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SCTO Remuneration Policy for Patient and Public Involvement (PPI) Activities

1 Introduction

The Swiss Clinical Trial Organisation (SCTO) and its Clinical Trial Unit (CTU) Network (hereafter referred to together as "SCTO") are strongly committed to ensuring that clinical research is patient relevant. This patient relevance is anchored in the SCTO's vision and mission statements, and many of the SCTO's past activities reflect this commitment.

In the 2021–2024 performance period, great emphasis will be placed on implementing patient and public involvement (PPI) in academic clinical research as one of the SCTO's key strategic goals (see the PPI section of the SCTO's website).

2 Objective and scope

This policy outlines the SCTO's framework for reimbursing and compensating patients and members of the public when they are involved in the network's activities as PPI contributors.

With regard to clinical trials, it is the responsibility of each sponsor/investigator to plan for and allocate a budget for PPI activities. This policy is meant to give advice and recommendations on what to consider when calculating a PPI budget.

Please note that the compensation of research study participants is a separate matter and is ***not*** within the scope of this document.

3 Definition of terms

3.1 Patient and public involvement (PPI)

Patient and public involvement (PPI) in academic clinical research is defined as research carried out with or by patients and members of the public rather than to, about, or for them.[1] This means that patients and members of the public become actively involved in shaping the goals, design, evaluation, dissemination strategies, and implementation of research projects by sharing their specific experience with a disease. For more information, please refer to the SCTO's PPI Fact Sheet.[2]

3.2 Patient

In this policy, the term "patient" is used as defined by the European Patients' Academy on Therapeutic Innovation (EUPATI):[3]

- "Individual patients" are persons with a personal experience of living with a disease. They may or may not have technical knowledge of R&D or regulatory processes, but their main role is to contribute to research with their subjective disease and treatment experience.
- "Carers" ("caregivers") are persons supporting individual patients, such as family members as well as paid or volunteer helpers.
- "Patient advocates" are persons who have insight and experience into supporting a larger population of patients living with a specific disease. They may or may not be affiliated with an organisation.
- "Patient organisation representatives" are persons who are mandated to represent and express the collective views of a patient organisation on a specific issue or disease area.
- "Patient experts" have, in addition to disease-specific expertise, technical knowledge of R&D and/or regulatory affairs through training or experience, for example EUPATI Fellows who have been trained by EUPATI on the full spectrum of medicines R&D.

3.3 PPI contributor

A PPI contributor is defined as a person who performs PPI, for example a patient, patient representative, caregiver, patient expert, or patient advocate.

3.4 Reimbursement

Reimbursement is defined as money paid for out-of-pocket expenses in connection with travel and accommodation (including meals).

3.5 Compensation

In general, compensation is defined as money paid for all activities within the framework of PPI (see Table 1 in Section 5.2 for an overview).

There is also the possibility of non-monetary compensation, for example for children or adolescents in paediatric studies. Non-monetary compensation might include gift vouchers or participation in courses, training, or conferences.

3.6 Contracting body

A contracting body is defined as the person or entity that requests PPI activities, for example the SCTO Executive Office, a single CTU, or the sponsor/investigator of a clinical trial.

[1] INVOLVE (2012). Briefing notes for researchers: Involving the public in NHS, public health and social care research. https://www.invo.org.uk/resource-centre/resource-for-researchers/, accessed 3 Oct. 2020.
[2] https://www.scto.ch/de/publications/fact-sheets.html
[3] https://toolbox.eupati.eu/resources/guidance-for-patient-involvement-in-industry-led-medicines-rd/

4 General principles

Remuneration for cooperation with and involvement in the SCTO's activities should reflect the time and contributions of all partners, including patients and members of the public. The SCTO is committed to fair financial compensation informed by the principles of equity. This demonstrates that contributions patients, caregivers, and patient/caregiver organisations make to the SCTO's activities – including the related commitments of time and effort – are valuable and appreciated.

If a patient or member of the public is employed by an organisation, for example a patient organisation, and this organisation delegates a PPI activity to the representative as part of his or her salaried duties, the person himself or herself does not receive any compensation except for the reimbursement of expenses (see Section 5.1). It is up to each individual organisation to decide whether or not to request compensation.

5 Reimbursement and compensation

5.1 Reimbursement

As a general rule, the SCTO reimburses travel and accommodation costs to PPI contributors as follows:

- tickets for second class train travel and other methods of public transportation within Switzerland and Europe
- flight tickets in economy class within Europe
- travel by private car within Switzerland, subject to prior approval (CHF 0.70 per km)
- taxi fare in exceptional cases, subject to prior approval
- three- or four-star hotel accommodation and meal expenses.

To be eligible for reimbursement, travel tickets, receipts for additional expenses, and hotel invoices must be submitted to the contracting body.

5.2 Compensation

PPI contributors have the right to be compensated for their experience, work time, and expertise. However, they also have the right to decline compensation and should know that working as a volunteer does not impact their ability to become involved.

To be eligible for compensation, a **written agreement** needs to be in place that defines the amount and level of PPI activities prior to the start of any project, initiative, or study (see also Section 6 "Procedural aspects"). The contracting body is responsible for initiating the written agreement process.

5.3 SCTO's blended model

Due to the various possibilities of PPI and in order to ensure flexibility, the SCTO recommends a **blended compensation model** and bases its compensation policy on the following two criteria:

1. compensation according to the level of engagement
2. compensation according to skills and competencies.

In general, the financial compensation of patients and members of the public who are involved in a research project or activity should reflect the level of expertise, commitment, and responsibility needed as well as the type of work involved. Fair compensation typically goes beyond partners' reasonable out-of-pocket expenses (see Section 5.1 "Reimbursement" above) and reflects their role in a research project or activity.

As a general rule, only the **active** hours of a PPI activity should be counted and compensated. Time spent travelling or staying overnight is not counted. Time spent preparing for the actual PPI activity will be credited but requires prior agreement by both parties on the estimated amount of time.

Compensation budgeting procedure for the contracting body:

1. Specify the level of involvement (according to Table 1).

2. Identify all skills and competencies needed and classify them as low, intermediate, or high (according to Table 2).
3. Define an hourly rate for the activity based on the principle that as the level of involvement and skills/competencies needed increases, the hourly rate increases as well.
4. Estimate the amount of time needed.
5. Calculate the budget for PPI compensation.

The SCTO's Executive Office can offer advice regarding remuneration and provide specific examples upon request (please contact: c.landgraf@scto.ch).

Table 1 Overview of examples of PPI activities categorised into four levels of involvement

Level of involvement	Description of PPI contribution *(not an exhaustive list)*
1 **Information:** Provide information	- Describe how patients live with a specific disease - Explain what patients expect from clinical research - Present at or contribute to a conference or event - Participate in a panel or discussion round at a conference or event
2 **Advice:** Respond to specific questions and provide general advice	- Identify research priorities - Provide input on what level of risk most patients would be willing to take - Give advice on endpoints that matter most to patients - Review study material (informed consent, protocol, etc.) - Provide input on articles for the SCTO's publication channels - Provide practical input on the conduct of a study - Participate in focus groups - Support recruitment strategies for a study
3 **Joint decision-making:** Contribute at a decision-making level	- Assist with the interpretation of study results - Write or review articles for the SCTO's publication channels or journals - Co-author publications of study results in lay language - Evaluate applications for grants - Become a member of an advisory board or committee
4 **Leadership** Take over or lead specific parts of an initiative or a project	- Lead a subgroup as a project manager - Chair an advisory board or committee

Depending on the type of involvement, different **skills and expertise** may be required. According to EUPATI (Geissler, Bereczky, Dierks, Schumacher-Wulf, Schmitt, Claussen, 2019/2020, unpublished; see Table 2), a distinction can be made between:

- medical expertise
- systems expertise
- methodological expertise
- personal framework.

Table 2 PPI skill/competency categories with definitions and ranking (1=low, 2=intermediate, 3=high).

Skills and competencies		Definition	1=Low	2=Intermediate	3=High
Medical expertise	**Basic medical expertise**	Medical, anatomic, and physiological expertise; knowledge of medicines research and development processes	Basic medical expertise (anatomy, physiology, use of treatments)	Extended medical expertise (medicines development, medical methodology)	In-depth medical knowledge of all aspects
	Indication-specific expertise	Knowledge of an indication/disease, its treatments, care, and the life circumstances of those living with it	Basic indication, treatment, and care expertise	Extended indication, treatment, and care expertise	In-depth indication, treatment, and care expertise incl. latest research results and treatment expertise
Systems expertise	**Regulatory expertise**	Knowledge of regulatory processes, e.g. evaluation, authorisation, and reimbursement processes of therapies	Basic knowledge of the medicines approval process, related assessments, and reimbursement procedures	Extended knowledge of the medicines approval process, related assessments, and reimbursement procedures	In-depth knowledge of the medicines approval process, related assessments, and reimbursement procedures
	Public health expertise	Knowledge of access and participation in the healthcare system (e.g. social law), knowledge of health policy	Basic knowledge of accessing and participating in the healthcare system	Extended knowledge of accessing and participating in the healthcare system; basic knowledge of health policy	In-depth knowledge of accessing and participating in the healthcare system and the underlying health policy
Methodological expertise	**Communication and representation**	Well-structured and solution-oriented communication skills (including digital and social media) and expertise on advocating appropriately for a patient community	Objective communication and appropriate conduct	Clear and focused communication with a sound and consistent opinion	High-level skills in communication, moderation, and group interaction

	Negotiation skills and political interaction	Expertise in political interaction and negotiation skills	No specific expertise in political interaction	Personal integrity and good negotiating skills	Sensible policy interaction and communication, strong negotiation skills, and consistent positions
Personal framework	**Transparency and integrity**	Transparency = declaration of interests; integrity = personal ethical integrity between financial aspects and advocacy activities	No transparency required	Declaration of interests in the context of a specific activity	Complete declaration of all interests, irrespective of whether or not they are related to a specific activity
	Personal experience	Indication-specific expertise based on personal experience	Empathic relation to those affected	Affected indirectly (e.g. family member)	Directly affected by a condition
	Community insight and involvement	Involvement in the patient and caregiver community in a specific indication area; ability to abstract from personal experience to represent a wider community	Direct interaction with other people living with a specific disease	Broad insights of different needs of a specific patient community and its subpopulations; frequent interaction with different community members	Structured approach to processes and decision-making when interacting with people across a specific community; ability to represent a community
	Capability to perform a specific task	Financial means or support that enables one to perform a specific role; availability to perform specific tasks; sufficient physical fitness	Ability to engage in a specific task within a strict time and effort limit	Ability to engage in continual, recurrent interaction	Ability to carry out more complex, long-term tasks requiring considerable commitment (in terms of effort, time, and health)

Source: EUPATI (Geissler, Bereczky, Dierks, Schumacher-Wulf, Schmitt, Claussen, 2019/2020, unpublished)

6 Procedural aspects

Prior to starting a PPI activity, the contracting body needs to identify the level of involvement, an estimation of the time needed, and the related compensation. A written agreement between the contracting body and a PPI contributor defines all aspects of the cooperation. In particular, certain key conditions – such as the overall aim of the contribution, mutual confidentiality, and a declaration of conflicts of interest – have to be addressed in the agreement. Depending on the activity/interaction, this does not necessarily need to be in the form of a formal agreement; however, it should at least be a written statement in the form of an e-mail.

7 Annex

An internal template with instructions on how to implement this policy is in the process of being drafted.