swiss medical weekly

ORIGINAL ARTICLE
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Supporting patient and public involvement and engagement in research through Swiss Clinical Trial Units: a national mixed-methods study

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Published
30 October 2026

doi
https://doi.org/10.57187/5152

Cite this as
Swiss Med Wkly. 2026;156:5152

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Summary

STUDY AIMS: The clinical research landscape is shifting towards broader Patient and Public Involvement and Engagement (PPIE) in Switzerland and abroad. Clinical Trial Units (CTU) provide methodological and logistical support for the conduct of clinical studies in academic institutions. However, their role with respect to PPIE remains undocumented. This study aims to describe current knowledge, experience, training and practices related to PPIE support among Swiss CTU staff.

METHODS: We conducted a mixed-methods study across nine CTUs (Basel, Bern, Geneva, Lausanne, Lugano, St Gallen, Zürich, ETH Zürich and Lucerne) between April and July 2025, combining a survey and semi-structured interviews. The survey was distributed to all CTU staff regardless of their involvement in PPIE, via email. Semi-structured interviews were held online with staff involved in PPIE support from each CTU. The survey explored involvement in PPIE support and self-reported knowledge, experience, training and confidence in advising researchers, frequency and type of support provided, perceived adequacy between support provided and expectations of researchers, and training needs. Interviews further explored organisational integration, concepts, and barriers and enablers. Descriptive analyses report counts, and percentages calculated excluding missing responses; denominators may vary between analyses.

RESULTS: Among 225 contacted staff members, 139/225 (61.8%) responded. Fifty-six respondents (40.3%) reported some involvement in PPIE support, of whom 18/56 (32.1%) reported that this was part of their formal CTU role, while 38/56 (67.9%) reported providing informal support. Only 20/53 (37.7%) reported having received PPIE training, while 27/53 (50.9%) reported interest in receiving it. Although 24/55 (43.6%) reported good to expert knowledge of PPIE and 34/55 (61.8%) considered themselves familiar with PPIE, 33/55 (60.0%) reported limited or no practical experience, and 42/55 (74.4%) were only slightly or not confident at all in advising researchers. The proportion of CTU-supported projects including PPIE ranged from 0% to 10%. Interviews showed that PPIE support emerged recently through institutional incentives and staff-led initiatives and remains largely informal. While its importance was widely recognised, uncertainties regarding its purpose and impact persist.

CONCLUSIONS: This study highlights PPIE support as an emerging practice within CTUs highly dependent on a few individuals and structural constraints within institutions. Growing demands in PPIE call for clarification of roles and clear institutional support for the development of realistic, flexible approaches grounded in critical reflection rather than blind enthusiasm.

Introduction

Over the past two decades, Patient and Public Involvement and Engagement (PPIE) has gained increasing attention in clinical research. Described as research carried out *with* or *by* patients rather than *about* or *for* them [1], PPIE represents a major change in how research is conceived and con-

ducted. Patients are no longer regarded solely as research participants but as collaborators whose experiential knowledge can enrich study design, strengthen feasibility and ensure that research outcomes reflect the priorities of those most directly affected [2-6].

This recognition is gradually reshaping international standards. For example, in 2023, the World Health Organization published a "Framework for Meaningful Engagement" [7], the 2024 revision of the International Council for Harmonisation's Good Clinical Practice (ICH E6) guidelines now explicitly references PPIE [8], and the revision of the Declaration of Helsinki reinforced the ethical imperative of involving patients and communities throughout research [9]. In 2025, major reporting guidelines implemented PPIE requirements [10, 11]. At the same time, national research organisations and funding agencies are increasingly encouraging, and in some cases requiring, the integration of PPIE into research funding applications.

In Switzerland, PPIE has only recently gained momentum, largely driven by the Swiss National Science Foundation (SNSF) which, since 2018, has gradually integrated PPIE as a requirement in its Investigator-Initiated Clinical Trials (IICT) programme. In 2022, the SNSF introduced a dedicated grant to support PPIE activities during grant preparation, and in 2025 swissethics (https://swissethics.ch/en) revised its protocol templates to include a section requiring the description of PPIE plans.

Clinical Trial Units (CTU), established in 2007 within Swiss academic hospitals, provide methodological and operational support for clinical research and researchers are strongly encouraged to collaborate with a CTU or equivalent infrastructure. Yet the role of CTUs in supporting PPIE remains undocumented.

This study aimed to describe current knowledge, experience, training, practices and perceived needs related to PPIE support among staff working in Swiss CTUs, and to explore how PPIE support is organised and implemented within these structures.

Materials and methods

Study design

This SPIRIT project includes three parts exploring the state of PPIE in research. Part 1 focuses on CTU staff, part 2 on researcher's perspectives and part 3 on patients' views. The present article reports the results of SPIRIT part 1. We used a sequential mixed-methods design [12], in which quantitative data collection and analysis preceded and informed the qualitative component. The survey examined CTU staff's knowledge of, experience with, and training on PPIE, as well as actual practices and perceived needs. The qualitative component was developed based on the survey results and used to expand upon and provide depth of understanding of the survey findings, as well as to explore the organisational and operational context of PPIE support within CTUs.

The study team benefited from a grant from the Swiss Clinical Trial Organisation (SCTO, project number RoR2025_009) and the support of at least one CTU staff member from each CTU. It is reported according to the STROBE [13] and SRQR [14] guidelines.

Setting

The study was led by a team based at Geneva University Hospitals (HUG), which worked with the SPIRIT group composed of a CTU staff representative from each Swiss CTU. Meetings with the SPIRIT group were held online, three times during the implementation of the project. The group helped identify and provide access to the contact details of CTU staff, reviewed the protocol and the questionnaires and was kept informed throughout the project. The questionnaires were sent out from 16 April 2025 to 14 May 2025. The interviews were held from 25 June 2025 to 31 July 2025.

Participants

All staff members working in one of the nine participating Swiss CTUs (Basel, Bern, Geneva, Lausanne, Lugano, St Gallen, Zürich, ETH Zürich and Lucerne) were eligible (n = 289), regardless of their involvement in PPIE. Approaches to survey distribution differed across CTUs. While most CTUs shared staff contact details for direct emailing, Zürich and Bern preferred to implement an opt-in procedure to safeguard employees' personal rights and privacy. Participation was voluntary.

Ten CTU staff members from 8 CTUs, identified through a dedicated survey item, were interviewed between June and July 2025. Although all CTU staff were invited to participate in interviews, as participation was voluntary, respondents who agreed to be interviewed were predominantly PPIE leads or their close collaborators.

Variables

The variables collected in the survey included: involvement in PPIE support (formal or informal), and self-reported knowledge, experience, training and confidence in advising researchers on PPIE. Questions on knowledge explored the staff's general understanding regarding PPIE. Questions on experience explored the staff's individual practical experience with PPIE in research. Questions on training examined the type of training followed by CTU staff.

Further variables included the actual practices in the CTU, including the frequency of PPIE support demand and type of support provided to researchers, the perceived adequacy between the support provided and the researchers' expectations, and the perceived needs including training needs as well as the barriers and facilitators to PPIE implementation. For the qualitative component, outcomes consisted of themes related to the organisational integration of PPIE, conceptual understandings, barriers and enablers, and emerging challenges.

Data sources and measurements

A self-administered questionnaire was developed on REDCap software and hosted on secure institutional servers at HUG. The questionnaire was informed by existing literature on PPIE and the study objectives, and designed to capture key dimensions of PPIE support within CTUs. Although no formal validation was attempted, the questionnaire was pilot-tested by three CTU staff members (one each in Basel, Geneva, Zürich) to assess clarity, relevance and feasibility, after which minor adjustments were made accordingly. The final questionnaire included both closed and open-ended questions (file 1 of the appendix) covering: (1) respondent role and involvement in CTU activities, (2) involvement in PPIE support, (3) knowledge, experience and confidence in advising on PPIE, (4) support provided (practices), training and training needs, and (5) perceived barriers, facilitators and institutional needs related to PPIE implementation. The survey took approximately 10 minutes to complete.

The interview guide (file 2 of the appendix) was developed iteratively, informed by the survey results and covered: origins and implementation; current support provided by CTUs; views on training; views on PPIE; assessment of the participatory process; challenges; enablers and successes; and future perspectives, complemented by inductively emerging themes. One topic, tokenism [16], was introduced from the literature. The guide addressed the types of support offered, availability of internal resources (e.g. time, funding, staff), perceived institutional barriers, and examples of good practice. Interviews were conducted online via Microsoft Teams. For the Bern Department of Clinical Research (DCR), where scheduling was not possible, the interview guide was completed in writing and returned by email. Interviews were held in English or French, recorded with the consent of participants, and transcribed verbatim. Each lasted 60–70 minutes. Transcripts were stored securely on institutional servers. Relevant parts of transcripts were extracted.

Eight CTUs provided additional information on the number of CTU-supported projects and the share involving PPIE in 2023–2024, the year their PPIE activities began, the number of staff dedicated to PPIE, and the existence of patient databases or remuneration model.

Researcher reflexivity and bias

Two interviewers (MA and NE) contributed to data collection and analysis. The senior author (NE) is also an active PPIE actor at HUG (though not CTU staff) and may have influenced the interview of the Geneva staff. To mitigate this, the team held regular discussions to reflect on potential biases and ensure analytical rigour. The study was funded by the SCTO, a central coordinating body for CTUs in Switzerland. The SCTO had no role in the study design, data collection, analysis, interpretation of the data, or writing of the manuscript.

Study size

No estimation of required sample size was made, as this was a descriptive study with no aim to draw inferences or test hypotheses; we aimed to exhaustively contact all CTU staff members in Switzerland.

Quantitative data

Several questionnaire variables were recoded into broader analytical categories to improve interpretability and ensure sufficient subgroup sizes for comparison. These recategorisations concerned age, professional role, years of experience, familiarity with PPIE, knowledge and experience with PPIE, training, confidence in advising researchers, and frequency of PPIE support requests. Detailed recoding procedures are provided in table S1.1 in the appendix.

Data analysis

Quantitative survey data were analysed using Stata 18 (StataCorp, College Station, TX, USA). Analyses were descriptive. Counts and proportions are reported overall and stratified by CTU, distinguishing respondents with or without a PPIE support role. Missing data were reported for each item and not accounted for in the percentage calculation. Open-ended responses were categorised when enough responses were available.

Qualitative data were analysed thematically following Braun and Clarke's approach [17, 18], without the use of dedicated qualitative data analysis software. This approach was chosen for its flexibility and suitability for identifying and reporting patterns across a heterogeneous dataset, in line with the descriptive and exploratory aims of the study. Interviews were conducted across 8 CTUs to capture the diversity of organisational contexts and approaches to PPIE support in Switzerland. Although recurring themes emerged, each interview contributed distinct perspectives and experiences. In addition, given the very small pool of PPIE-engaged staff in Switzerland, achieving thematic saturation was not feasible. Analysis followed the interview guide. The lead author read all transcripts multiple times and conducted an initial coding round to identify subthemes and illustrative verbatim quotes. A second round refined and consolidated subthemes across interviews. All codes and subthemes were reviewed by the senior author. The final synthesis grouped themes into four clusters: (1) organisational integration, (2) concepts, (3) barriers and enablers, and (4) emerging themes. Prevalent subthemes per cluster were selected for results presentation, supported by representative verbatim quotes. In addition, examples of original or repeatedly observed situations and practices were summarised.

Ethics approval

Upon request, swissethics confirmed that the study fell outside the scope of the Swiss Human Research Act [15] and therefore did not require their formal ethics approval (req-2025-00682).

Open science statement

The study protocol is publicly available on the Open Science Framework (OSF) (https://osf.io/dpn45/overview) and describes the overall SPIRIT project, including the present study (Part 1). No major deviations from the protocol occurred.

Results

Participants

The survey was distributed to 225 of the 289 (77.9%) identified CTU staff members across 9 CTUs; 139 responded, yielding a response rate of 61.8%. Response rates ranged from 28% (Zürich) to 87% (St Gallen) (figure 1). Ten respondents agreed to be interviewed; all were subsequently interviewed.

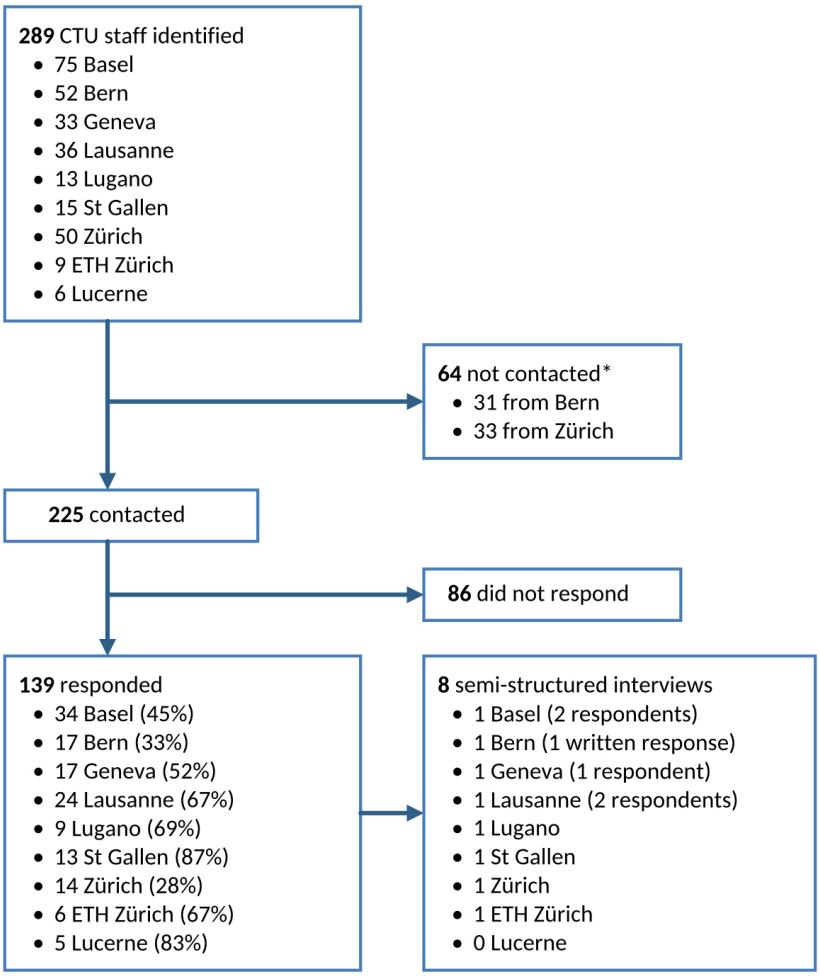


Figure 1: Flowchart. * 2 CTUs chose an opt-in procedure for confidentiality purposes. Abbreviations: CTU: clinical trial unit.

Descriptive data

Respondents were mostly women, aged 40 or older, with four or more years of CTU experience. Their expertise and primary roles (the role for which they were employed within the CTU) varied from methodology and statistics support to leadership and project management, reflecting the various profiles typically found in Swiss CTUs (table 1, appendix 3.1 and 3.2).

Table 1: Respondent characteristics. Percentages exclude missing data.

Respondent characteristics		All respondents, n = 139	PPIE-active staff, n = 56
Sex	Man	36 (27.5%)	15 (27.8%)
	Woman	83 (63.4%)	34 (63.0%)
	Prefer not to say	12 (9.2%)	5 (9.3%)
	Missing data	8	2
Age	Under 30	4 (3.3%)	0
	30–39	32 (26.2%)	13 (26.0%)
	40+	86 (70.5%)	37 (74.0%)
	Missing data	17	6
Experience within a CTU	<4 years	45 (32.4%)	15 (26.8%)
	≥4 years	94 (67.6%)	41 (73.2%)
Primary role	CTU director & project management	36 (26.7%)	21 (38.2%)
	Methodology, Statistics	37 (27.4%)	13 (23.6%)
	Clinical operations	22 (16.3%)	7 (12.7%)
	Regulatory, Quality & Safety	15 (11.1%)	2 (3.6%)
	Education/Teaching	6 (4.4%)	1 (1.8%)
	PPIE	3 (2.2%)	3 (5.5%)
	Support roles & other	16 (11.9%)	8 (14.5%)
	Missing data	4	1

CTU: Clinical Trial Unit; PPIE: Patient and Public Involvement and Engagement.

Main results

Fifty-six of the 139 respondents (40%) declared playing a role in PPIE support (formal or informal), of whom 3 (one each in Bern, Basel and Zürich) reported having PPIE as their primary role in the CTU. Twelve named PPIE as one of their domains of expertise (appendix 3.1). One quarter of CTU staff indicated having received training in PPIE (table 2, figure 2, appendix 3.3). Their training sources included internal CTU trainings (n = 7), a hospital-based course offered by Lausanne University Hospital (CHUV) and HUG (n = 7), SCTO online initiatives (n = 6), other online modules (n = 5), EUPATI courses (n = 4) and online trainings organised by the SNSF (n = 3). One respondent did not specify their training source.

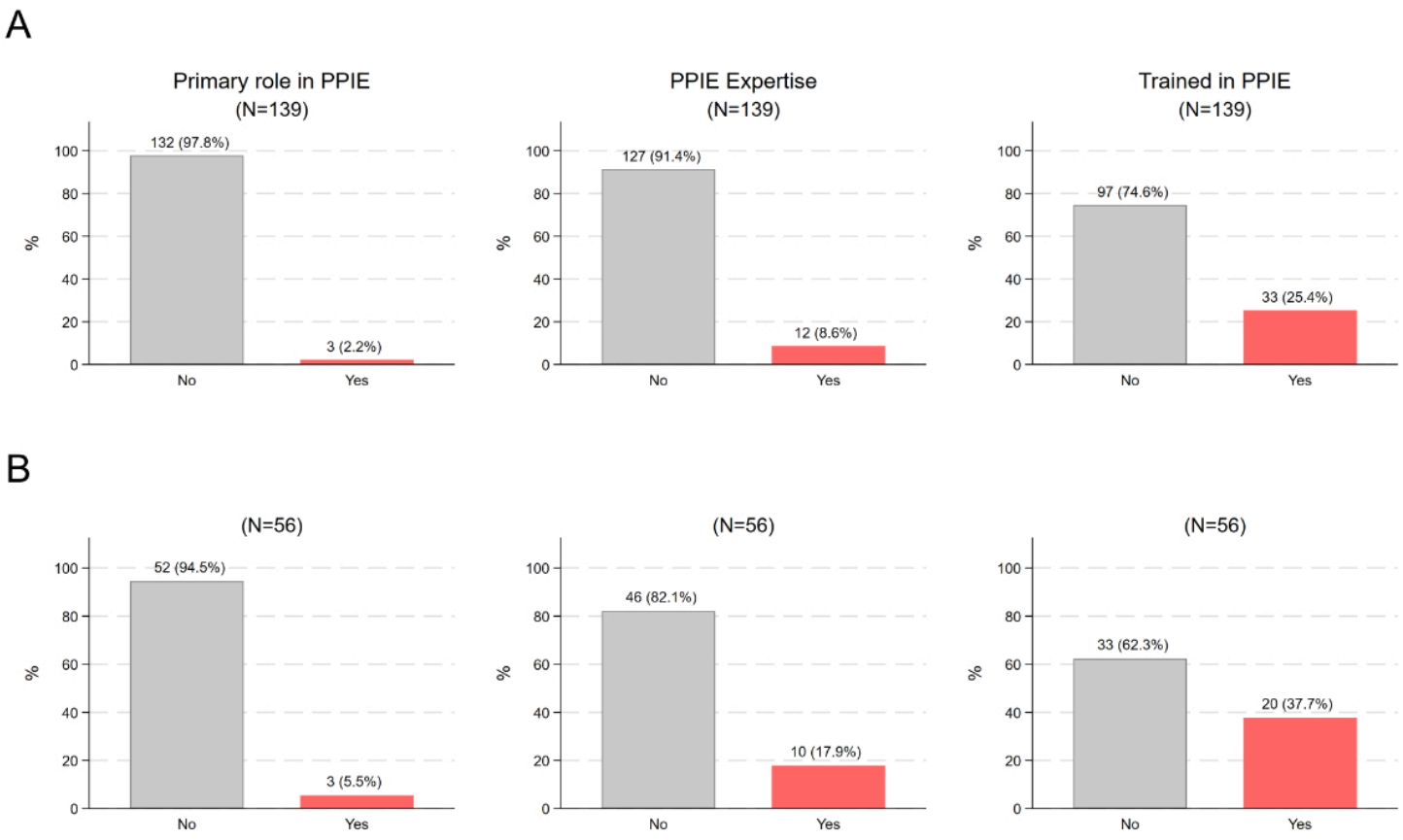


Figure 2: CTU staff and PPIE. A: All CTU staff; B: Staff involved in PPIE support; CTU: Clinical Trial Unit; PPIE: Patient and Public Involvement and Engagement; Primary role: main function for which the respondent is employed within the CTU; PPIE expertise: self-reported, reflects whether respondents consider PPIE to be one of their domains of expertise; Trained in PPIE: any formal or informal training reported by respondents (e.g. courses, workshops or online modules).

Detailed results, by CTU, are provided in table 2.

Table 2: PPIE support within CTUs: an overview. Percentages exclude missing data.

PPIE support		Basel	Bern	Geneva	Lausanne	Lugano	St Gallen	Zürich	ETH Zürich	Lucerne	Total
		n = 34	**n = 17**	**n = 17**	**n = 24**	**n = 9**	**n = 13**	**n = 14**	**n = 6**	**n = 5**	**n = 139**
Primary role in PPIE	No	32 (97.0%)	15 (93.8%)	17 (100.0%)	23 (100.0%)	9 (100.0%)	13 (100.0%)	12 (92.3%)	6 (100.0%)	5 (100.0%)	132 (97.8%)
	Yes	1 (3.0%)	1 (6.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (7.7%)	0 (0.0%)	0 (0.0%)	3 (2.2%)
	Missing data	*1*	*1*	*0*	*1*	*0*	*0*	*1*	*0*	*0*	*4*
Advisory role on PPIE	Yes, formal role	4 (12.5%)	3 (17.6%)	2 (11.8%)	4 (18.2%)	1 (11.1%)	1 (7.7%)	3 (21.4%)	0 (0.0%)	0 (0.0%)	18 (13.3%)
	Yes, informal help	12 (37.5%)	2 (11.8%)	4 (23.5%)	6 (27.3%)	2 (22.2%)	2 (15.4%)	4 (28.6%)	3 (50.0%)	3 (60.0%)	38 (28.1%)
	No involvement	16 (50.0%)	12 (70.6%)	11 (64.7%)	12 (54.5%)	6 (66.7%)	10 (76.9%)	7 (50.0%)	3 (50.0%)	2 (40.0%)	79 (58.5%)
	Missing data	*2*	*0*	*0*	*2*	*0*	*0*	*0*	*0*	*0*	*4*
Self-reported PPIE expertise	No	32 (94.1%)	15 (88.2%)	16 (94.1%)	20 (83.3%)	9 (100.0%)	13 (100.0%)	12 (85.7%)	5 (83.3%)	5 (100.0%)	127 (91.4%)
	Yes	2 (5.9%)	2 (11.8%)	1 (5.9%)	4 (16.7%)	0 (0.0%)	0 (0.0%)	2 (14.3%)	1 (16.7%)	0 (0.0%)	12 (8.6%)
Trained in PPIE	No	25 (83.3%)	13 (76.5%)	13 (86.7%)	15 (68.2%)	8 (88.9%)	11 (84.6%)	5 (35.7%)	5 (83.3%)	2 (50.0%)	97 (74.6%)
	Yes	5 (16.7%)	4 (23.5%)	2 (13.3%)	7 (31.8%)	1 (11.1%)	2 (15.4%)	9 (64.3%)	1 (16.7%)	2 (50.0%)	33 (25.4%)
	Missing data	*4*	*0*	*2*	*2*	*0*	*0*	*0*	*0*	*1*	*9*
PPIE support request frequency (n = 56)	At least once a week	2 (12.5%)	2 (40.0%)	2 (33.3%)	3 (30.0%)	0 (0.0%)	0 (0.0%)	2 (28.6%)	0 (0.0%)	0 (0.0%)	11 (19.6%)
	Few/year or less	14 (87.5%)	3 (60.0%)	4 (66.7%)	7 (70.0%)	3 (100.0%)	3 (100.0%)	5 (71.4%)	3 (100.0%)	3 (100.0%)	45 (80.4%)

CTU: Clinical Trial Unit; PPIE: Patient and Public Involvement and Engagement; Primary role: main function for which the respondent is employed within the CTU; Advisory role on PPIE: providing support or advice to researchers on PPIE, either as part of a formal role or informally; PPIE expertise: self-reported, reflects whether respondents consider PPIE to be one of their domains of expertise; Trained in PPIE: any formal or informal training reported by respondents (e.g. courses, workshops or online modules).

Focus on 56 staff members providing PPIE support

Fifty-six participants reported being involved in PPIE support, whether this was part of their official role in the CTU (18; 32.1%) or not (38; 67.9%) (appendix 3.4, 3.5). Only 3 declared advising on PPIE at least once a week while 80.3% reported interacting with researchers only a few times per year or less (table 3, appendix 3.6).

When asked about their knowledge of PPIE, less than half reported having good knowledge. Two thirds reported having no or only limited experience with PPIE and less than one quarter reported being confident when advising researchers; 7 (12.7%) reported not being confident at all. The support provided to researchers included providing information on existing resources, budgeting and funding advice, and providing hands-on support for conducting PPIE activities (figure 3, appendix 3.7).

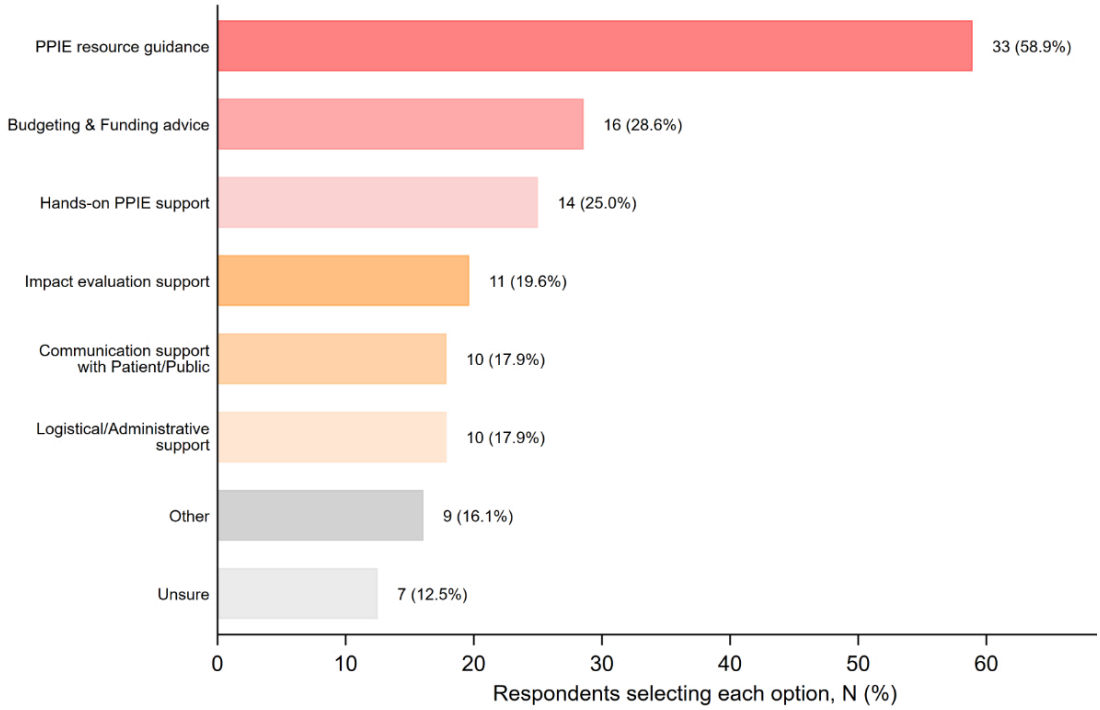


Figure 3: Types of PPIE support provided by CTUs. This figure reports on the 56 staff members involved in PPIE support. CTU: Clinical Trial Unit; PPIE: Patient and Public Involvement and Engagement.

One third of the 56 respondents involved in PPIE support reported having received specific training in PPIE; 51.0% wished to be trained. The 56 respondents involved in PPIE support did not think a specific training was necessary (table 3).

Table 3: Focus on CTU staff providing PPIE advising within CTUs (n = 56). Percentages exclude missing data.

CTU staff providing PPIE advising within CTUs		**n (%)**
Advisory role on PPIE	Formal role	18 (32.1%)
	Informal help	38 (67.9%)
PPIE support request frequency	Weekly+	3 (5.4%)
	Monthly+	8 (14.3%)
	Few/year	25 (44.6%)
	Rare/never	20 (35.7%)
Trained in PPIE	Yes	20 (37.7%)
	No, but would like to receive a training	27 (51.0%)
	No, and think it is not necessary	6 (11.3%)
	Missing data	*3*
Use of PPIE-related guidelines, frameworks or tools	Yes	22 (40.0%)
	No	28 (50.9%)
	Unsure	5 (9.1%)
	Missing data	*1*
Source of PPIE experience	Current position	40 (90.9%)
	Previous position	4 (9.1%)
	Missing data	*12*
Self-reported familiarity	No familiarity	0 (0%)
	Moderately familiar	21 (38.2%)
	Familiar	34 (61.8%)
	Missing data	*1*
Self-reported knowledge	No knowledge	3 (5.5%)
	Basic knowledge	28 (50.9%)
	Good to expert knowledge	24 (43.6%)
	Missing data	*1*
Self-reported experience	No experience	11 (20.0%)
	Limited experience	22 (40.0%)
	Moderate experience	22 (40.0%)
	Missing data	*1*
Self-reported confidence in advising	Not confident at all	7 (12.7%)
	Slightly confident	35 (63.6%)
	Confident	13 (23.6%)
	Missing data	*1*

CTU: Clinical Trial Unit; PPIE: Patient and Public Involvement and Engagement; Advisory role on PPIE: providing support or advice to researchers on PPIE, either formally or informally; PPIE support request frequency: how often respondents reported being contacted by researchers for PPIE-related support; Trained in PPIE: any formal or informal training reported by respondents (e.g. courses, workshops or online modules); Use of documentation: use of any guidelines, frameworks or tools to support PPIE activities; Position providing experience: whether respondents' experience with PPIE was acquired in their current or previous role; Self-reported familiarity, knowledge, experience and confidence: based on respondents' subjective assessment. Percentages are calculated on available data, excluding missing values.

The most frequently requested training topics are reported in figure 4.

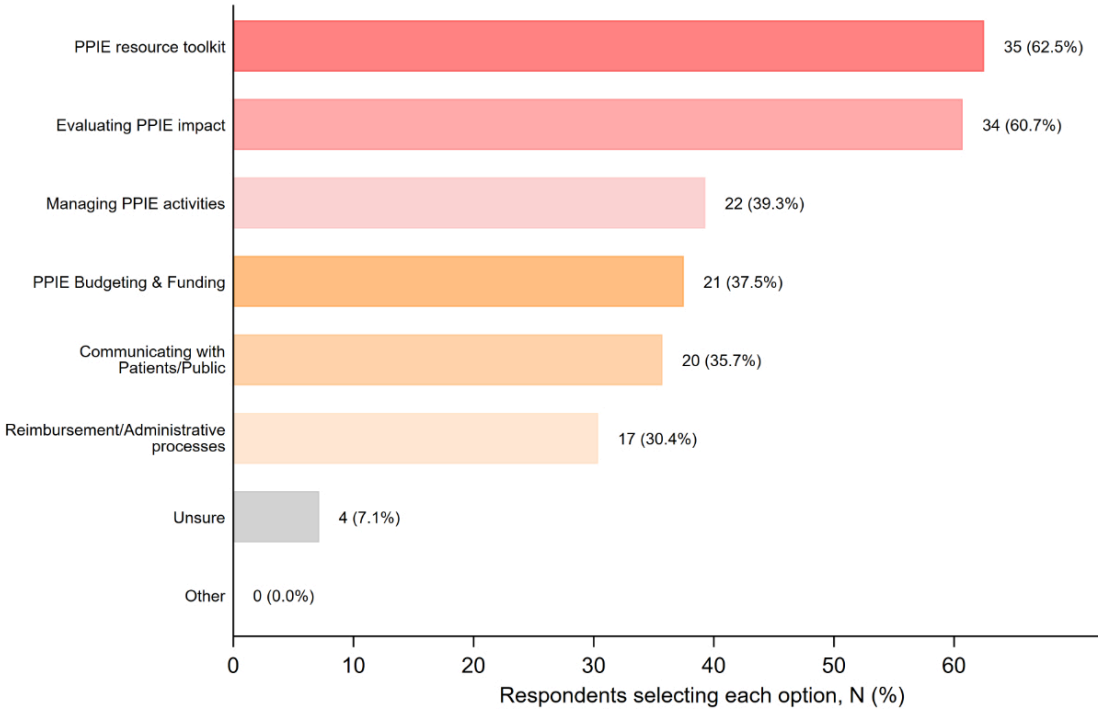


Figure 4: Training needs in PPIE. This figure reports on the 56 staff members involved in PPIE support. CTU: Clinical Trial Unit, PPIE: Patient and Public Involvement and Engagement. Responses reflect self-reported training needs. Multiple selections were allowed. Topics were derived from predefined questionnaire categories on PPIE-related training priorities.

Twenty-three of the staff invovled in PPIE support (48.9%) believed that the support offered met the researcher's needs. When asked about additional types of support that would be relevant to provide, respondents selected a broad and balanced range of options with no single option clearly standing out (appendix 1, Q18), and none being rejected or considered irrelevant. Notably, only 3 respondents reported that no additional support needed to be offered (appendix 3.8).

To improve PPIE integration into clinical research, respondents most frequently cited the need for institutional recognition, a dedicated budget, clearer policies and dedicated staff. The importance of a strong umbrella organisation was mentioned by 26.8% of respondents. Barriers identified included low researcher awareness, lack of dedicated resources and absence of an institutional policy or strategy for PPIE (figure 5).

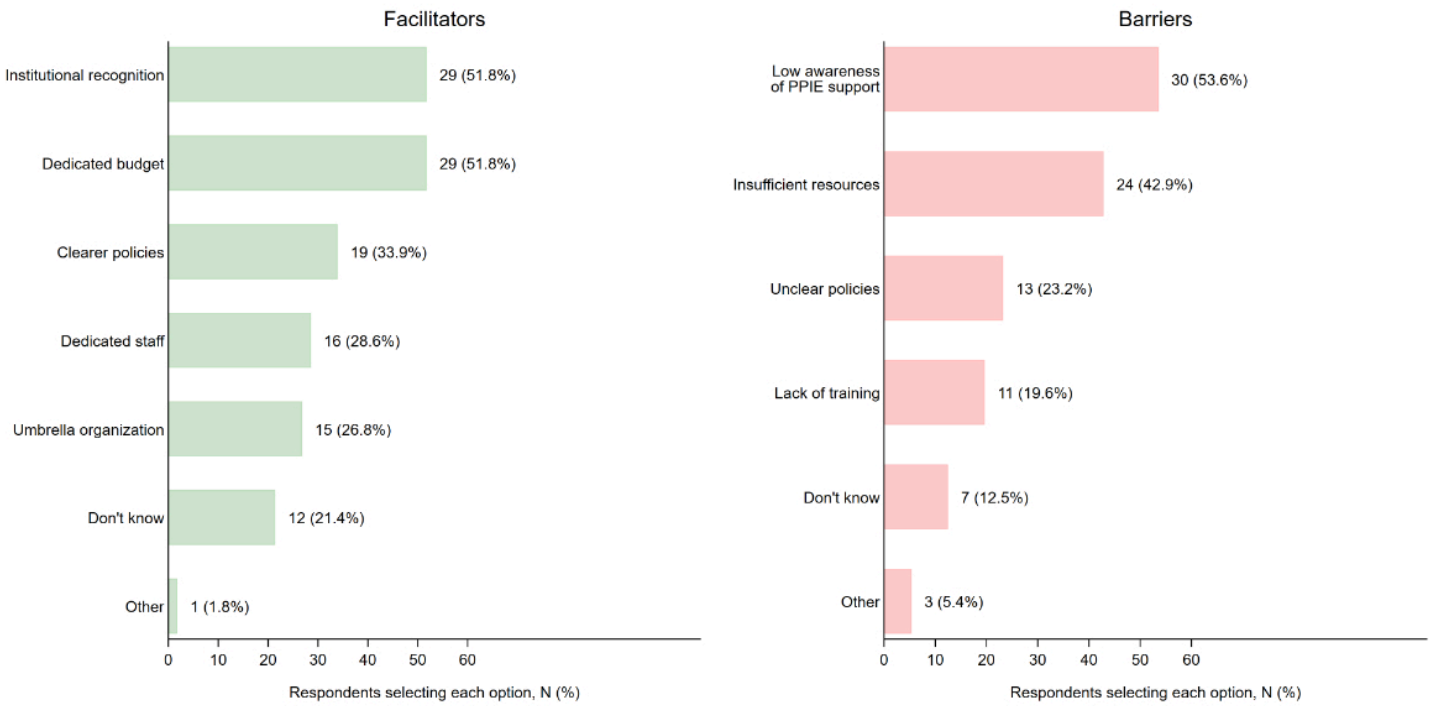


Figure 5: Facilitators and barriers to PPIE implementation in CTUs. This figure reports on the 56 staff members involved in PPIE support. CTU: Clinical Trial Unit, PPIE: Patient and Public Involvement and Engagement. Responses reflect self-reported training needs. Multiple selections were allowed. Topics were derived from predefined questionnaire categories on PPIE-related training priorities.

A detailed description of these results by CTU is available in file 3 of the appendix.

Qualitative study

Participants

In total, 10 staff members, 8 women and 2 men, from 8 CTUs provided qualitative insights; 9 were interviewed online and 1 provided a written response. The interviews were conducted with two representatives each for Lausanne and Basel CTUs. A selection of relevant verbatim transcripts is provided in file 4 of the appendix.

CTU characteristics

Table 4: An overview of the characteristics of the participating CTUs. The Lucerne CTU is not included as its PPIE activities started in 2025.

CTU	Number of CTU- supported projects involving PPIE / all projects		Start of PPIE activities	Dedicated staff	Patient database for PPIE	PPIE remuneration model
	2023	2024				
Basel	15/227 (6.6%)	27/267 (10.1%)	2020	1 role, part-time	Yes, expert patients only (not condition-specific)	Expert patients paid from project budgets (SCTO recommendations)
Bern	6/138 (4.3%)	8/109 (7.3%)	2023	2 roles, part-time (PPIE support outside of CTU, but with the same department of clinical research)	Yes, public representatives, including patients (not condition-specific)	Public representatives paid from project budgets (SCTO recommendations)
Geneva	12/404 (3.0%)	6/349 (1.7%)	(2018) *	External group financially supported by the hospital, no formal position within CTU	Yes, coordinated externally; different levels of expertise and engagement	Patients paid from project and institution budgets (internal remuneration policy)
Lausanne	5/206 (2.4%)	14/226 (6.2%)	2023	5 roles of which 3 employed by the CTU part-time; 1 project manager also 1 patient representative	Yes, different levels of expertise and engagement	Patients and staff paid from project budgets; internal remuneration policy
Lugano	0/133 (0.0%)	2/166 (1.2%)	2023	1 role, part-time	No; relies on patient associations	Patient associations paid from project budgets
St Gallen	0/119 (0.0%)	0/106 (0.0%)	NA	1 role, part-time	No	NA
Zürich	18/550 (3.3%)	12/617 (1.9%)	2020	1 role, part-time	Yes, different levels of expertise and engagement	Patients paid from project and institution budgets (internal remuneration policy)
ETH Zürich	1/15 (6.7%)	2/25 (8.0%)	2023	1 role, part-time; engaged in EUPATI and patient representative	No	No

CTU: Clinical Trial Unit; NA: Not Applicable; PPIE: Patient and Public Involvement and Engagement; SCTO: Swiss Clinical Trial Organisation. In Geneva, PPIE support was provided through the PartnerREC network rather than within the CTU. Synthesis of the qualitative analysis

Organisational integration

The implementation of PPIE across CTUs originates from both institutional directives and individual initiatives. Formal or informal impulses from CTU leadership, such as encouragement from directors, or external funder requirements, like the SNSF calls for IICT proposals, have initiated PPIE activities through a soft top-down approach. As one participant illustrated: *"The request came out of a discussion with (a director...). Researchers didn't really know what to do with this whole PPI concept. And naturally, it was directed toward us (...)."*

This institutional backing was often driven by motivated individuals whose personal commitment and expertise sustained and developed these initiatives. While such grassroots efforts (understood as actions emerging from individuals operating outside formal mandates) demonstrate important bottom-up energy, they expose PPIE activities to risks of discontinuity if not supported by institutional mandates or stable resource allocation. As another participant mentioned: *"If I'm away, I really don't know if it would continue."*

Over time, some CTUs have begun developing internal resources such as patient databases (table 5, first row). In parallel, other structures to support PPIE have emerged, including the SCTO working group on PPIE, independent initiatives like PartnerREC in Geneva or PatientsLab in Lausanne, and networks of patient organisations. Yet, substantial variability persists in how CTUs formalise their support, with some having established structures and others lacking direct activities altogether.

Table 5: Original practices reported across CTUs.

Patient databases	Implementation and content of patient databases varied across CTUs. Some databases include contributors without medical histories, leaving researchers responsible for condition-specific recruitment. One CTU invited patients and citizens to self-register via an online form, with no selection criteria. Other teams curate smaller lists of "research-expert patients", though there is no shared definition of "research-expert". Others rely on PPIE networks coordinated outside the CTU within institutions, outsource contact to patient associations or operate without any database at all.
Patient hiring	No CTU formally employs a patient as "patient-partner" in a dedicated PPIE role. In two exceptional cases, some staff combined professional expertise with lived experience; though recruited mainly for their professional qualifications, their partnership expertise may have influenced selection. One example involved a project manager who was a patient research-expert and was also active in a patient association. Another was a PPIE lead whose background as a patient was considered an asset, but not the decisive factor in the hiring decision.
Outsourcing patient perspectives	One CTU has no direct contact with patients and therefore outsources the collection of patient perspectives to patient associations. To do so, researchers develop questions regarding their study aims and design, which the associations, remunerated for their role, use to organise focus groups or interviews. The collected responses are then returned to the research team.
Matchmaking	To connect researchers and patients, one CTU organises "speed dating" style events. In these events, researchers present their projects in short sessions to different patient audiences, and patients get to listen to different research projects. Researchers receive immediate feedback from patients, and both can explore opportunities for collaboration.
The ambiguity of the patient expert	The contributions of patient partners range from sharing lived experience to co-leading research projects or shaping health policies. The Montreal Model classified these roles through different "levels of involvement" from consultation to genuine partnership [19]. Recent approaches have emphasised the recognition of *patient knowledge* as central to co-production, although *the knowledge of what exactly is needed* remains unclear. The status of patient expert remains debated by patients themselves. A Canadian survey of more than 600 patient partners [20] highlighted that for some, lived experience is sufficient to confer expertise, while others argue that additional training, skills or formal recognition are required. Some reject the label altogether, noting that their experience was not a chosen pursuit of knowledge but an imposed condition. In research, the meaning of patient expert is particularly ambiguous. For the EUPATI programme [21], it refers to patients trained in research methodology and regulatory processes, enabling them to act as informed interlocutors within clinical research teams. In contrast, Anglo-Saxon models often frame expertise less in terms of mastering research methodology but rather through skills such as communication, reflexivity or representation of diverse patient perspectives [22, 23].

Procedural challenges are frequent, particularly concerning remuneration models for patient partners, legal contracts and follow-up with researchers (table 5, second row).

Despite researchers receiving funding for PPIE activities, feedback loops to the CTU team are often lacking, limiting opportunities for continuous evaluation and improvement. *"Very often (…), once they [the researchers] have this PPI plan and receive the funding, we usually don't hear back from them."*

Concepts

Interviewees emphasised the intrinsic value of patients' lived experience in making studies more relevant and meaningful. As a participant noted: *"Research has to be patient-relevant. There's no question about it. That's why I think PPI should become the new normal. Patients should be included in every project, to make sure it really is meaningful for them. And to make sure we choose the right endpoints, the ones that matter to patients, not just to researchers."* Some expressed doubts about the genuine purpose and added value of PPIE, questioning whether it is a guiding principle or merely a procedural requirement linked to funding. One interviewee summarised this tension: *"But do you know what's harder for me to understand? It's what the actual purpose is, what they're trying to achieve. Is this just something we do to get funding, or is it supposed to be a real principle guiding the organisation?"*

Tokenism, whether intentional or not, manifesting as superficial patient involvement with limited real influence, was acknowledged by participants as likely present, though not a primary concern. Participants rather highlighted how genuine patient partnership develops when researchers move towards intrinsic motivation, particularly when supported by evidence demonstrating PPIE's positive impact. Evaluating the impact of PPIE on research outcomes and process was viewed as essential for learning and improving partnerships, though defining assessment methods remains challenging. Most agreed that demonstrating the real benefits of PPIE is more important than documenting procedural compliance.

Barriers and enablers

Perceived barriers to sustainable PPIE implementation included limited formal institutional support, unclear mandates and unstable resource allocation. Small teams, often managing competing priorities, faced capacity constraints that threatened the continuity and depth of PPIE activities. Unclear guidelines, fragmented coordination and complex administrative processes further complicated implementation.

A recurrent concern was the limited clarity of SNSF regarding what constitutes an acceptable PPIE plan, and how it is evaluated in grant reviews. This places CTUs in a challenging position, expected to advise researchers without established reference points. As one participant noted: "*The SNSF does not provide clear examples of what they consider as a 'good' implementation of PPI and can hardly take into account the amount of resources needed to implement PPI*."

Interviewees reported that researchers' ability to engage meaningfully with PPIE was another barrier, which they explained by both attitudes and practical issues such as heavy workloads, clinical duties and scarce resources. Many seek support only at the last minute, when meaningful involvement is difficult to achieve. Interviewees felt that perceptions of PPIE among researchers ranged from scepticism, seeing it as an administrative burden, to recognition of its concrete benefits, for example in outcome design and recruitment.

Despite these challenges, progress is evident. Networks are maturing and bringing together researchers, professionals and patients. In some cases, CTUs have responded creatively to capacity constraints (table 5, rows 3 and 4).

Participants emphasised the need for research and evaluation to demonstrate PPIE's impact. Establishing centralised platforms to promote and coordinate PPIE evaluation nationally was highlighted as a strategic priority. As one participant noted: *"But if you want to do research-on-research, it probably won't work if you only do it in one study (...) You would need something bigger, like a survey comparing lots of trials (...) led by SCTO or another central body. It's hard to do on a single-study level."*

Showcasing success emerged as a critical enabler of awareness. Visible examples of effective PPIE, through accessible communication channels and informal interactions were seen as powerful ways to highlight benefits and motivate researchers towards PPIE. As one participant observed: "*Researchers want to read: 'Involving PPI in this way improved recruitment' or 'It improved the relevance of the endpoints'. If we can show that with evidence, they'll be much more likely to engage."*

Emerging themes

Bias and conflicts of interest were recognised as issues affecting both patients and researchers. Although interviewees showed awareness of these risks, they believe these could be addressed through transparency, fairness in managing patient roles, clarifying expectations, rotating responsibilities, or ensuring that patient input is balanced.

The evolving identity of "patient experts" also raised concerns. Some were described as "super patients" blending both scientific and lived experience, which could bias authentic representation and induce academic insularity. As one participant noted: "*I seriously wonder: do we really need patients to be experts to that extent? ... I really like the [research-]naïve patient side, which maybe corresponds more to your average Joe and Jane in the population. At least for many things, the naïve patient is almost more useful to us than the expert patient.*" (table 5, fifth row)

Training was another recurrent theme. Embedding PPIE principles in medical and nursing curricula was seen as essential to foster awareness among future researchers and clinicians. Views diverged on how to train patients and CTU staff: some supported joint sessions to build mutual understanding, while others favoured separate tracks. A few warned against "over-training" patients, arguing that excessive professionalisation could dilute the value of lived experience. Some participants also recognised the importance of training researchers.

Communication challenges between researchers and patients further underscored the need for facilitation. PPIE experts were seen as mediators who could bridge gaps and help identify where patients might contribute most meaningfully. As one participant put it: *"It's difficult, sometimes, to know in which projects patients could really help or contribute meaningfully (...). Maybe that's exactly where an expert could play an important role, as a moderator between the two."*

Capacity building also emerged as critical. Participants called for stronger infrastructures, including a clear training curriculum for CTU staff, better knowledge sharing, and more systematic evaluation of PPIE's impact to consolidate efforts into coherent national practices.

Finally, practices around patient remuneration or compensation varied, reflecting different administrative approaches and highlighting the complexity of formalising compensation.

Discussion

Our findings show that PPIE support is a recent development in Switzerland, unevenly implemented and largely dependent on motivated individuals with some training but lacking experience. These results should be situated within international developments and considered through the lens of organisational readiness [24-26].

International development of PPIE

Countries with strong national structures have adopted PPIE earlier: the United Kingdom created INVOLVE in 1996 as a dedicated advisory body [27]; the United States followed with PCORI in 2010, mandating patient engagement in all funded projects [28], while Canada launched SPOR in 2011, building national networks and training programmes [29, 30]. National frameworks in the Netherlands and Australia have also promoted patient involvement in research since the 2000s [31-33].

In Scandinavia, with decentralised health systems and strong public-sector research, PPIE began to gain formal recognition during the early 2010s but remains variably institutionalised. A Nordic scoping review reports growing use of PPIE with heterogeneous terms, methods, and uneven evidence on management and impact, underscoring the need for clearer frameworks and "international agreement on terms and definitions" [34]. In Norway, a NorCRIN-linked national survey of researchers and PPIE contributors found broadly positive attitudes yet persistent gaps in time, budget, tools and role clarity, pointing to underuse in dissemination [35]. In Denmark, a case study highlights practical challenges around workload, insurance and honoraria, reflecting the relative novelty of PPIE and limited national guidance [36].

In low- and middle-income countries, engagement is often tied to community participation in disease-specific trials (e.g. HIV, TB), rather than research-based infrastructures [37, 38].

Switzerland: delayed uptake and the limits of incentive-based policies

In Switzerland, PPIE support within CTUs is still at an early stage, with fewer than 10% of all projects implementing PPIE in 2024, according to our findings. Most initiatives were launched only from 2021 onwards. One earlier exception is Geneva, where PPIE activities emerged in 2018 through a grassroots initiative developed outside CTU structures [39]. Adoption has been uneven, reflecting CTUs' original mandate to provide methodological and regulatory expertise rather than participatory approaches [34], making PPIE both a cultural and structural shift.

The SCTO, founded in 2009 [40, 41], began to prioritise PPIE only in its 2021–2024 strategy. Overall, development has been mainly stimulated by SNSF IICT requirements, while emerging enablers such as patient databases, matchmaking events and outsourcing remain fragile without broader institutionalisation. Limited prioritisation at the institutional level means progress relies on motivated individuals and local initiatives to sustain PPIE.

While more than half of CTUs report providing theoretical support, only 25% of CTU staff reported being involved in hands-on PPIE activities (figure 3). This suggests that PPIE support in CTU mostly focuses on advice to researchers rather than concrete help in the engagement processes. This can be due to PPIE being developed as a response to a funding incentive, rather than as an institution-funded mandate. This illustrates a limitation of incentive-based policies: although they can stimulate awareness and local initiatives, they do not ensure the structural and human resources required for lasting implementation. This contrasts, for example, with Canada, where national or regional governments have rapidly funded dedicated PPIE coordinator roles resulting in more concrete implementation [28].

Fragility of support and organisational readiness

A key finding was the absence of dedicated PPIE roles and resources within Swiss CTUs, with most staff reporting limited to no experience, and low confidence in advising researchers. Reliance on motivated individuals risks discontinuity, as champions cannot compensate for absent institutional structures [24]. Limited expertise and training compound the problem.

This reflects low organisational readiness, defined as the collective commitment and capability of an institution to implement new practices [25, 26]. By contrast, UK CTUs employ dedicated PPIE managers and advisory panels; Canadian SPOR SUPPORT Units include engagement specialists who provide training and methodological support; and Australia's Consumer and Community Involvement Program has built capacity through networks and tailored resources [42-45].

These examples highlight possible pathways for Switzerland. Meaningful integration of PPIE will require investment in organisational readiness, including dedicated CTU positions, research on PPIE methods, clear mandates, protected resources, systematic training and stronger national coordination. Embedding PPIE into training curricula for researchers and CTU staff would further reinforce readiness.

Our results confirm recent national observations showing that, although awareness and acceptance of PPIE are increasing in Switzerland, structural and financial support remain limited, with progress still reliant on local leadership and resources [46, 47].

Low visibility of patients in CTU teams

No CTU currently employs patients as "patient-partner" in their support teams or, when they do, they hire them as a scientific collaborator or project manager – which are not roles explicitly defined by their patient expertise. This is not unique to Switzerland. In the UK and Canada, patient partners are typically engaged through advisory, governance or project-based mechanisms rather than as salaried CTU staff [34, 45, 48-51]. The reasons for this remain unclear. It may reflect limited organisational readiness to accommodate new profiles within established research infrastructures, or hesitation among professionals to share leadership.

Conceptual ambiguity around "patient expertise"

Interviews highlighted an absence of a common understanding of what constitutes an appropriate patient profile for inclusion in research ranging from "research-naïve patients" to "expert patients" without clearly defining the term, others preferring the perspective of "hybrid" profiles. In the absence of agreed definitions, recruitment and evaluation of practices remain inconsistent, and remuneration policies difficult to harmonise. This echoes findings from a mapping review of HIV research, where differing levels of knowledge and expertise between PPI members and researchers emerged as common challenges [52].

Similar issues have been documented internationally. In the Nordic countries, reviews and surveys note heterogeneous terminology and a lack of consensus on expectations for user representatives [34]. In the Netherlands, role definitions are often negotiated project by project [33]. In the UK, blurred boundaries between "lay" and "expert" roles have been observed [53], although case studies also show that clearly defined roles can add tangible value [49]. In Canada, the SPOR programme explicitly emphasises the need for shared frameworks to guide role definition [29, 50], and several adaptations of the national SPOR framework have since been developed [54-56]. Evidence suggests, however, that while these resources are frequently cited, their use remains uneven, with many teams adapting them flexibly to local contexts [5, 30, 57].

This ambiguity may be intrinsic to the idea of partnership itself. Patients can be experts in living with a disease, experts in patient-partnership, they can master methodological, training or advocacy skills, and no single definition captures this diversity. Switzerland therefore mirrors a broader debate, and progress may lie less in imposing a single definition than in adopting flexible role descriptions, transparent recruitment and remuneration, and recognising both lay and expert contributions as complementary.

Limitations

Several limitations should be acknowledged. First, although we aimed to reach all CTU staff, confidentiality constraints prevented us from obtaining all email addresses, and only 62% of those contacted responded. It is possible that individuals more interested or involved in PPIE were more likely to respond, as suggested by the 40% of respondents reporting being involved in PPIE sup-

port, leading to an overrepresentation of PPIE-active staff and to an overestimation of the level of awareness, involvement and support for PPIE within CTUs. Second, the questionnaire was delivered by email, and we cannot be certain who completed it. However, invitations were sent to professional email accounts, which should have limited responses from non-concerned individuals. Third, inconsistencies were observed in some responses. For instance, multiple respondents within the same CTU reported being the "head of the unit", raising questions about the reliability of certain items. Also, the lack of a standardised definition of expertise with regards to PPIE may have led to different interpretations. Fourth, the direct comparison of the proportion of supported projects including PPIE should be taken cautiously since the denominators were gathered unevenly across CTUs. Fifth, the interviews, although guided by a structured script, were flexibly conducted to allow participants to expand on issues of importance to them. Full thematic saturation was not reached due to the heterogeneity of PPIE practices across Swiss CTUs. Additionally, one of the interviewer's own involvement in PPIE support (outside CTU) may have influenced the discussions. Finally, no patient participated in this part 1 of the SPIRIT project. This decision was made at the start of the project. To allow an initial mapping of institutional and professional viewpoints, patient participation was not deemed necessary; patients will collaborate in parts 2 and 3.

Conclusion

This first national study on how Swiss CTUs support PPIE highlights that support is recent, with only a few staff holding formal PPIE roles and most advice provided informally. Training and expertise are limited, and many respondents express low confidence in advising researchers. PPIE relies largely on motivated individuals and rarely on employed patients. These findings highlight important gaps in institutional support, resources, roles and conceptual clarity and calls for institutional mandates, dedicated budgets, protected staff positions and systematic training. Clarifying the role of patient partners while allowing flexible forms of contribution will be essential. Whether the PPIE support provided by the CTU aligns with researchers' needs and expectations is unknown and will be the topic of SPIRIT part 2.

Data sharing statement

Custom analytical code and deidentified quantitative data underlying the findings of this study may be made available upon reasonable request to the corresponding author. Due to the qualitative nature of the study and the small number of participants within each CTU, full interview transcripts cannot be shared as they may contain potentially identifiable information. Selected deidentified excerpts are provided in the appendix. Additional study documents, including the questionnaire and the interview guide, are available in the appendix.

Notes

Acknowledgements: We warmly thank the members of the SPIRIT group – Sandra Kohlmaier (Basel); Kristin Marie Bivens and Amélie Guyon (Bern); Cindy Allenbach and Marie-Josée Crevier (Lausanne); Maria Montilla and Tatiana Terrot (Lugano); Uwe Ramsperger (St Gallen); Silke Ludwig (Zürich); Ivo Schauwecker (ETH Zurich); and François Curtin (Luzern) – for their valuable feedback on the study protocol and questionnaire design. We are also grateful to the Swiss Clinical Trial Organisation (SCTO) for its support in facilitating contacts and collaboration across CTUs. We would like to extend our thanks to Prof. Audrey L'Esperance (École Nationale d'Administration Publique, Montréal, Canada) for her insightful input on the study interpretation. Finally, we acknowledge the use of artificial intelligence tools, which assisted with transcription refinement and language editing. Responsibility for the analysis and interpretation of findings remains entirely with the authors.

Use of AI: Minor corrections such as grammar and repetitions were made using ChatGPT (GPT-4o, OpenAI, 2025), based on selected deidentified excerpts.

Financial disclosure

This study received a funding from the Swiss Clinical Trial Organisation (SCTO), project number RoR2025_009.

Potential competing interests

All authors have completed and submitted the International Committee of Medical Journal Editors form for disclosure of potential conflicts of interest. Maëlle Achard was affiliated to the Geneva CTU for the duration of this study, and her salary was paid by the STCO grant. She is member of PartnerREC network in Geneva. Maël Barthoulot is a member of the Geneva CTU, although not involved in PPIE counselling. Alexandra Calmy is the head of the Geneva CTU. Nadia Elia is co-coordinator of the PartnerREC network in Geneva, not a member of the CTU. Angèle Gayet Ageron has nothing to declare.

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1 Questionnaire

_S_upporting _P_atient and public _I_nvolvement in _R_esearch through clinical trial un/_T_s – The SPIRIT survey

Dear Participant,

This questionnaire aims to assess how Clinical Trial Units (CTUs) in Switzerland support researchers in facilitating Patient and Public Involvement and Engagement (PPIE) in Investigator-Initiated Clinical Trials (IICTs). **It is divided in 6 sections assessing** :

- Your **role(s) and expertise** as a CTU professional
- Your **role in supporting PPIE**
- Your **knowledge, experience, and confidence levels** with PPIE support
- Your **training needs** to enhance PPIE capacity within CTUs
- The extent of the **PPIE support** provided by your CTU
- Demographic characteristics

Your responses **will be analyzed anonymously**, and the estimated time for completion is 10 minutes.

This project is supported by the Swiss Clinical Trial Organization (SCTO) as part of its efforts to enhance patient and public involvement in clinical research across Switzerland.

Thank you for your time and contribution!

Section 1: Your primary role in CTU

1. What is your PRIMARY role within your CTU?
   - ☐ CTU Director
   - ☐ Project Manager
   - ☐ Methodologist
   - ☐ Biostatistician
   - ☐ Medical Monitor
   - ☐ Research Nurse
   - ☐ Pharmacist
   - ☐ Clinical Trial Coordinator
   - ☐ Clinical Research Associate (CRA)
   - ☐ Clinical Data Manager
   - ☐ Data Analyst
   - ☐ Regulatory Affairs Specialist
   - ☐ Quality Assurance Officer
   - ☐ Clinical Safety Officer / Pharmacovigilance Specialist
   - ☐ PPIE lead / Patient engagement specialist
   - ☐ Training and Education
   - ☐ Secretary
   - ☐ Other (Please specify) ____

2. Area of expertise (several answers possible)
   - ☐ Clinical trial leadership & management
   - ☐ Study design & methodology
   - ☐ Medical oversight & patient safety
   - ☐ Patient care & trial implementation
   - ☐ Operational coordination & site management
   - ☐ Data management
   - ☐ Data analysis
   - ☐ Regulatory compliance & ethics

- ☐ Quality assurance & risk management
- ☐ Training and education
- ☐ Communication
- ☐ Patient and Public Involvement and Engagement

3. How many years of experience do you have working in a CTU?
   - ☐ <1 year
   - ☐ 1-3 years
   - ☐ 4-6 years
   - ☐ 7-10 years
   - ☐ >10 years

Section 2: Your role in supporting PPIE

Patient and Public Involvement and Engagement (PPIE) refers to the active collaboration between researchers, patients, and the public throughout the research process. This may include co-developing study questions, reviewing materials, or participating in governance and decision-making.

4. Are you involved in advising researchers on how to integrate PPIE into their IICT proposals?
   - ☐ Yes, as part of my formal role. (Continue the interview.)
   - ☐ No, but I provide informal guidance when needed. (Continue the interview.)
   - ☐ No, I am not involved in PPIE support. (Go to section 3)

5. How frequently do you interact with researchers seeking support for PPIE in IICTs?
   - ☐ At least once a week
   - ☐ At least once a month
   - ☐ A few times a year
   - ☐ Rarely or never

6. What type of PPIE support do you provide? (Select all that apply)
   - ☐ Guiding researchers on existing PPIE frameworks & resources

- ☐ Providing hands-on support for conducting PPIE activities (e.g., facilitating meetings with patient partners, co-designing materials, moderating discussions, supporting data collection involving patients)
- ☐ Assisting researchers in identifying and engaging patient/public partners
- ☐ Providing logistical & administrative support (assisting with organizing PPIE activities, reimbursing patient partners, and managing documentation)
- ☐ Helping researchers evaluate the impact of PPIE
- ☐ Advising on budgeting & funding for PPIE
- ☐ I am not sure
- ☐ Other (Please specify):

Section 3: Knowledge, experience and confidence with PPIE
(All CTU professionnals)

7. How familiar are you with the concept of PPIE in clinical research?
   - ☐ Not familiar at all
   - ☐ Somewhat familiar
   - ☐ Neutral
   - ☐ Familiar
   - ☐ Very familiar

8. How would you rate your current knowledge of PPIE in clinical trials?
   - ☐ No knowledge at all
   - ☐ Basic understanding
   - ☐ Some knowledge
   - ☐ Good knowledge
   - ☐ Expert knowledge

9. How would you rate your experience with PPIE in clinical trials?
   - ☐ No experience
   - ☐ Limited experience
   - ☐ Some hands-on experience

- ☐ Moderate experience
- ☐ Extensive experience

10. Was this experience acquired while working in your current position or a previous one?
    - ☐ Current position
    - ☐ Previous position (please specify)

11. Do you use specific guidelines, frameworks or tools regarding PPIE?
    - ☐ Yes, which ones? (Please specify)
    - ☐ No
    - ☐ Unsure

12. How confident are you in advising/supporting researchers regarding PPIE?
    - ☐ 1. Not confident at all
    - ☐ 2. Slightly confident
    - ☐ 3. Somewhat confident
    - ☐ 4. Confident
    - ☐ 5. Very confident

Section 4: Training needs

13. Have you received any **formal training** on PPIE (e.g., online seminars, workshops, courses, certifications)?
    - ☐ Yes (Please specify)
    - ☐ No, but I would like to receive training
    - ☐ No, and I don't think it's necessary (skip to section 5)

14. What aspects of PPIE would you like **more training** on? (Select all that apply)
    - ☐ Key frameworks, guidelines or tools for PPIE
    - ☐ Engaging & communicating with patients and public partners

- ☐ Budgeting & funding for PPIE
- ☐ Managing PPIE activities (e.g., meeting organization, patient involvement)
- ☐ Reimbursement and administrative processes for PPIE
- ☐ Evaluating the impact of PPIE in research
- ☐ Other (Please specify):
- ☐ Unsure / I don't know yet.

Section 5: Current PPIE support and areas for improvement in your CTU
(All CTU professionnals)

15. Does your CTU have a **dedicated person or team** for PPIE support?
- ☐ Yes
- ☐ No
- ☐ No, but it collaborates with a dedicated support program (please, specify)
- ☐ I don't know

16. What type of support does your CTU offer to researchers regarding PPIE? (Select all that apply)
- ☐ Guiding researchers on existing PPIE frameworks & resources.
- ☐ Providing hands-on support for conducting PPIE activities (e.g., facilitating meetings with patient partners, co-designing materials, moderating discussions, supporting data collection involving patients).
- ☐ Assisting researchers in identifying and engaging patient/public partners.
- ☐ Providing logistical & administrative support (assisting with organizing PPIE activities, reimbursing patient partners, and managing documentation).
- ☐ Helping researchers evaluate the impact of PPIE.
- ☐ Advising on budgeting & funding for PPIE
- ☐ Other (Please specify):
- ☐ None
- ☐ I don't know

17. Do you think that the PPIE support offered by your CTU meets researchers needs ?
- ☐ Yes
- ☐ No
- ☐ Somewhat
- ☐ I have no opinion

18. What additional type of support would be relevant? (Select all that apply)
- ☐ Guiding researchers on existing PPIE frameworks & resources
- ☐ Providing hands-on support for conducting PPIE activities (e.g., facilitating meetings with patient partners, co-designing materials, moderating discussions, supporting data collection involving patients)
- ☐ Assisting researchers in identifying and engaging patient/public partners
- ☐ Providing logistical & administrative support (assisting with organizing PPIE activities, reimbursing patient partners, and managing documentation)
- ☐ Helping researchers evaluate the impact of PPIE
- ☐ Advising on budgeting & funding for PPIE
- ☐ Other (Please specify):
- ☐ I don’t know

19. In your opinion, what would help your CTU better integrate PPIE into its support services? (Select all that apply)
- ☐ Dedicated staff
- ☐ Dedicated budget
- ☐ Clearer policies
- ☐ Institutional recognition
- ☐ Umbrella organization (i.e. unique organization providing overview and guidance)
- ☐ Other (Please specify)
- ☐ I don’t know

20. What do you see as the main barriers to implementing PPIE support in your CTU? (Select all that apply)
- ☐ Lack of dedicated resources (staff, funding)
- ☐ Lack of clear institutional policies on PPIE
- ☐ Lack of researcher awareness or demand for PPIE support
- ☐ Lack of training or expertise within the CTU

- ☐ Other (Please specify) ____
- ☐ I don’t know

21. If yes to Q19 option 1 to 4
You may provide additional details (optional)

Section 6 : Demographics

22. What is your age group?
- ☐ Under 30
- ☐ 30–39
- ☐ 40–49
- ☐ 50–59
- ☐ 60+
- ☐ Prefer not to say

23. What is your gender? ___
- ☐ Male
- ☐ Female
- ☐ Prefer to self-describe (please specify): ____
- ☐ Prefer not to say

24. Would you be willing to be contacted for a more in-depth interview?
These interviews will be conducted to explore CTU organizational practices, the number of projects supported, the resources dedicated to PPIE, training and knowledge about PPIE, types of PPIE support provided, and the frequency and challenges of PPIE-related activities.
- ☐ Yes (please give your email of contact)
- ☐ No

Thank you for your participation.

1.1 Summary of variable recoding and category groupings

These groupings were intended to improve the readability of tables and figures and focus comparisons on contrasts that are most meaningful in the context of PPIE support.

Age (age_3): The original five-category variable was recoded into three groups: *under 30*, *30–39*, and *40 and over* (merging the 40–49, 50–59, and 60+ categories). "Prefer not to say" responses were treated as missing.

Primary role (role_7): The 18 original role categories were collapsed into 7 functional domains: *Leadership & project management* (CTU director, project manager); *Methodology, statistics & data* (methodologist, biostatistician, data manager, data analyst); *Clinical operations* (medical monitor, research nurse, trial coordinator, CRA); *Regulatory, quality & safety* (regulatory affairs, quality assurance, pharmacovigilance, pharmacist); *PPIE*; *Education/teaching*; and *Support roles & other* (secretary, other).

CTU experience (years_exp_4): Recoded into a binary variable: *less than 4 years* (combining the <1 year and 1–3 year categories) vs. *4 years or more* (combining the 4–6, 7–10, and >10 year categories).

Frequency of PPIE support requests: Two recodings were produced. A binary variable (interact_few) distinguishes *monthly or more frequent* from *a few times per year or less*. A three-category variable (interact_freq3) further distinguishes *weekly or more*, *monthly or more*, and *a few times per year or less*.

Familiarity with PPIE (familiar_3cat): The five original levels were collapsed into three: *not familiar* (level 1), *moderately familiar* (level 3), and *familiar* (levels 4–5). Level 2 was absorbed into the intermediate category given its proximity to level 3.

Knowledge of PPIE (knowledge_3cat): The five original levels were collapsed into three: *no knowledge* (level 1), *basic knowledge* (level 3), and *good knowledge* (levels 4–5).

Experience with PPIE (experience_3cat): The five original levels were collapsed into three: *no experience* (level 1), *limited experience* (level 2), and *moderate to extensive experience* (levels 3–5).

PPIE training (trained): Recoded into a binary variable: *yes* (level 1) vs. *no* (levels 2 and above, corresponding to "no, but would like training" and "no, and does not consider it necessary").

Confidence in advising researchers (confident_advising_3cat): The five original levels were collapsed into three: *not confident at all* (level 1), *slightly confident* (level 3), and *confident* (levels 4–5).

2 Interview guide

Origins and implementation

- How and when did your CTU start supporting PPIE?
- What were the first steps taken, and how has your approach evolved since then?
- Who/what gave the impulsion? Are there any external stakeholders (e.g., funders, universities, hospitals, patient organizations) that have influenced how your CTU supports PPIE?
- Was a person responsible for PPIE recruited in your CTU? How quickly? On which qualifications? And which funding?

Current support

- What types of PPIE support do you provide to researchers? Can you describe what that looks like in practice?
- Do you have a patient database? Are you involved in matching patient and researchers? if so, how do you do it?
- Do you pay the patients you work with? If yes, do you have fix rates? A contract? Etc.
- Do you have PPIE specific work tools?
- Do you know the levels of engagement from the Montreal model (information, consultation, collaboration, partnership), and the different patient's roles (experiential knowledge, expert, leader). What do you think about them?
- How do researchers usually respond to your support? Do you measure their satisfaction?
- Can you give me a specific example of how you've supported a researcher in identifying partners, or planning activities, or budgeting for PPIE?

Staff and training

- Did you have a specific training on PPI? If yes, what was it?
- Does your CTU offer specific training to its staff? To researchers? Patients?
- Do you think a centralized training would be a good idea? For PPI professionals? For researchers?

Views on PPIE

- In your view, what is the core purpose of involving patients and the public in research? Do you feel this view is shared by researchers?
- Some argue that PPIE risks becoming a checkbox exercise. What are your thoughts about this?

Assessing the participatory process

- Many templates and reporting tools focus on when patients are involved, and what they do, but rarely on the description/evaluation of the process of patient involvement itself. Do you do this? If yes how? if not, why?
- From your experience, are there practices or conditions that foster a truly collaborative and co-constructed approach to PPIE?
- Some argue that patients are involved in research to "tick a box" (tokenism), What do you think about that?
- Do you see any conflict of interest that could emerge from a patient's participation (e.g. a same patient expert participating in many studies, a patient linked to the industry, etc.)

Challenges

- What are the main challenges (if any) your CTU faces in implementing or maintaining PPIE support?
- Do you see any challenges linked to funder expectations, for example from the SNSF, when it comes to implementing PPIE?

Enablers and successes

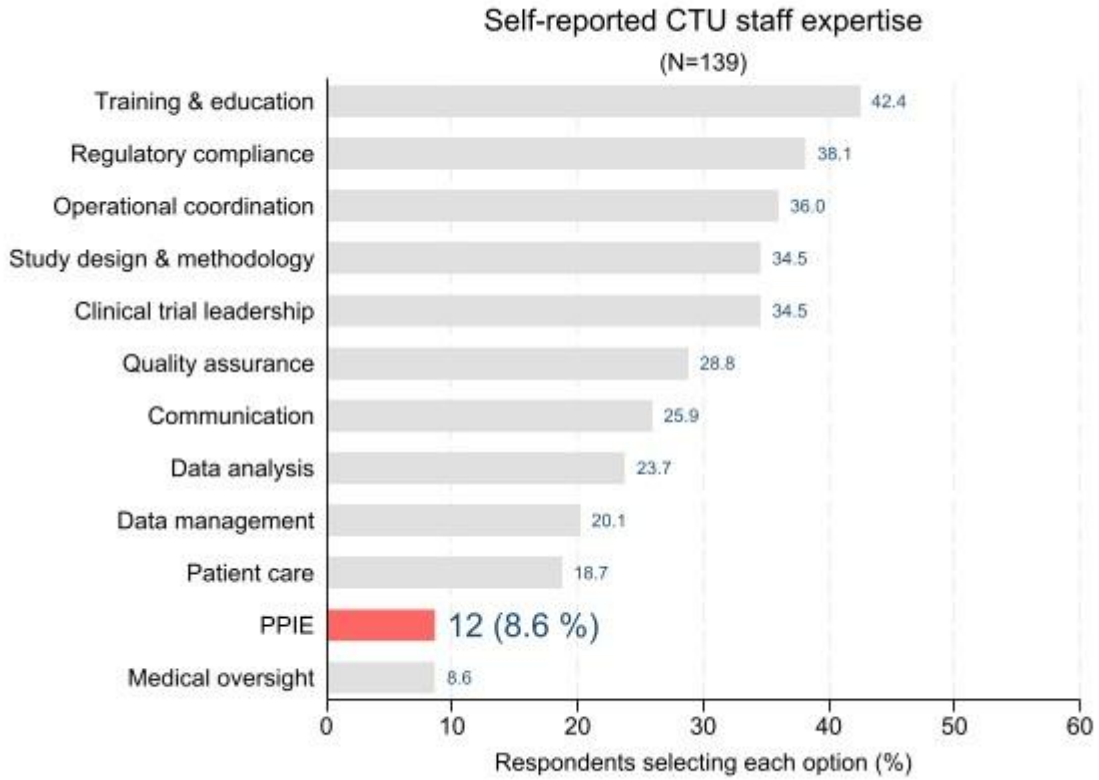
- Are there conditions or factors that help make PPIE support work well in your CTU?
- Can you share an example of a project where PPIE went particularly well?
- What made it successful?

Future perspective

- How do you see the future of the PPIE in the CTU?

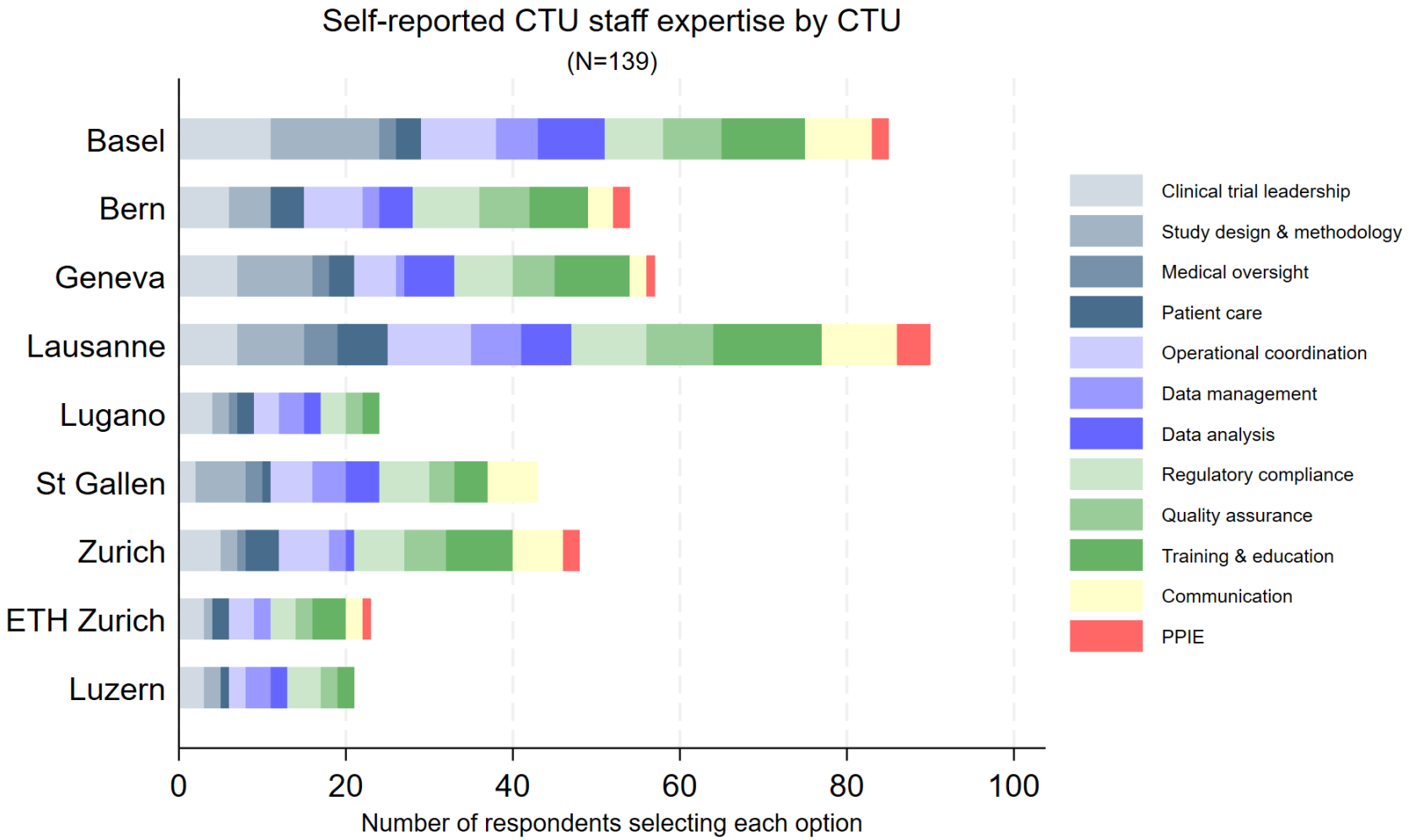
3 Supplementary data

Supp. Figure 1 Self-reported CTU staff expertise (N=139)



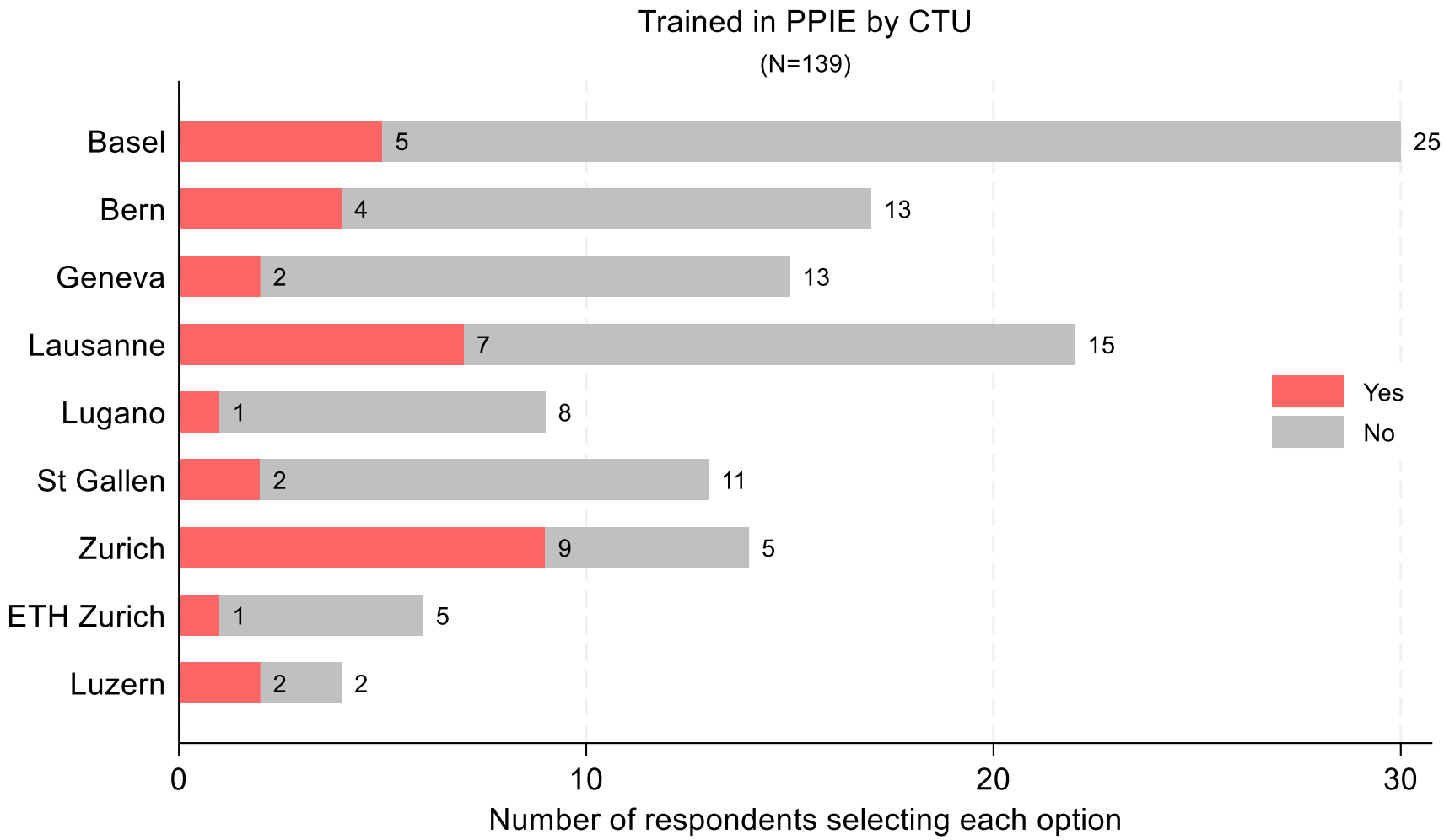
CTU: Clinical Trial Unit, PPIE: Patient and Public Involvement and Engagement

Supp. Figure 2 Self-reported CTU staff expertise by CTU (N=139)



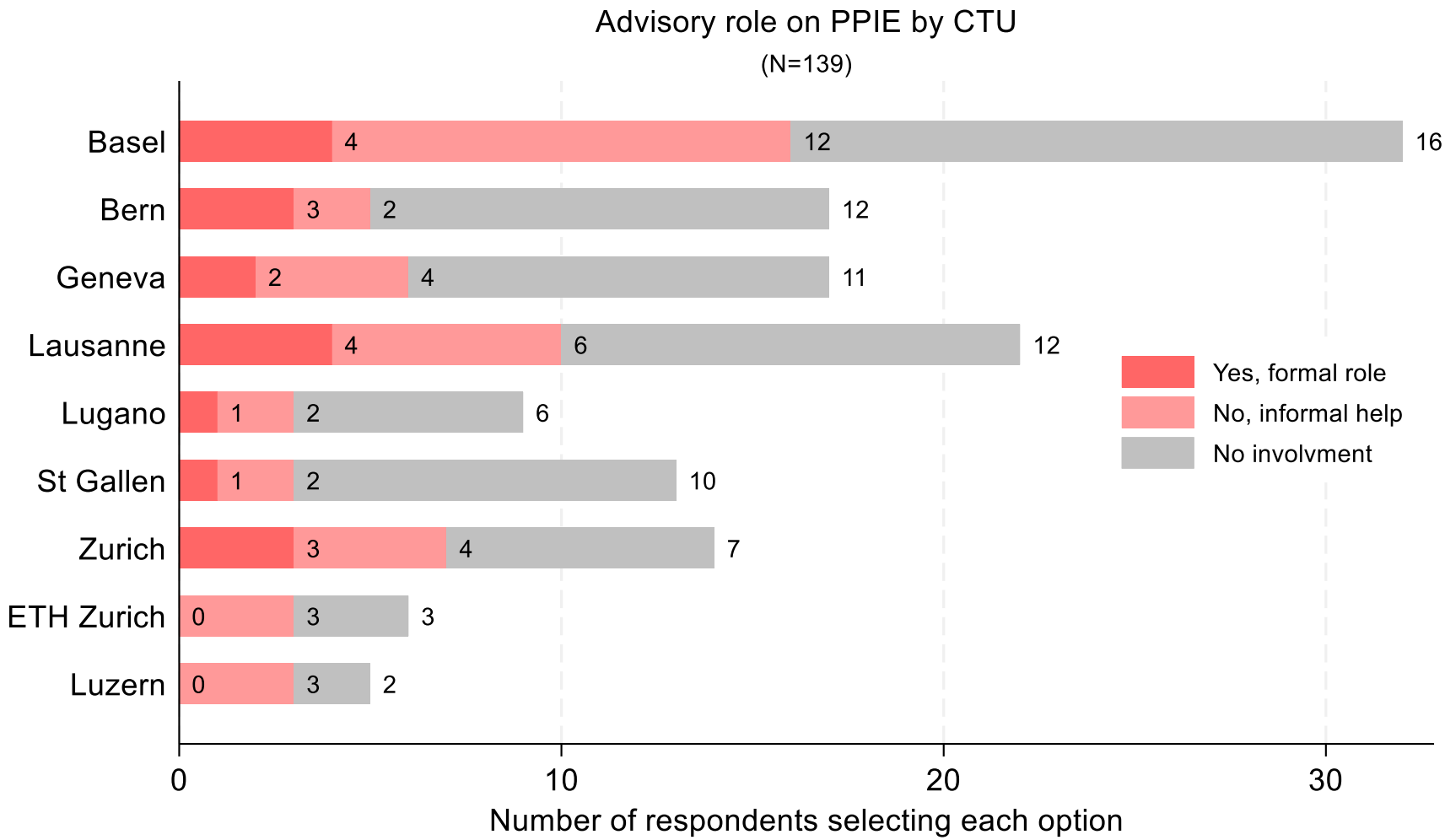
CTU: Clinical Trial Unit, PPIE: Patient and Public Involvement and Engagement

Supp. Figure 3 Trained in PPIE by CTU (N=139)



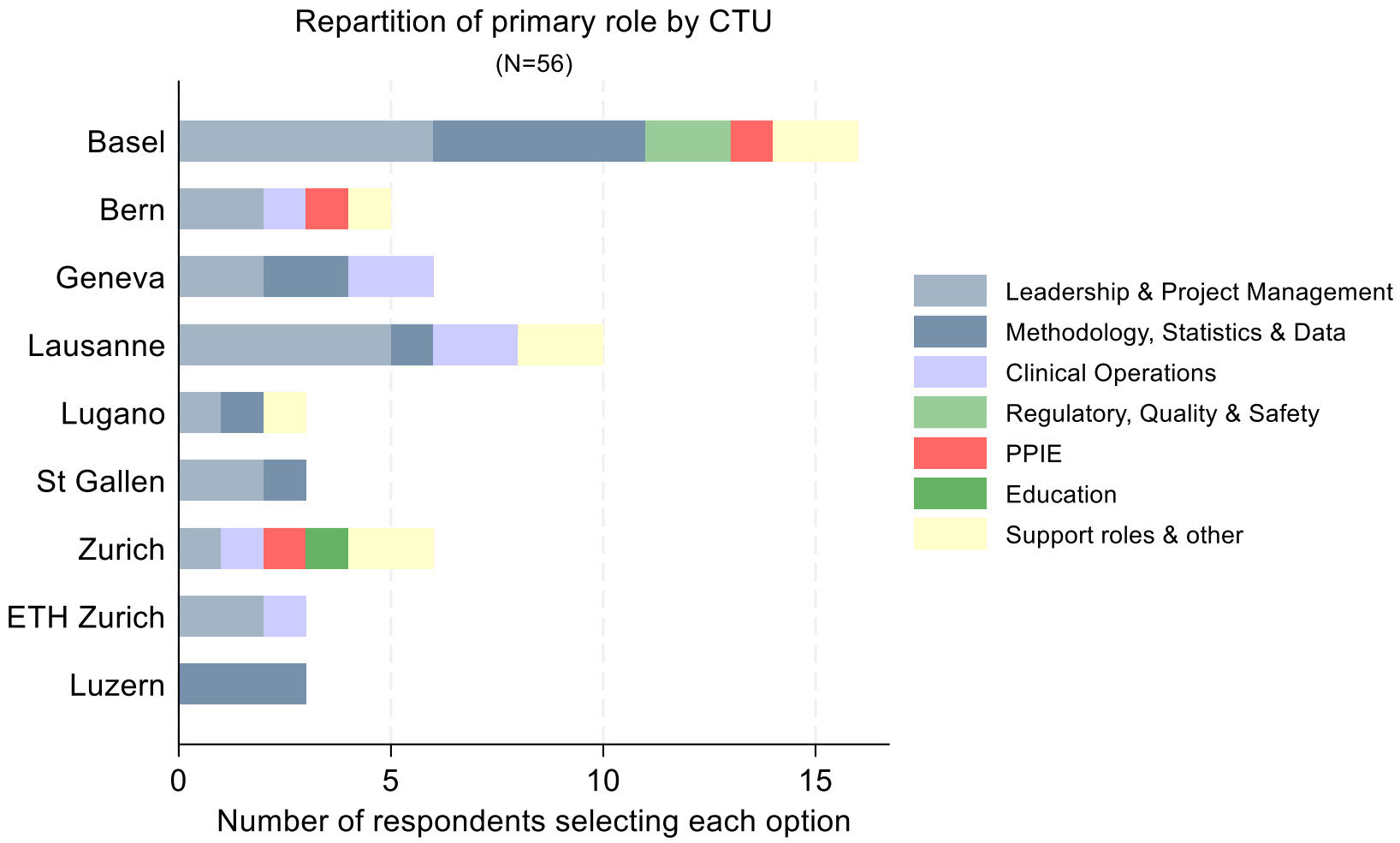
CTU: Clinical Trial Unit, PPIE: Patient and Public Involvement and Engagement

Supp. Figure 4 Advisory role on PPIE by CTU (N=139)



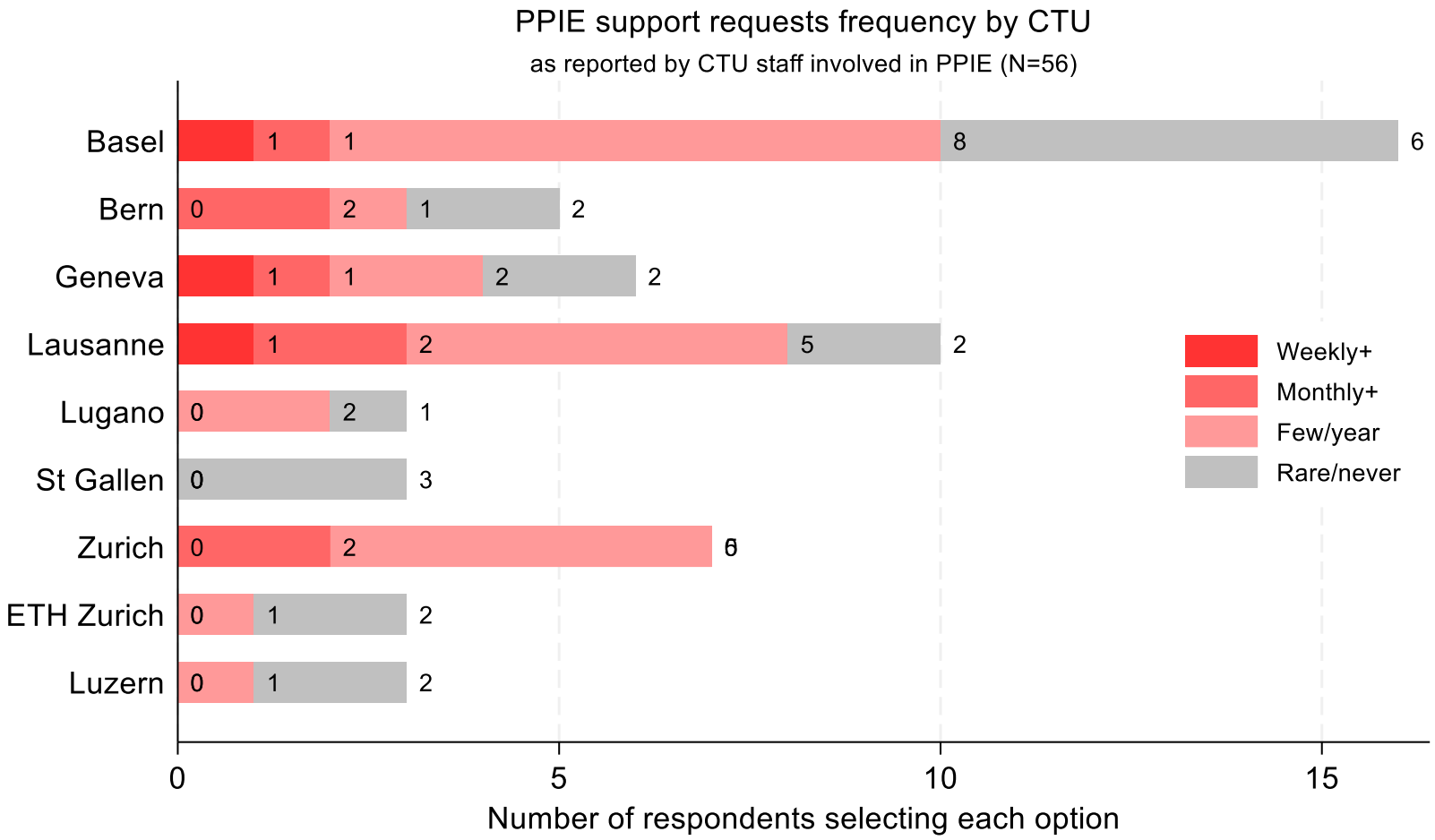
CTU: Clinical Trial Unit, PPIE: Patient and Public Involvement and Engagement

Supp. Figure 5 Repartition of primary role by CTU (N=56)



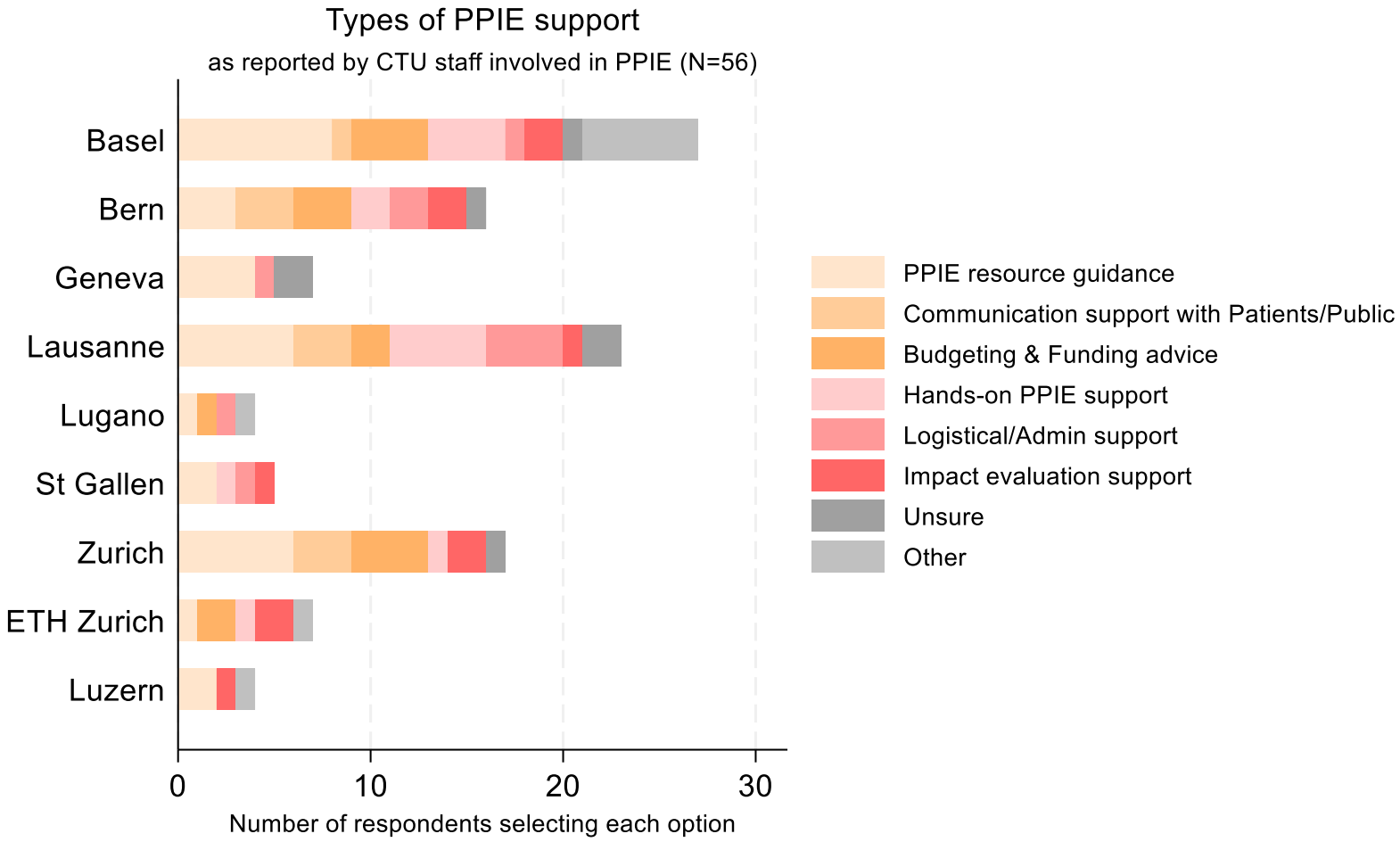
CTU: Clinical Trial Unit

Supp. Figure 6 PPIE support requests frequency by CTU, as reported by CTU staff involved in PPIE (N=56)



CTU: Clinical Trial Unit, PPIE: Patient and Public Involvement and Engagement

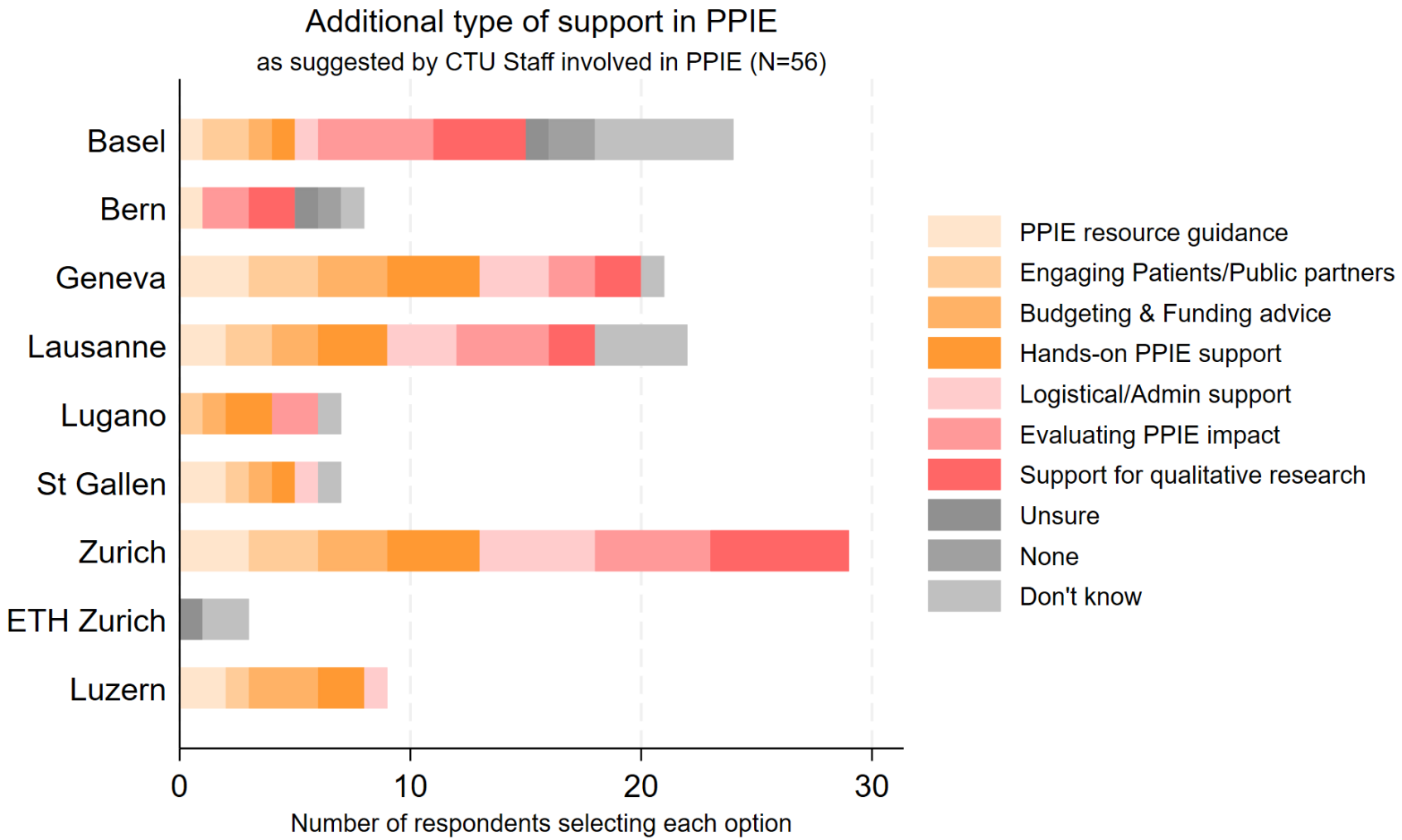
Supp. Figure 7 Types of PPIE support, as reported by CTU staff involved in PPIE (N=56)



CTU: Clinical Trial

Unit, PPIE: Patient and Public Involvement and Engagement

Supp. Figure 8 Additional type of support in PPIE as suggested by CTU staff involved in PPIE (N=56)



CTU: Clinical Trial Unit, PPIE: Patient and Public Involvement and Engagement

Supp. Table 1 Characteristics of staff providing PPIE support in each CTU (N=56)

	CTU									
	Basel	Bern	Geneva	Lausanne	Lugano	St Gallen	Zurich	ETH Zurich	Luzern	Total
	16 (28.6%)	5 (8.9%)	6 (10.7%)	10 (17.9%)	3 (5.4%)	3 (5.4%)	7 (12.5%)	3 (5.4%)	3 (5.4%)	56 (100.0%)
Age										
30-39	3 (23.1%)	2 (40.0%)	2 (40.0%)	1 (11.1%)	0 (0.0%)	1 (33.3%)	2 (33.3%)	0 (0.0%)	2 (66.7%)	13 (26.0%)
40+	10 (76.9%)	3 (60.0%)	3 (60.0%)	8 (88.9%)	3 (100.0%)	2 (66.7%)	4 (66.7%)	3 (100.0%)	1 (33.3%)	37 (74.0%)
Gender										
Man	4 (26.7%)	0 (0.0%)	1 (20.0%)	3 (30.0%)	2 (66.7%)	2 (66.7%)	1 (14.3%)	1 (33.3%)	1 (33.3%)	15 (27.8%)
Woman	9 (60.0%)	5 (100.0%)	4 (80.0%)	5 (50.0%)	1 (33.3%)	1 (33.3%)	5 (71.4%)	2 (66.7%)	2 (66.7%)	34 (63.0%)
No answer	2 (13.3%)	0 (0.0%)	0 (0.0%)	2 (20.0%)	0 (0.0%)	0 (0.0%)	1 (14.3%)	0 (0.0%)	0 (0.0%)	5 (9.3%)
Experience within a CTU										
< 4 years	4 (25.0%)	3 (60.0%)	2 (33.3%)	3 (30.0%)	0 (0.0%)	1 (33.3%)	1 (14.3%)	0 (0.0%)	1 (33.3%)	15 (26.8%)
>= 4 years	12 (75.0%)	2 (40.0%)	4 (66.7%)	7 (70.0%)	3 (100.0%)	2 (66.7%)	6 (85.7%)	3 (100.0%)	2 (66.7%)	41 (73.2%)
Primary role										
Leadership & Project Management	6 (37.5%)	2 (40.0%)	2 (33.3%)	5 (50.0%)	1 (33.3%)	2 (66.7%)	1 (16.7%)	2 (66.7%)	0 (0.0%)	21 (38.2%)
Methodology, Statistics & Data	5 (31.2%)	0 (0.0%)	2 (33.3%)	1 (10.0%)	1 (33.3%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	3 (100.0%)	13 (23.6%)
Clinical Operations	0 (0.0%)	1 (20.0%)	2 (33.3%)	2 (20.0%)	0 (0.0%)	0 (0.0%)	1 (16.7%)	1 (33.3%)	0 (0.0%)	7 (12.7%)
Regulatory, Quality & Safety	2 (12.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (3.6%)
PPIE	1 (6.2%)	1 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (16.7%)	0 (0.0%)	0 (0.0%)	3 (5.5%)
Education	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (16.7%)	0 (0.0%)	0 (0.0%)	1 (1.8%)
Support roles & other	2 (12.5%)	1 (20.0%)	0 (0.0%)	2 (20.0%)	1 (33.3%)	0 (0.0%)	2 (33.3%)	0 (0.0%)	0 (0.0%)	8 (14.5%)

CTU: Clinical Trial Unit, PPIE: Patient and Public Involvement and Engagement

Supp. Table 2 Focus on staff providing PPIE support in each CTU (N=56)

	CTU									
	Basel	Bern	Geneva	Lausanne	Lugano	St Gallen	Zurich	ETH Zurich	Luzern	Total
	16 (28.6%)	5 (8.9%)	6 (10.7%)	10 (17.9%)	3 (5.4%)	3 (5.4%)	7 (12.5%)	3 (5.4%)	3 (5.4%)	56 (100.0%)
Advisory role on PPIE										
Yes, formal role	4 (25.0%)	3 (60.0%)	2 (33.3%)	4 (40.0%)	1 (33.3%)	1 (33.3%)	3 (42.9%)	0 (0.0%)	0 (0.0%)	18 (32.1%)
No, informal help	12 (75.0%)	2 (40.0%)	4 (66.7%)	6 (60.0%)	2 (66.7%)	2 (66.7%)	4 (57.1%)	3 (100.0%)	3 (100.0%)	38 (67.9%)
As part of their main role or area of expertise										
No	15 (93.8%)	3 (60.0%)	5 (83.3%)	7 (70.0%)	3 (100.0%)	3 (100.0%)	5 (71.4%)	2 (66.7%)	3 (100.0%)	46 (82.1%)
Yes	1 (6.2%)	2 (40.0%)	1 (16.7%)	3 (30.0%)	0 (0.0%)	0 (0.0%)	2 (28.6%)	1 (33.3%)	0 (0.0%)	10 (17.9%)
Trained in PPIE										
No	12 (80.0%)	2 (40.0%)	4 (80.0%)	5 (50.0%)	2 (66.7%)	2 (66.7%)	3 (42.9%)	2 (66.7%)	1 (50.0%)	33 (62.3%)
Yes	3 (20.0%)	3 (60.0%)	1 (20.0%)	5 (50.0%)	1 (33.3%)	1 (33.3%)	4 (57.1%)	1 (33.3%)	1 (50.0%)	20 (37.7%)
Use of documentation										
Yes	6 (37.5%)	3 (60.0%)	0 (0.0%)	6 (60.0%)	1 (33.3%)	1 (33.3%)	4 (57.1%)	1 (33.3%)	0 (0.0%)	22 (40.0%)
No	7 (43.8%)	2 (40.0%)	5 (100.0%)	4 (40.0%)	2 (66.7%)	2 (66.7%)	2 (28.6%)	1 (33.3%)	3 (100.0%)	28 (50.9%)
Unsure	3 (18.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (14.3%)	1 (33.3%)	0 (0.0%)	5 (9.1%)
Position providing experience										
Current position	11 (91.7%)	5 (100.0%)	4 (100.0%)	7 (77.8%)	2 (100.0%)	2 (100.0%)	6 (100.0%)	2 (100.0%)	1 (50.0%)	40 (90.9%)
Previous position	1 (8.3%)	0 (0.0%)	0 (0.0%)	2 (22.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (50.0%)	4 (9.1%)
Self-reported familiarity										
Moderatly familiar	5 (31.2%)	0 (0.0%)	5 (100.0%)	3 (30.0%)	2 (66.7%)	2 (66.7%)	1 (14.3%)	1 (33.3%)	2 (66.7%)	21 (38.2%)
Familiar	11 (68.8%)	5 (100.0%)	0 (0.0%)	7 (70.0%)	1 (33.3%)	1 (33.3%)	6 (85.7%)	2 (66.7%)	1 (33.3%)	34 (61.8%)
Self-reported knowledge										
No knowledge	1 (6.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)	3 (5.5%)
Basic knowledge	6 (37.5%)	1 (20.0%)	5 (100.0%)	6 (60.0%)	1 (33.3%)	3 (100.0%)	3 (42.9%)	2 (66.7%)	1 (33.3%)	28 (50.9%)
Good knowledge	9 (56.2%)	4 (80.0%)	0 (0.0%)	4 (40.0%)	1 (33.3%)	0 (0.0%)	4 (57.1%)	1 (33.3%)	1 (33.3%)	24 (43.6%)
Self-reported experience										
No experience	4 (25.0%)	0 (0.0%)	1 (20.0%)	1 (10.0%)	1 (33.3%)	1 (33.3%)	1 (14.3%)	1 (33.3%)	1 (33.3%)	11 (20.0%)
Limited experience	5 (31.2%)	1 (20.0%)	4 (80.0%)	6 (60.0%)	1 (33.3%)	2 (66.7%)	2 (28.6%)	1 (33.3%)	0 (0.0%)	22 (40.0%)
Moderate experience	7 (43.8%)	4 (80.0%)	0 (0.0%)	3 (30.0%)	1 (33.3%)	0 (0.0%)	4 (57.1%)	1 (33.3%)	2 (66.7%)	22 (40.0%)
Self-reported confidence in advising										
Not confident at all	1 (6.2%)	0 (0.0%)	2 (40.0%)	0 (0.0%)	2 (66.7%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	1 (33.3%)	7 (12.7%)
Slightly confident	13 (81.2%)	2 (40.0%)	3 (60.0%)	7 (70.0%)	0 (0.0%)	2 (66.7%)	4 (57.1%)	2 (66.7%)	2 (66.7%)	35 (63.6%)
Confident	2 (12.5%)	3 (60.0%)	0 (0.0%)	3 (30.0%)	1 (33.3%)	0 (0.0%)	3 (42.9%)	1 (33.3%)	0 (0.0%)	13 (23.6%)

CTU: Clinical Trial Unit, PPIE: Patient and Public Involvement and Engagement

4 Selection of relevant verbatims

4.1 Origins and Implementation

Initiation and institutional request
“The request came out of a discussion with the Director... researchers didn’t really know what to do with this whole PPI concept. And naturally, it was directed toward us...”
"My involvement in PPIE actually started when there was a request to join the SCTO working group on PPIE. At that time, our operational head asked if I had any capacity to participate because my three colleagues were already heavily involved in other SCTO platforms and didn’t have time. I was the only one not yet part of any platform, so I volunteered."

Collaborative PPIE method developed by learning from doing
“We tried to understand the rationale behind it... We decided on three main activities: a focus group, individual interviews with patients, and an informal meeting where we shared patient feedback with doctors.”
“We created a database... Patients could fill out an online form... then we’d meet with them (…) We quickly said: ‘Whoa! we need to pause. We’ve already got 30 people.’”

Fragility of PPIE initiatives due to key-person dependency
“No (I wasn't specifically hired for PPI). It was because the colleague was leaving, and I was very interested in the topic. So, I took it over.”

Current status and institutional support
“I find it unfortunate that today, we still don’t have that institutional support.”

Uncertainty about institutional prioritization and formalization of PPIE
"[whether my] institution is actually planning that to pursue that or not, there is a question mark."
"If I'm away, I really don't know if it would continue."

Challenges in formal recognition and employment
“I didn’t even try [to hire officially as patient partner].”
“Today, I think it remains complicated... We hire someone who is ALSO a patient.”

4.2 Current support provided by ctus

Practical questions beyond IICT requirements
“A lot of times it's really practical questions: ‘where can I find PPI representatives? What kind of PPI representatives would be necessary?’”

Tools and support documents
“Well, we can set up focus groups if a researcher wants to talk to several patients... But if by ‘tools’ you mean documents explaining how to build a partnership... no, we don’t really have anything like that... we don’t give them any additional documents..."

Lack of visibility on implementation
“Actually, we have no idea what happens behind the scenes. What are they really doing concretely?”
“Very often (at least these last two years) once they have this PPI plan and receive the funding, we usually don’t hear back from them.”

Lack of formal evaluation process of PPI support
"We don’t have, right now, a real evaluation process (…) researchers are so busy, (…) reluctant about that (…). OK with a quick conversation on the phone, but nothing formal."

Informal PPIE processes
"It’s kind of a ‘do first, then write the process’ approach."

General recognition of importance but institutional barriers
"Everybody thinks it’s important to do... but what it actually implies on a legal level, on a remuneration level, and in terms of institutionalization… That’s a different story."

Need for remuneration model for patient experts
"And also a remuneration model; that should be in place. Let’s put it very directly: [my institution] is far from there."

Unclear criteria from funding bodies
“I’m quite unclear about what is really analyzed and taken into account by the FNS regarding these PPI elements... I said: ‘It would be good to know the criteria...’ In short, I find it very vague at the moment.”
"I’m quite unclear about what is really analyzed and taken into account by the FNS regarding these PPI elements."
"We had one rebuttal where (…) we really didn’t know what they (the SNSF reviewers) meant. So I thought: "wouldn’t it be great if, when you get a rebuttal letter, you could book a half-hour slot just to ask questions about it?""

4.3 CTU staff training

Informal initial training
“I got, of course, an introduction from my colleague (...) but no official training.”
"No, no, it’s just learning by doing."
"No, no. So far, I haven't received any formal training; neither myself nor our team."

Need for harmonized training and terminology
“And it would also be great to have national definitions, a shared terminology for PPI. For example, I say PPI but many people talk about PPIE. That’s one thing that could really be harmonised at the national level”
"It would be great to have some basic training or foundational information provided for everyone who needs it or wants to get a clear overview just to make sure we’re all talking about the same thing, whether it's with researchers, with patients, or between CTUs.

4.4 Views on PPIE

Added value of PPI
“For me, it really means going back to the basics and asking: Why am I doing research? Who will it serve? It serves the patient (…) It’s research that’s much more human-centered (…) stronger, more impactful research (…) better recruitment and retention.”
"PPIE is a missing puzzle piece in research.

Openness to multiple perspectives enhances impact
"As a researcher, the more open you are to look at your problem from different angles, the higher is the chance that you'll change something with research."

Importance of patient lived experience
"It’s absolutely mandatory to recognize that the lived experience of patients... is part of the condition... to ignore the patient’s lived experience... is simply ignorant."

Skepticism about the value of PPI in complex research
“I don’t think it’s that valuable for research, to be honest (...) Researchers are often at a loss as to how patients could meaningfully contribute (...). Many of them see it as just another burden (...). I also have my doubts. I mean, how can patients or patient organisations really provide valuable input on such complex and technical projects?”

Questioning the purpose
"But you know what's harder for me to understand? It's what the actual purpose is, what they're trying to achieve. Is this just something we do to get funding, or is it supposed to be a real principle guiding the organization?

4.5 Tokenism

Tokenism can be unintentional and still harmful
"Sometimes you can imagine that you have all the tools but just it doesn't work(…). It's not really like intentional tokenism, but then it's factual tokenism, because there's really no interaction that happens."

Overcoming tokenism through intrinsic motivation and evidence
"Mostly when researchers are doing PPI for the first time (...) it's a box to tick. I call it extrinsic motivation (...) But once they realize it's actually helpful for the project, it changes. They start to see the intrinsic motivation, and that's really the key shift we need to make."

Ideal of patient partnership as shared decision-making
"The gold standard to avoid tokenism is (…): "do not only let the patients advise but actually let the patients decide.""

4.6 Assessing the participation process

"It is one of our goals. It is difficult to do yet, but we are working on it.

Evaluating actual PPIE process and need for guidance
"Not... not as an obligation (to evaluate the PPI process). You know, if you look at the IICT call, you have all these processes (...). But it's a huge amount of work, and you don't see any money coming with it. So it gets really burdensome. And if you add another process on top, the researchers are going to be really reluctant. But still… it needs to happen. Not in the form of 'you have to do it this way,' but rather with more support, more guidance, more examples."

Learning through evaluation
"Yes, I think [it is important to assess the participatory process]. First of all, it's a way to learn. it's not always perfect the first time, but we can improve. And taking a step back to reflect on what was done; that helps when setting up future partnerships, in new projects."

4.7 Challenges

Need for clearer guidance
"I do think it's useful. What I think is missing is a bit more clarity on how to actually do it."

Fragmentation and coordination issues at national level
"… different groups forming around PPI at the national level. … are these groups actually talking to each other? … It's kind of all over the place."

Lack of integration of PPIE into research methodology
"What's blocking the development of partnership at the CRC is mostly that it hasn't been fully integrated into research methodology yet."

Resource constraints and limited capacity
"I think the biggest barrier is definitely resources, capacity. We're a small team, and the people who could support PPI are already overwhelmed with regular study management tasks."

Limited capacity for dedicated PPI roles
"Filling that role isn't easy, especially when you already spend 99% of your time on other tasks in the CTU and PPI is only 1% of your work. So I'm a bit… skeptical, yes."

Risk of marginalization of PPIE at institutional level
"The risk is definitely that it's marginalized before it even starts to being implemented."

Risk of PPIE support disappearing due to lack of institutional support
"There is a risk that it [PPIE] disappears again [in my institution] already now (…), not being taken as really important [by the institution]."

4.8 Enablers and successes

Demonstrating benefits to researchers
"I think we need to show investigators that they have everything to gain from partnership. Because right now, there aren't really any striking examples. We can't say, 'Look, without partnership, this never would have happened.' Or maybe such cases exist, but we don't showcase them enough."

Raising awareness through accessible communication
“Researchers want to read: ‘involving PPI in this way improved recruitment’ or ‘It improved the relevance of the endpoints.’ If we can show that with evidence, they’ll be much more likely to engage.”
"Raising awareness. (…) Not just with scientific papers (those are important for us as researchers) but also with more accessible, eye-catching tools.”
"Social media campaigns and success stories can help. Showing the benefits of PPI, maybe even with more commercial formats, like a short TV spot... That kind of visibility really helps.”

Gradual growth and learning from others
“So maybe we just need to jump into the cold water when the first request comes. Reach out to other CTUs, learn from them. Like you said, by looking at their different models, whether it’s involving patient organizations or external experts.”

Raising awareness through communication and informal channels
"If one day we could also get on social media, (…) to gently open minds (…). Maybe in a less formal way than training, but it could also be an interesting channel to foster this culture."

4.9 Future perspectives

Institutional leadership and support
"Our leadership needs to be supportive and… really say it loud and clear."

Plans to embed PPI in CTU’s own work and patient involvement in project management
" (…) we should have patients in our project management team."

Early integration of PPIE into professional training
"I think it would be really good to implement PPI early in medical training."
"I've also been talking with my boss about how important it is to build capacity among students, especially from the nursing school here. I think this topic should be included as part of the educational program."

Scale and centralization needed for evaluation
“But if you want to do research-on-research, it probably won't work if you only do it in one study (...) You would need something bigger, like a survey comparing lots of trials (...) led by SCTO or another central body, it’s hard to do on a single-study level.”

4.10 Emerging themes

Concern about biases due to personal interest
"Patients are biased because they're only interested in their own benefit. Well, of course! But that's part of it!"
"Scientists are biased because they want pure science. Industry is biased because they want to sell a product. We all are, in a way, biased."
"With experts we ask them to declare the conflict of interest and to patient, not yet because it's not common."
"But we'll never be 100% sure that a patient isn't putting their own interests first."
"Yes, it can happen (…). We often have patients who don't have the condition being studied, and I think that helps reduce conflicts of interest."

Identity as "super patients" combining science and experience
"Quite a few of the patient experts (…), a large number (…) are actually scientists, in a certain way."
"We call ourselves 'super patients'... we know science, and we know the patient perspective, and so we can combine that... but that's really risky."

Risk of creating an academic bubble among patient experts
"Quite a large number of these patients are actually scientists, in a certain way... The risk is to just create another academic bubble, right?
So to really make sure that you represent patients, it's quite a different story."

Vision for establishing professorship in PPIE
"[my institution] or maybe another university, should really aim to establish a professorship in Patient and Public Involvement..."
"There are universities in the UK, for example, where they have professorships specifically dedicated to PPI."

Training as core to culture
"For me, if we really want to implement a culture, people need to know, they need to be trained. Training is at the heart of all this."

Value of the "naïve patient"
"I seriously wonder: do we really need patients to be experts to that extent? ... I really like the naïve patient side which maybe corresponds more to your average Joe and Jane in the population. At least for many things, the naïve patient is almost more useful to us than the expert patient."

Challenges in researcher-patient communication and role of experts
"It's difficult, sometimes, to know in which projects patients could really help or contribute meaningfully (…). Maybe that's exactly where an expert could play an important role, as a moderator between the two."