Hôpitaux Universitaires Genève

Inclusion of the patient perspective in clinical research: Reflections and experiences from the Partner REC (Partenariat en Recherche Clinique), HUG, Geneva

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- MSc Publishing, academic & research publishing
- patient member of the Partenariat en Recherche Clinique, HUG: 2019 to present
- patient expert, trained on medicines R&D for patient experts with the European Patients' Academy on Therapeutic Innovation (EUPATI, 2015-2016)

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Relevant experience

- 15 years as patient advocate (endometriosis)
- EUPATI alumna
- IMI pool of 150+ patient experts
- bringing the patient voice, engaging with HUG
- *British Medical Journal* (patient peer review & Opinion piece)
- "What's in a name? From 'subject' to 'participant'", article published in *The Advisor*
- patient input on R&D application for funding to SNSF
- pharma consulting, e.g. on lay communications material with patients, risk-benefit, health literacy, etc.

Who got the ball rolling?

After the 1990s, HIV+ patients demanding engagement…

BMJ 2013;346:f2614 doi: 10.1136/bmj.f2614 (Published 14 May 2013)

BMJ

EDITORIALS

Let the patient revolution begin

Patients can improve healthcare: it's time to take partnership seriously

Tessa Richards *analysis editor*[1], Victor M Montori *professor*[2], Fiona Godlee *editor in chief*[1], Peter Lapsley *patient editor*[1], Dave Paul *secretary of the patient advisory group*[2]

For its part the *BMJ* is stepping up its commitment to patient partnership. We already have an online collection of articles on shared decision making and a growing library of patient journey articles.[13] Now we want to develop a strategy for patient partnership that will be reflected across the entire journal. We plan to establish a panel of patients and clinicians to help us with this work and will report back on our progress.

Key questions

Patient implication in research:

- **What** is it?
- **Why** do we need it?
- What is the **current** setting?
- **How and when** should it happen?
- What **evidence** exists to build it?

What is patient involvement?

Patient and public involvement entails research being carried out *with* or *by* members of the public, rather than *to*, *about* or *for* them.

The word *public* can refer to **patients, potential patients, carers and people** who use health and social care services, people from organisations that represent people who use services as well as members of the public. **Patient and public involvement** is often abbreviated to PPI.

INVOLVE (now NIHR Centre for Engagement and Dissemination)

Nothing about me, without me.

Why do we need it?
What can go wrong *without* patient involvement?

- e.g. "Attractiveness of women with rectovaginal endometriosis: a case-control study", 2013, Vercellini P, et al.
- "a 5-point rating scale: 5 = very attractive to 1 = not at all attractive"
- noted: weight & height assessment; measurement of hip, waist, breast & under-breast circumferences; sexual history (age at which they became sexually active).
- The women taking in part in the study had *not given their consent to be judged for their attractiveness* and did not know this was happening as part of their medical consultations.

Article retracted seven years later…

the guardian

‘Disgusting’ study rating attractiveness of women with endometriosis retracted by medical journal

Fertility and Sterility took seven years to take down Italian study, which was criticised by doctors for ethical concerns and dubious justifications

What changes are underway in Switzerland?

Investigator initiated clinical trials (IICT)

FNSNF
SWISS NATIONAL SCIENCE FOUNDATION

Patient and public involvement

In the research plan, applicants must explain what they have done to involve patients and members of their family or the general public in the conception and planning of the project. If no patient or public involvement was possible, the reasons for this need to be given in the research plan.

Where and how can patient involvement take place?

Table 1: Examples of possible patient and public involvement during clinical research stages

Clinical research stage	How patients and the public can be involved
Choice of the research topic	• Participate in surveys and focus groups on the relevance of the study topic • Propose a research theme or topic
Elaboration of the protocol	• Proofread, revise, and/or co-write parts of the study protocol • Discuss, advise on, and/or test the relevance of patient-centred outcomes • Proofread, edit, and/or co-write patient information
Conduct of the study	• Contact patient organisations to inform them about the study and facilitate the recruitment of interested patients • Liaise between the patients participating in the study and the research team in order to obtain feedback on their experiences and impressions
Interpretation of the results	• Discuss the appropriateness of intermediate or final results • Modify patient information, if necessary • Discuss the relevance of the results
Writing and publishing	• Participate in writing and proofreading the research article • Disseminate study results via patient organisation networks • Set up patient forums to inform others about the study results • Review documents that are intended for the public and/or published on HUG websites • Become involved in public events related to the research study
Implementation and change of practice	• Help develop recommendations for better hospital management • Advise on the practical aspects of implementing recommendations

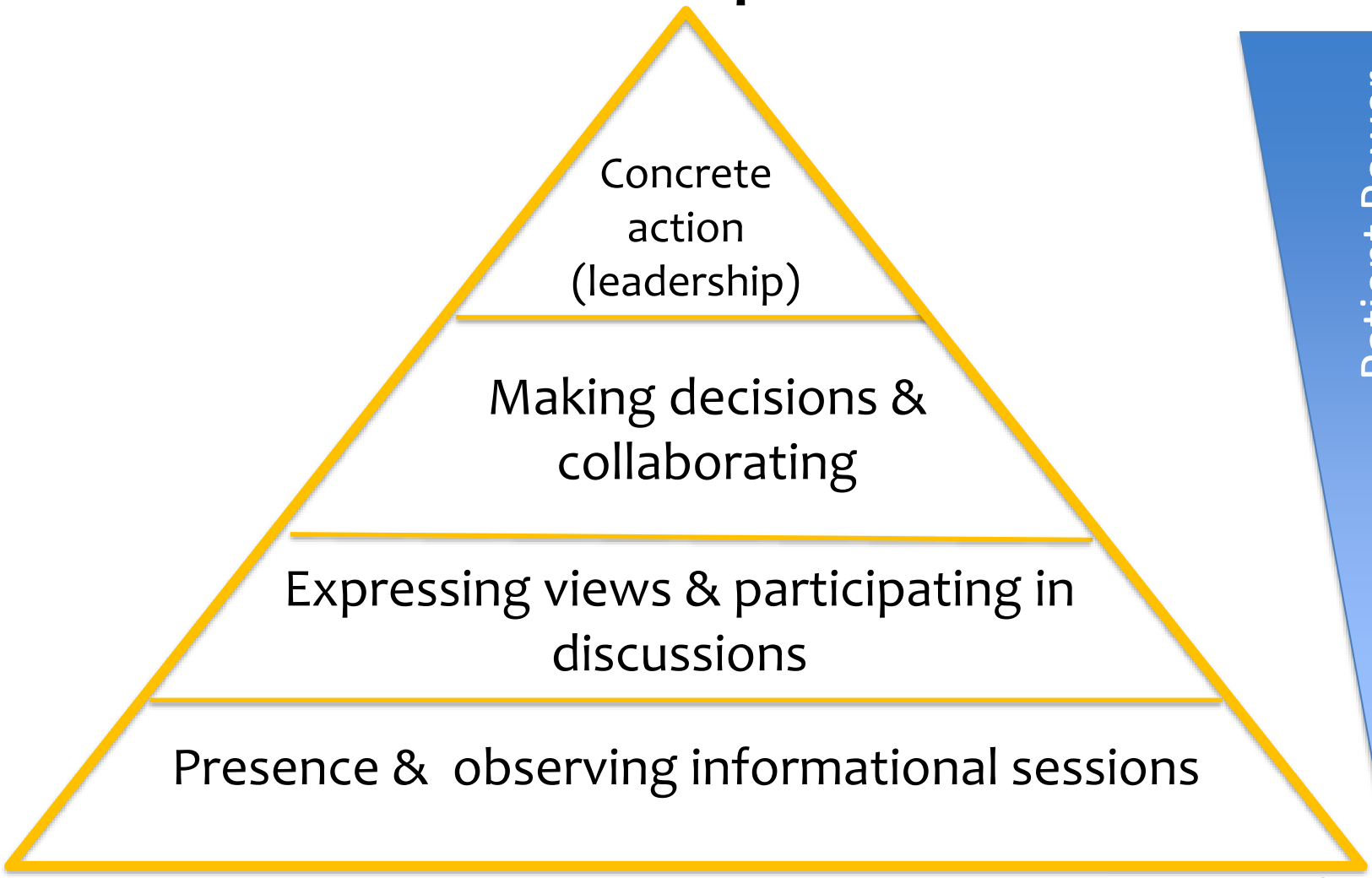
Beyond Europe: the FDA perspective

Further integrating patient perspective into medicines development and decision making

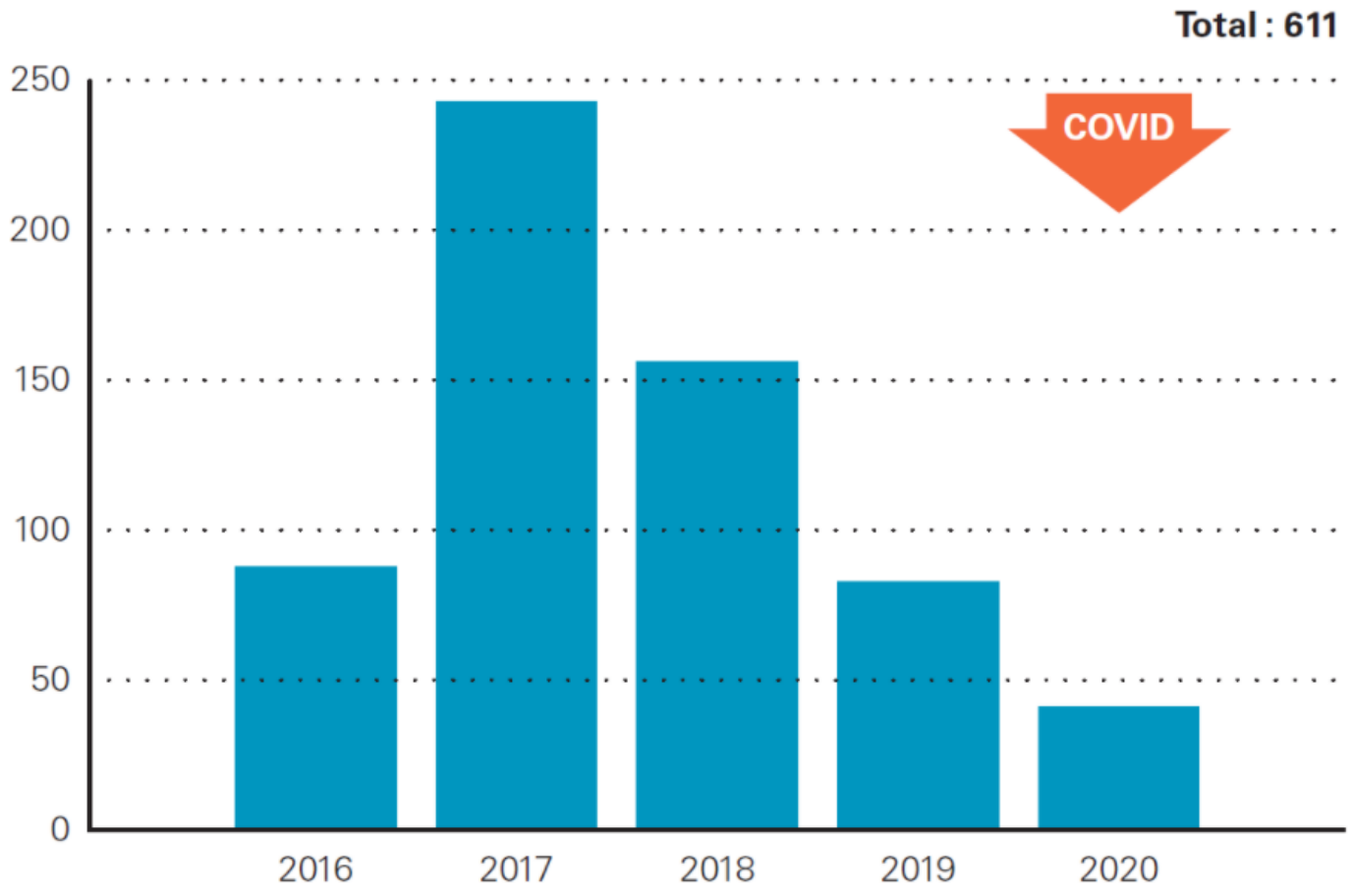
Translational	Clinical Studies	Pre-market review	Post-market
What impacts (burden of disease and burden of treatment) matter most to patients and how to measure them?	What aspects of clinical trials can be better tailored to meet the patients who (might) participate in the trial?	How to better integrate patient reported outcome data or elicited patient preferences into Benefit-Risk (BR) assessments?	How to best communicate the information to patients and prescribers?

Source: Dr Theresa Mullin, Associate Director, Strategic Initiatives, FDA Center for Drug Evaluation and Research, Geneva presentation at Council for International Organizations of Medical Sciences (**CIOMS**) meeting, 30.04.2019

What is the continuum of patient involvement?



HUG: How did patient recruitment evolve?



PROGRAMME Patients Partenaires +3P Proches Professionnels Public

Who makes up our working group, Partner REC?

In collaboration with the Patients-Partenaires team, HUG

PROGRAMME Patients Partenaires +3P Proches Professionnels Public

Feb 2019 till the present:
Our working group is made up of… patients, researchers, nurses, a member of a Cantonal Research Ethics Committee (CCER), and the +3P patient partnership team (staff)

What is the diversity of roles in our group?

Dre ès Sc Tourane CORBIERE
Patiente partenaire
Cheffe de projet

Pr Nadia ELIA
Médecin adjointe agrégée
Département MA
Cheffe de projet

Pr Angèle GAYET-AGERON
Médecin adjointe agrégée
Responsable d'unité,
Direction médicale et qualité

Dre Angela HUTTNER
Médecin adjointe agrégée,
Département de médecine

Pr Caroline SAMER
Médecin adjointe agrégée
Responsable d'unité
Département MA

Estelle JOBSON
patiente partenaire

Pr Klara POSFAY BARBE
Médecin cheffe de service
Département de la femme
de l'enfant et de l'adolescent

Aurélie Perret
Cheffe de prog vision 20+5. +
de recherche et innovation
au quotidien

Sylvie TOUVENEAU
Programme Patients
partenaires

Pr Thomas AGORITSAS
Médecin adjoint agrégé
Département de médecine

Sonia CARBONI
Collaboratrice scientifique
Centre de recherche clinique

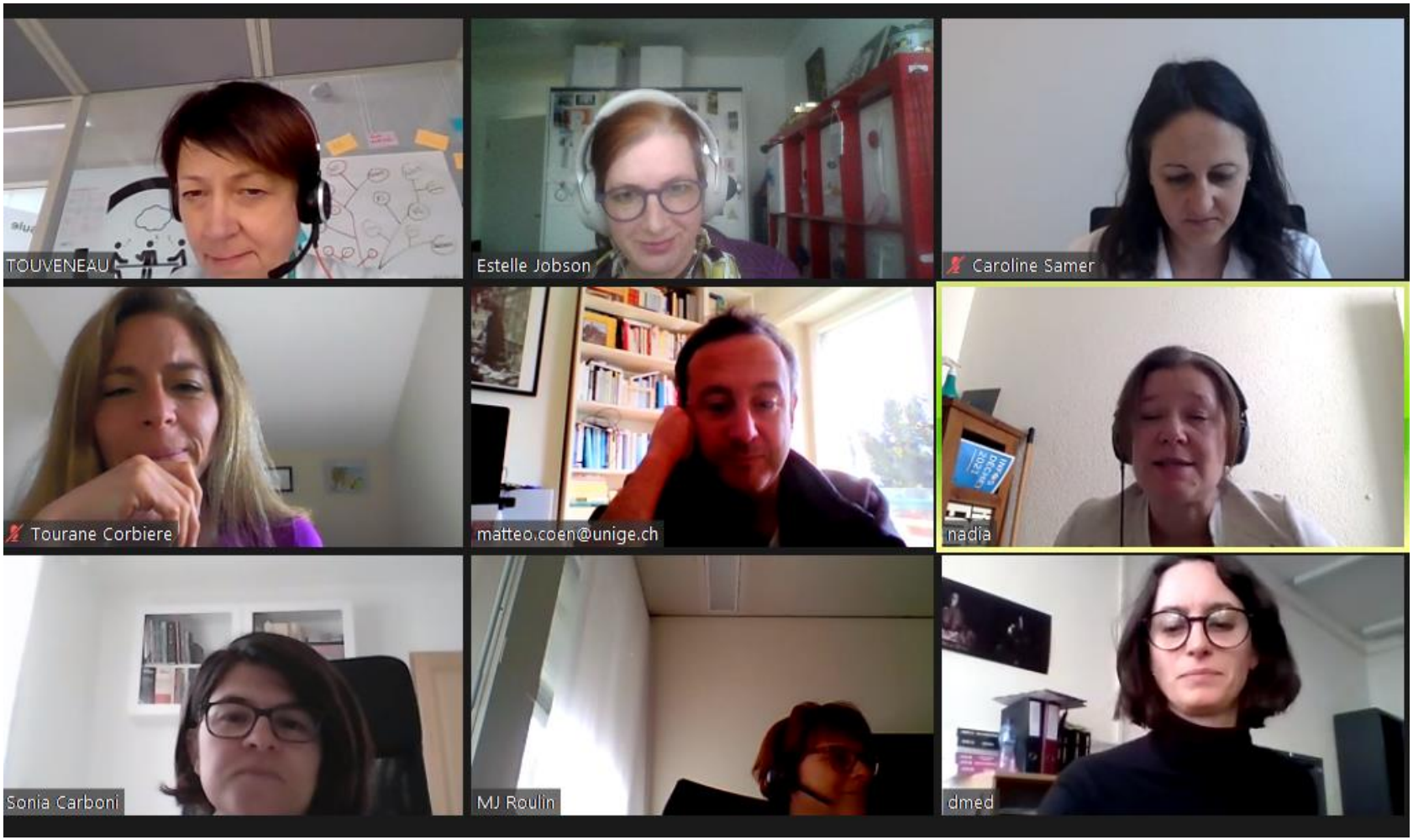
Monique A. CAILLAT
Avocate, spécialisée en
médecine et science de la vie

Dr. Matteo COEN
Chef de clinique
Département de médecine

Marie-José ROULIN
Adjointe de direction,
Direction des soins

Malek CICETTI-LAHMAR
Secrétaire
Direction médicale et qualité

What happened during lockdown?



Key developments to date

- brainstorming 6 stages of engagement
- developing toolbox: **recherche.hug.ch**
- to summarise opportunities to partner with the group
- presentations at HUG conferences, e.g. Journée de la Recherche
- inviting clinical researchers to propose opportunities in their own projects
- article in *Regulatory Affairs Watch* newsletter, 28 Oct 2021
- declarations of conflict of interest / statement of transparency & intention

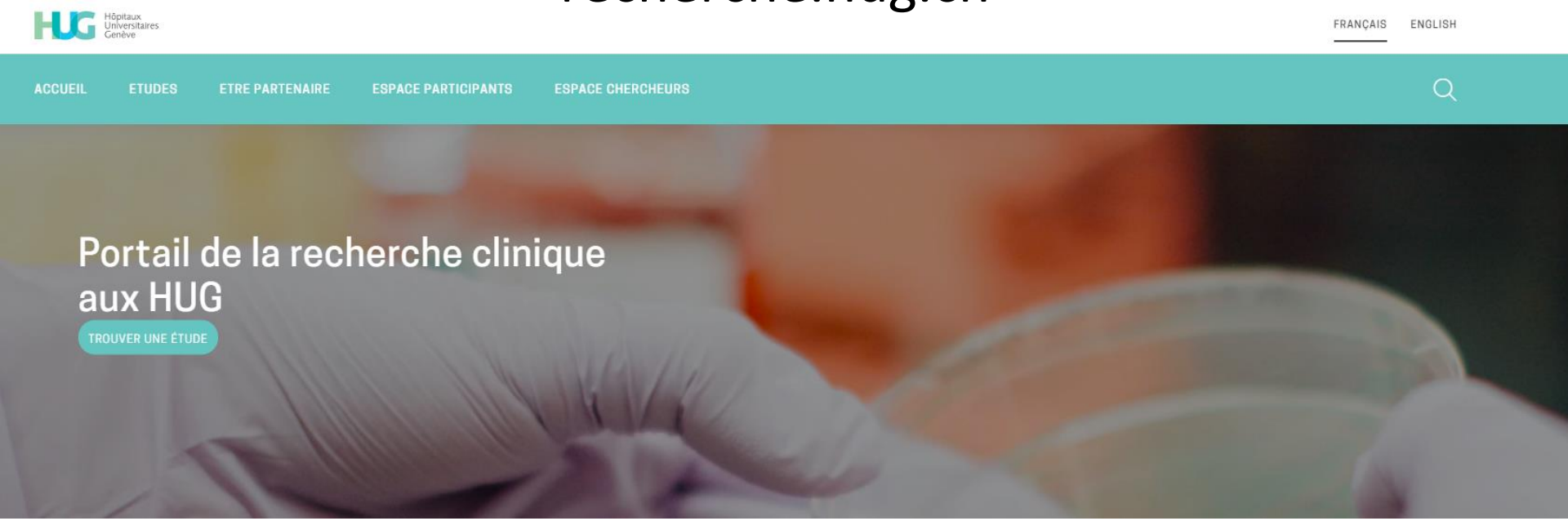
As of September 2021: seven projects discussed

- structured brainstorming > different ideas and strategies emerge > new contact with patients for potential further involvement or organisation of a focus group

- areas of R&D covered, at different stages of advancement: e.g. cancer therapies, neonatology, gerontology, neurology, neuropathic pain

- for certain projects, patients or alternative partners suggested (e.g. caregivers, prior patients)

recherche.hug.ch



La recherche s'ouvre au grand public. Vous pouviez déjà participer à une étude en tant que sujet ou contribuer à l'avancée de la science en partageant vos données médicales. Désormais, il est possible d'intégrer une équipe et devenir co-chercheur ou co-chercheuse.

Cette plateforme informe sur toutes les modalités de partenariat pour la recherche médicale et présente les études en cours aux HUG.

Etre partenaire

Patients, patientes, proches, citoyens, citoyennes… découvrez comment participer activement à la recherche médicale.

CONTRIBUER

Participants, Participantes

Vous participez ou avez participé à une étude ?

Consultez notre documentation, ou donnez-nous votre avis.

SUIVRE

Chercheurs et chercheuses

Membre d'une équipe de recherche ?

Trouvez les incontournables de la recherche, ou donnez-nous votre avis.

PARTAGER

Fondation privée des HUG

recherche.hug.ch

Contribuer à la recherche médicale

La recherche médicale vous intéresse ?
Il existe différents moyens d'y contribuer.

Participer à une étude clinique

Participer à une recherche en tant que sujet d'étude. Trouvez l'étude qui vous convient

EN SAVOIR PLUS

Devenir contributeur de la recherche

Travailler avec une équipe de recherche à la mise en place d'une étude clinique

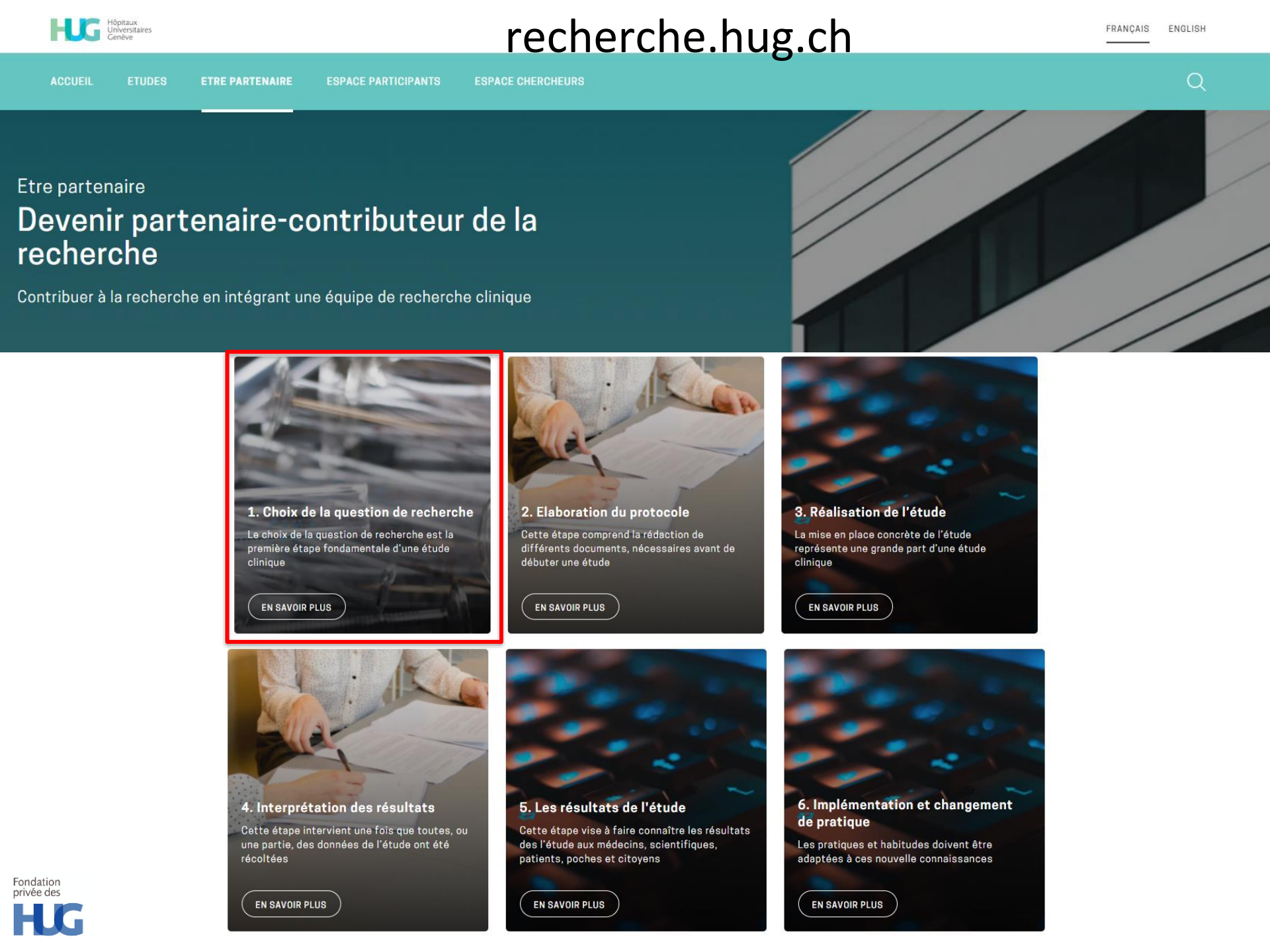
EN SAVOIR PLUS

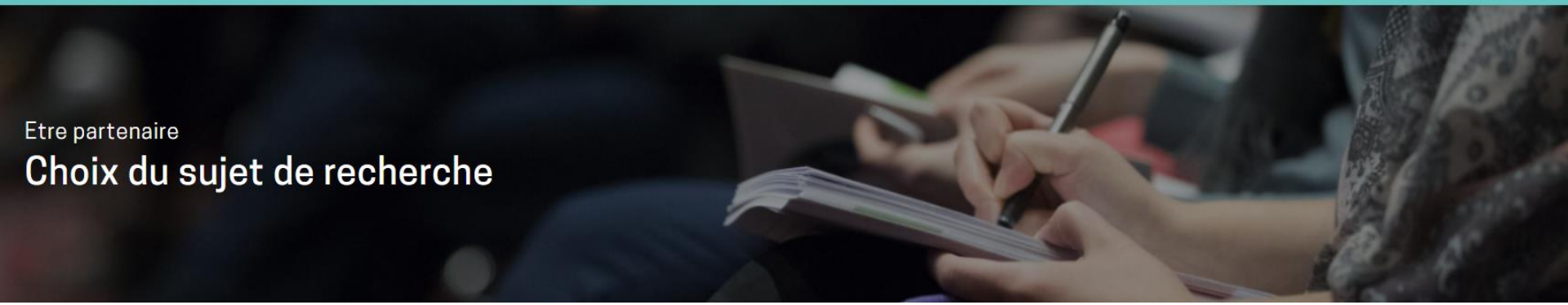
Autoriser l'utilisation des vos données

Partager vos données personnelles en autorisant leur utilisation pour des recherches futures.

EN SAVOIR PLUS

recherche.hug.ch





Etre partenaire

Choix du sujet de recherche

Le choix du sujet est la première étape d'une étude. Il se caractérise par une réflexion en groupe afin de clarifier, affiner et définir une question pertinente du point de vue de la science mais aussi du grand public. C'est un moment privilégié pour initier un partenariat et poser les jalons de la collaboration pour les étapes suivantes.

Exemples d'implications :

- sonder les intérêts et priorités auprès des associations de patients et patientes
- mener des enquêtes et des groupes de discussion avec des patients et des patientes autour de la pertinence du sujet de l'étude
- établir un projet de recherche compréhensible et acceptable d'un point de vue pratique et moral
- proposer un thème ou un sujet de recherche

Intérêt pour les chercheurs et les chercheuses

- faciliter le recrutement grâce à des informations compréhensibles pour le grand public
- garantir une étude dans laquelle les patients et patientes se sentent à l'aise
- publier des documents clairs et compréhensibles pour le grand public.

Intérêt pour les patients et patientes

- suggérer des mesures de résultats pertinentes du point de vue du public
- proposer un déroulement de l'étude plus pratique et plus confortable pour les patients et les patientes
- améliorer le contenu des documents d'information
- pouvoir poser des questions et comprendre en détail la recherche
- valoriser l'expérience de la maladie pour améliorer le parcours d'autres patients et patientes.

What are the current setbacks or challenges?

- a delay in patient involvement in research
- lack of compensation framework
- patients too often considered primarily as sources of data
- patients viewed as “subjects”, not as equals or participants
- and not as true partners in research

Hear it from a peer

Researcher turned patient:

*[Getting cancer] … **really shaped the way that I do research**. It's most importantly given me the **perspective** of what it means to be a patient, and I see things through **that lens** as well as the **research lens**, now. So when someone comes to me and says I have this great idea, I'm asking myself not just **can I get this idea published**, will it make me more famous, will it advance my career; I'm asking myself is this actually going to help anybody? Is this going to cure anything? **Is this going to progress the field forward**?*

Explore our toolbox,
follow our lead, get in touch.

Partner.Rec@hcuge.ch
recherche.hug.ch

Thank you for your attention

with thanks to co-leaders:
Dr Nadia Elia
Unité d'Investigations Anesthésiologiques
Anesthésie-DMA, HUG
&
Dr Tourane Corbière
Fellow patient participant