Value Care practices



Menu

Home » Network » Ongoing projects » Project page_NDS_LUCID

LUCID, Low Value of Care in Hospitalized Patients - a National Data Stream on Quality of Care in Swiss university hospitals

Main PIs: Marie Méan (CHUV), Guillaume Obozinski (EPFL)

Project consortium: Christian Lovis (UniGE/HUG), Jean-Louis Raisaro (CHUV), Drahomir Aujesky (Inselspital), Stefano Bassetti (USB), Christophe Meier (USZ), Jerome Stirnemann (HUG), Alexander Leichtle (Inselspital), Christine Baumgartner (Inselspital), Florence Vallelian (USZ), Bram Stieltjes (USB), Oksana Riba Grognuz (EPFL), Florian Rüter (USB), Manuela Eicher (CHUV), Arnaud Chiolero (UniFr), Jérémie Despraz (CHUV)

Project manager: Tommaso Guffi (CHUV)

Data manager: Stefan Milosavljevic (ETHZ/EPFL), Cyril Matthey-Doret (SDSC)

Patient partners: Jennifer Woods, Eric Pilet, Beat Meyer, Ute Studer, Ursula Ganz-Blätter, Patrick Staeger, Ulrika Axius

PPI CONTRIBUTION TO THE INTENDED PROJECT

Consultation with PPI experts / CTU / citizen lab to start and challenge you

Select a small sample of patient contributors (according to your trial)

- Male and female
- Different age ideally
- French and German speaking (ideally also English for doc review)
- Trained ideally (see web training FORCE: https://www.forces-sante.ch/formations/formation-copy)

<u>In LUCID, PPI contributed for the pre-funding phase :</u>

- Confirmation that research question was relevant
- Lay summary writing (native English speaker PP)
- Co-creation of questionnaire in the field of low value care (using interviews)
- Inclusion as Board members or in the structure of the future panel (PPIE panel)

FREQUENTLY ASKED PPI QUESTIONS FOR RESEARCHERS

Sheffield Teaching Hospitals NHS
NHS Foundation Trust

Lay Advice on Diabetes & Endocrine Research (LADDER)
Academic Directorate of Diabetes & Endocrinology

SECTION 1 - Standard PPI questions researchers can ask a patient panel:

Pre Funding

1. **Identify Clinically Related Problem**
   - Do you think patients perceive this to be a problem?
   - Do you think this problem is worth investigating?
   - Is the proposed idea seen as worthwhile to patients?

2. **Establish the Research Question**
   - Is the research question clear to patients?
   - Do you think that the project is worthwhile?
   - Do you think the project will benefit patients?
   - Do you support the research in principle?

3. **Research Design**
   - Is the reason for doing the study clear?
   - Is the purpose of the study understandable?
   - Did you understand what the project was about from the Lay Summary alone without looking up terminology?
   - Do you think Lay members of the grant review panel would understand the lay summary and consider it a 'plain English' description?
   - Do you think patients will agree to participate?
   - Would high risk patients want to participate?
   - Is the patient journey clearly set out?
   - Is the patient journey appropriate?
   - Is the frequency of visits acceptable?
   - Is the interval between proposed study visits appropriate?
   - Are the requirements of the study acceptable to the participants?
   - Is the researcher asking too much of the patient at each study visit?
   - Are the proposed visits too long/intensive?
   - What could be done to make the project more acceptable to patients/participants?
   - Do you have concerns about the tolerability of the procedures?
   - Do you think the chance of receiving placebo would put people off participating in the study?
   - Should patients be offered longer term use of the medication being trialled, if it proves effective?

Contact

Executive summary

Goal of the National Data Stream on Quality of Care

National Data Streams (NDS) are set to play an important role in making Swiss healthcare more effective, cost-efficient, data-driven, and evidence-based. Our project will focus on hospital inpatient quality of care and will attempt to find ways of improving healthcare processes in Swiss hospitals. As both the number of patients and the cost of acute care are expected to increase in the future, avoiding healthcare waste, while satisfying inpatients expectations, is key for the Swiss health system. Since value-based healthcare aims at preventing low-value healthcare processes while keeping costs under control through **a patient-centered outcome orientation, and within an evidence-based and data-informed framework**, our **broad objective** is to build an NDS permitting **to monitor and study the quality** of care in Swiss hospitals **using existing hospital data and Patient Reported Outcomes (PROs)**. While the current project will focus on **hospitalized patients in medicine** who represent the largest part of hospitalizations, the project's infrastructure and processes are applicable for hospitalized patients from other specialties.

Click here to read the full executive summary.

Patient and public involvement and engagement

Click here to download the lay summary of LUCID in English. The lay summary can also be found in German and French.

Good lay summary guidelines:
Microsoft Word - GLSP_EudraLex_Submitted to CTEG_24Sep2021_FINAL-B4 (europa.eu)

EXAMPLE OF LAY SUMMARY (here : READING AGE was 14)

Lay Summary, V2

LUCID, a project studying how often hospitalized patients receive low-value care

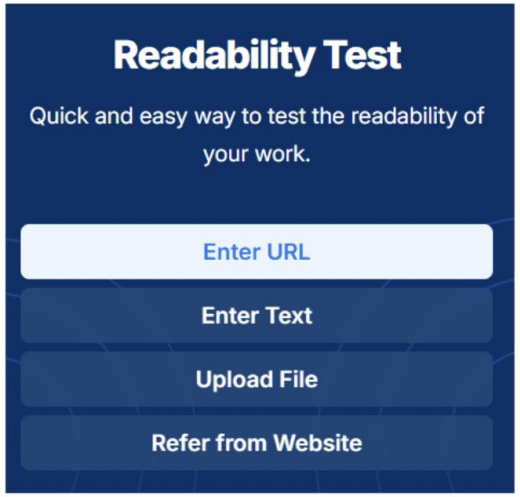
What is low-value care? Low-value care can be defined as services that provide little or no benefit to patients. They also can cause harm, cause unnecessary cost to patients, or waste limited healthcare resources.

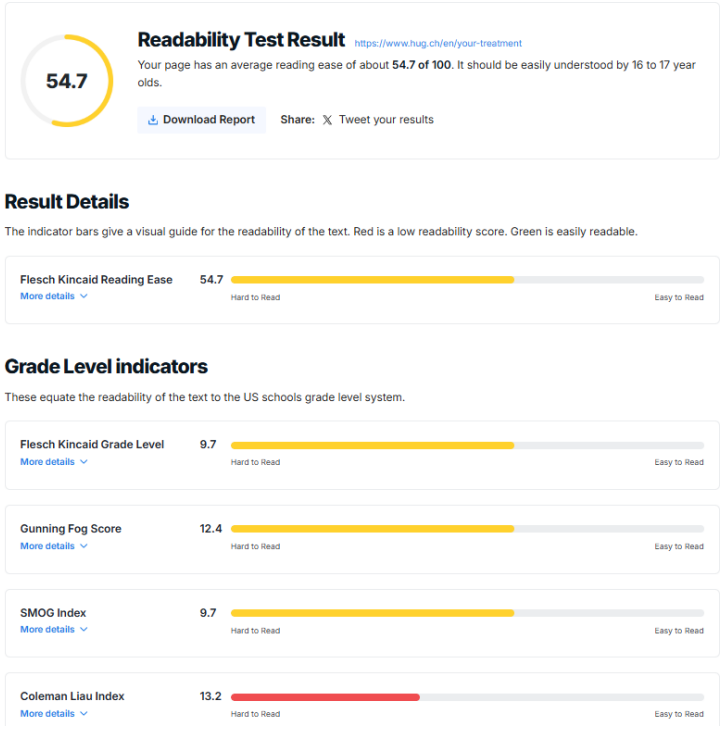
One example of low-value care is when a nurse gives a sedative (a medicine to help them sleep) to an elderly patient who doesn't necessarily need it. Older people who take sedatives have a tendency to fall and hurt themselves more often. This low-value practice has two costs – firstly, because medicine can be expensive, and secondly, because the patient is more likely to fall and require treatment for the resulting injury. It will become increasingly important for healthcare workers to help patients better, while spending less money and wasting less resources.

TOOLS TO CHECK COMPREHENSION

Examples of tests :

- **Flesch-Kincaid Grade Level** (FKGL): ideally score 6-7
- **Flesch Reading Ease Score** (FRES): ideally 80-89





PATIENT & PUBLIC RESEARCH PANEL OF LUCID NDS (PRE FUNDING PHASE)

Plan to create a **Patient and Public Research Panel**

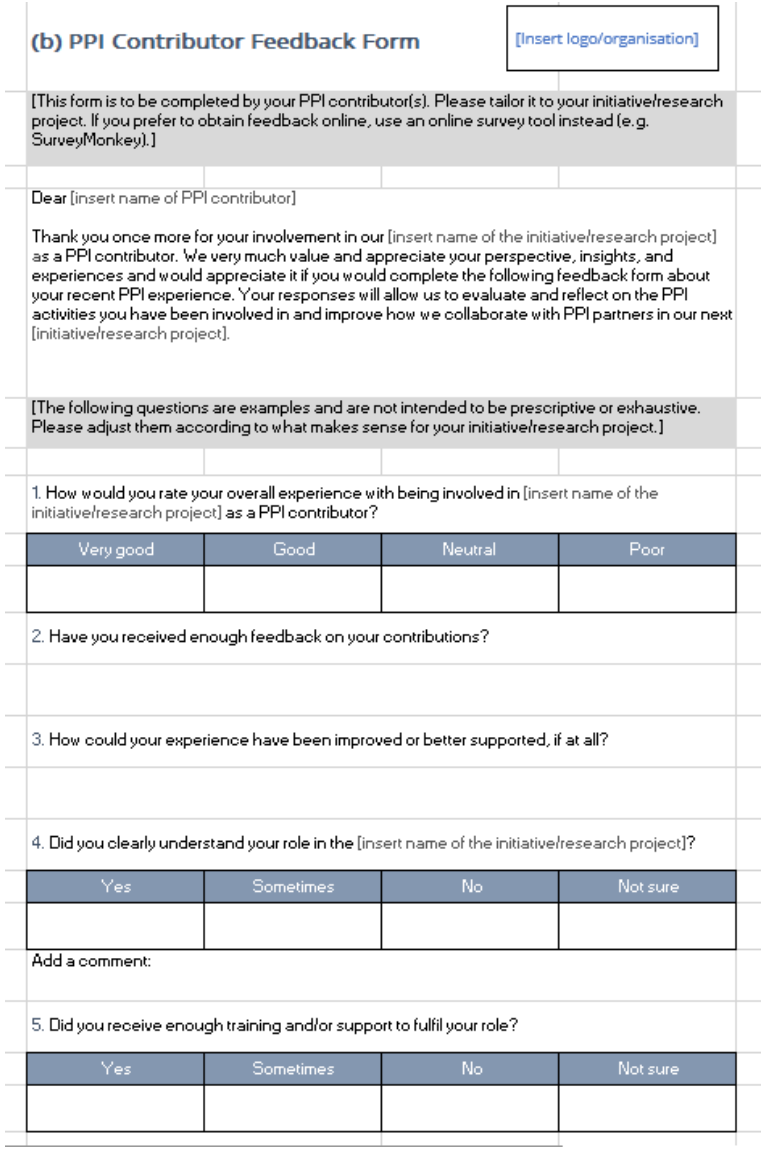
GOAL : to ensure that the Patient and public voice was guaranteed in LUCID NDS.

- ❑ Composition of the panel: foe e.g. in LUCID :
  - 8 members (ideally between 10-15 people)
  - 4 women and 4 men
  - 3 French speakers
  - 5 German speakers
- ❑ Selection criteria of panel members:
  - At least one chronic disease and/or the experience of a hospitalization in medical acute care.
- ❑ Recruitment channels:
  - Advertising on social media
  - Patient and public association (such as Fédération Romande des consommateurs, Schweizerischen Patientenstellen)
  - Recommendation given by Patient & Public Research Panel members themselves

PPI Reporting

- PPI reporting is essential. PPI activities should be evaluated in a structured and regular manner **by investigators and patients**
  - Communicate the impact of PPI in research
  - Identify best practices
  - Orientate future investigators
  - Improve the quality and consistency of PPI actions

- SCTO: Planning, Tracking, and Evaluating PPI activities template
- Guidance for Reporting Involvement of Patients and the Public (GRIPP)
  - first international guidance for reporting PPI in health and social research



(b) PPI Contributor Feedback Form [Insert logo/organisation]

[This form is to be completed by your PPI contributor(s). Please tailor it to your initiative/research project. If you prefer to obtain feedback online, use an online survey tool instead (e.g. SurveyMonkey).]

Dear [insert name of PPI contributor]

Thank you once more for your involvement in our [insert name of the initiative/research project] as a PPI contributor. We very much value and appreciate your perspective, insights, and experiences and would appreciate it if you would complete the following feedback form about your recent PPI experience. Your responses will allow us to evaluate and reflect on the PPI activities you have been involved in and improve how we collaborate with PPI partners in our next [initiative/research project].

[The following questions are examples and are not intended to be prescriptive or exhaustive. Please adjust them according to what makes sense for your initiative/research project.]

1. How would you rate your overall experience with being involved in [insert name of the initiative/research project] as a PPI contributor?

Very good	Good	Neutral	Poor

2. Have you received enough feedback on your contributions?

3. How could your experience have been improved or better supported, if at all?

4. Did you clearly understand your role in the [insert name of the initiative/research project]?

Yes	Sometimes	No	Not sure

Add a comment:

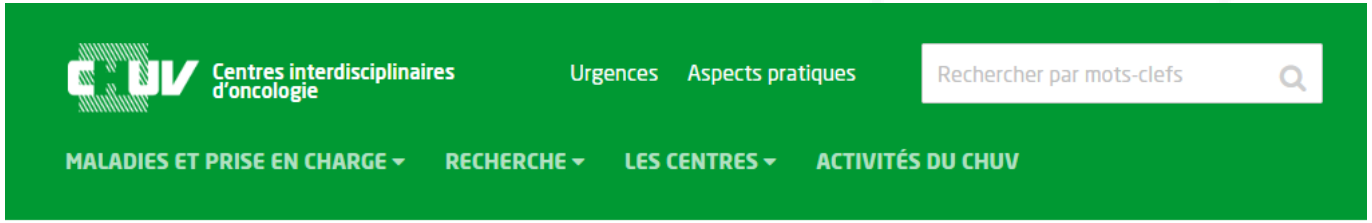
5. Did you receive enough training and/or support to fulfil your role?

Yes	Sometimes	No	Not sure

PUBLIC CONTRIBUTION VIA MEDIA COVERAGE

At the start of the study (or later when results are published)

1. At the institution level (colleagues are also your public)



Réduire les soins inappropriés à l'hôpital: le défi du projet LUCID

Publié le 08 juin 2022

Le projet LUCID analysera les données des soins hospitaliers et les avis des patient·e·s pour identifier, évaluer et réduire les soins inappropriés et la surmédicalisation. Il vient de recevoir deux importants financements et débutera en septembre.

Le projet LUCID - *Low valUe of Care in medical hospitalized patients, a national Data stream* - vient de recevoir deux importants financements pour les trois prochaines années. **Mis sur pied par la Dre Marie Méan,** médecin cadre et chercheuse clinicienne au Service de médecine interne et par **Dr Guillaume Obozinski**, chercheur au Swiss Data Science Center (SDSC) à l'EPFL, LUCID analysera les **données des soins hospitaliers** ainsi que les **avis des patients** pour **identifier, mesurer, évaluer et réduire les soins inappropriés et la surmédicalisation**. LUCID profitera ainsi autant au système de santé qu'aux patients. Son slogan, « *Less care for better care* » fait écho à la campagne « *Plus n'est pas toujours plus. Décidons ensemble* » de l'association Smarter medicine.

PUBLIC CONTRIBUTION VIA MEDIA COVERAGE

At the start of the study (or later when results are published)

2. Using media coverage for **Public** information

Media coverage

SUISSE

Publié 25 août 2022, 22:43

Ils veulent traquer les soins inutiles prescrits aux patients

Le CHUV et l'EPFL vont se pencher sur la surmédicalisation. L'étude vise à faire réagir prescripteurs de médicaments et patients.

par
Lauren von Beust

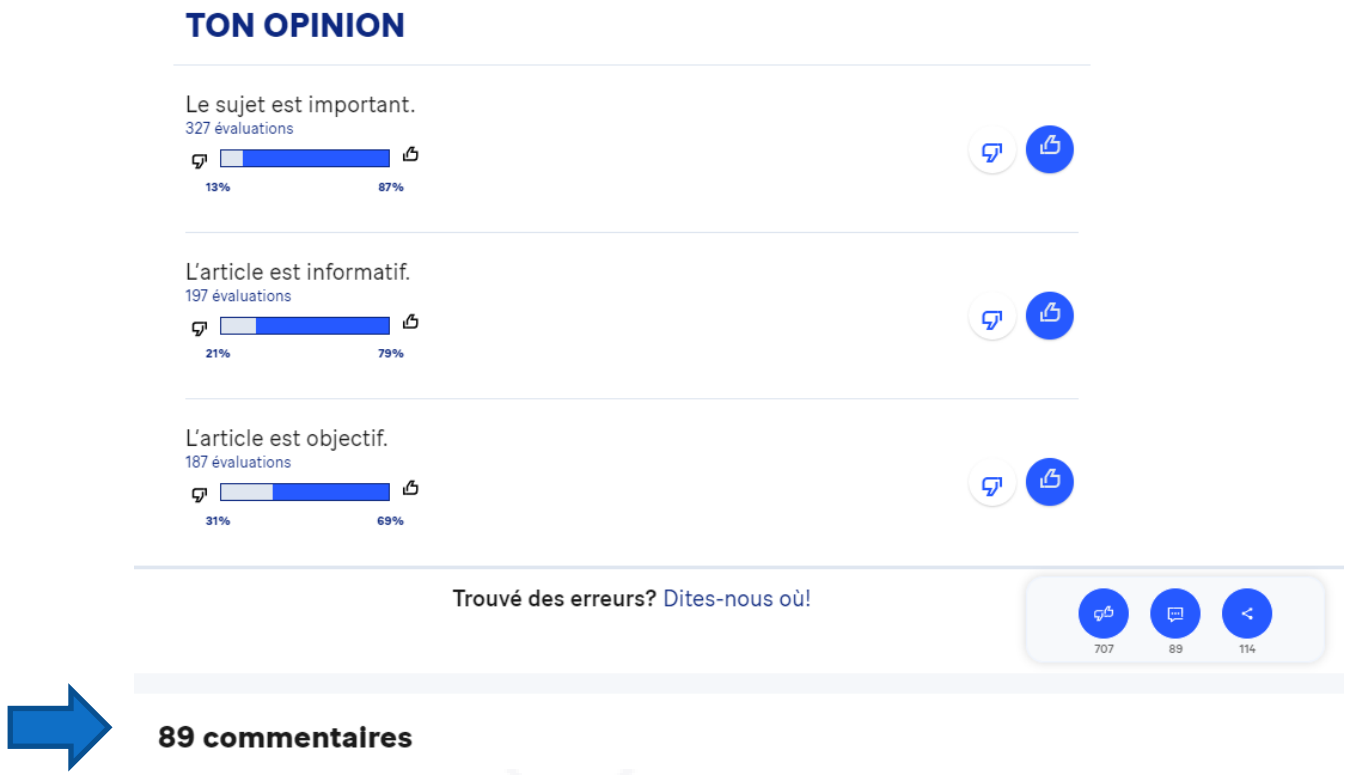
707 89 114

PUBLIC CONTRIBUTION

Media coverage

Take advantage of media coverage (plan it !)

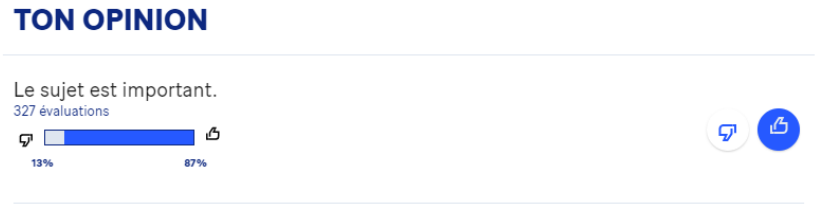
Use public **comments**, likes or feedbacks for PPI reporting

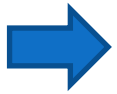


PUBLIC CONTRIBUTION

Use public **comments**, likes or feedbacks for PPI reporting

Media coverage





Remuneration: Recognize the value of lived experience

PPI contributors have the right to be compensated for their expertise and work time.

They also have the right to decline compensation. Working as a volunteer does not impact their ability to become involved.

Travel costs should be reimbursed.

SCTO Remuneration Policy for PPI activities

What is important when putting PPI into practice?

- **PPI is about partnership, not tokenism**
  - Involve PPI contributors early, not after decisions are made
  - Give them the possibility to have a real influence on priorities, design, interpretation, …
  - Recognize lived experience as expertise
- **Clarity is essential**
  - Precise why PPI contributors are involved and how they can influence the study
- **Support and training make a big difference**
- **Communication** must be accessible and ongoing throughout the study

Take home messages

- PPI takes time! **Anticipate** to fit in the 4 months schedule proposed in the IICT call calendar
- Start PPI recruitment early
- Do not set unachievable objectives, plan actions according to available resources and competencies
- Involve other persons/structures (e.g CTU) to help you set up PPI actions
- **Fully involve PPI contributors and take their opinions into account**

marie.mean@chuv.ch
cindy.allenbach@chuv.ch