

# Patient Engagement in Cancer Research: A Comparative Evaluation between Europe and Japan

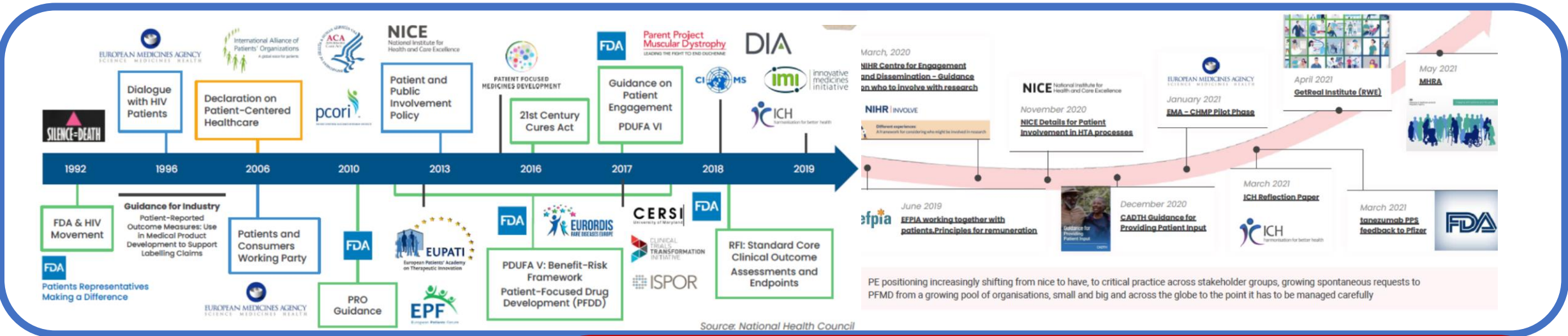


**Laureline Gatellier, PhD, MBA**

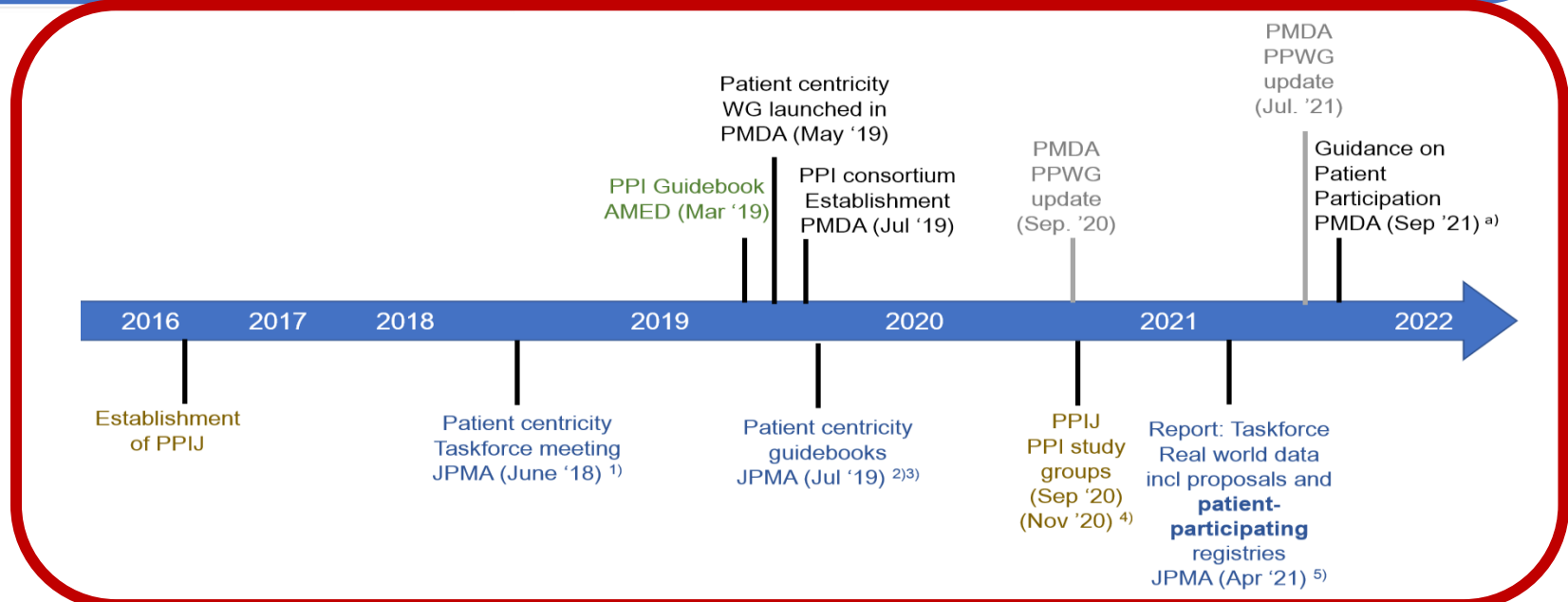
- **Researcher** @ National Cancer Center Japan
- **Board member** @ Rare Cancers Japan
- **President** @ Japan Brain Tumour Alliance

**Béatrice Serckx, PhD - EU Support**

# Background of patient engagement



- EU: Faster advances in the last 2-3 years as much as 27 previous
- Japan: relatively newer



# Project Methodology (1)

## Preliminary decision

To capture the differences between Japan and EU, it was decided **early** to conduct a survey on Cancer Research in EU and Japan. The survey was originally planned to be conducted by Principal Investigators belonging to academia and pharmaceutical companies. On this basis a **Pilot Survey** was launched a year ago

Beatrice, ... a rediscute  
ce que je pensais dire  
que la pilote a ete en  
pharma et a l'academ  
en resultat de la "pilote"  
avons decide de nous  
sur l'academia. Bien  
veux pas me repea  
pourrait eliminer les re  
ailleurs alors

## Pilot Study (May – June 2022)

- Japan: 10 sent questionnaires  
Response rate: 80% (8 answers)
- EU: 14 sent questionnaires  
Response rate: 7% (1 answer)

Outcomes

## Identified Challenges

Big difficulty to get answers in EU due to potentially

- Lack of motivation of responders
- Generic addresses
- Questionnaire might be too long
- Cultural difference
- Uniformized responses of pharmaceutical companies
- Major incentive in JP : **Leader in the field** (JCOG Director) is part of the project steering Committee

## Countermeasures

- Identify the “sponsors” of the selected Cancer Research to get their support for the survey.
- Review the questionnaire to make it shorter

# Project Methodology (2)

**Meet with experts, key players in Cancer Research & funding organisations and Authorities (EMA)** to get support, review the survey questionnaire, to better understand blocking points, vision and overall landscape

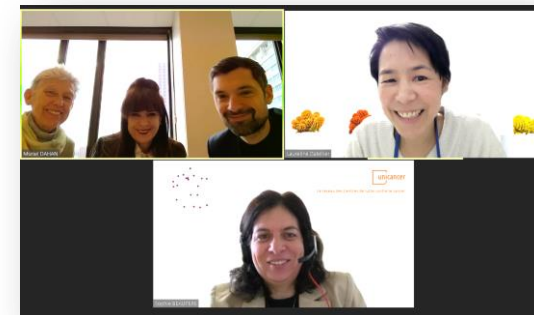


- OECI : T. Philip, G. Apolone
- UNICANCER : S. Beaupère, M. Dahan, M. Canovas, B. Juzyna
- ESMO/UNICANCER: JY Blay
- EORTC : D. Lacombe, S. Lejeune, I. Shakhnenko
- EMA : M. Mavris
- PFMD, The Synergist : N. Brooke, L. Dewulf, E. Priest
- Hosp. St Luc /previous President EORTC: B. Tombal
- Hosp. Bordet: P. Miqueu
- Inst. Paoli-Calmettes: M. Bouyssié
- Patient Organisations
- **JCOG/NCCJ: K Nakamura**

And others

Outcomes

- Fine-tune the survey criteria
- Fine-tune the survey questionnaire
- Active survey support
- Invitation as speaker in different public audience (JSCTR, PPI-Japan, JPPaC, OECI, JSNO...)
- EMA 's proposal to launch a parallel survey with the EU Patient Organisations



# Project Methodology (3)

2) **Main survey** launched **with Research Principal Investigators** of **academia-led clinical trials / clinical research**

## Survey Criteria summary

<b>Research Steps</b> (EUPATI scheme) <ul style="list-style-type: none"> <li>- Research priorities</li> <li>- Research design and planning</li> <li>- Research conduct and operations</li> <li>- Dossier submission</li> </ul>	<b>Selected Cancers</b>		<b>Research Sponsor</b> Academia, Institutions, Hospitals
	<b>Breast</b> Common, F <b>Prostate</b> Common, M <b>Colorectal</b> Common <b>Lung</b> Common, most frequent in EU/JP <b>Pancreas</b> Common, low survival rate <b>Brain</b> Rare <b>Sarcoma</b> Rare	<b>Research Period</b> 1-Jan-2018 to 31-Dec-2022	
<b>Patient Engagement self assessment</b> <ul style="list-style-type: none"> <li>- Principal investigator (through surveys)</li> </ul>	<b>Region</b> <ul style="list-style-type: none"> <li>- <b>JP</b></li> <li>- <b>EU:</b> France, Belgium, UK, Germany (+OECI)</li> </ul>		<b>Clinical Trial Databases</b> <ul style="list-style-type: none"> <li>- <b>EU:</b> EudraCT</li> <li>- <b>JP:</b> UMIN and JRCT</li> </ul>

## Survey PE/PPI Maturity scale

- Co-Creation / Partnership
- Actively involved
- Informed / consulted
- Considered
- No PE/PPI

Region	# Selected ID from Database
EU	205
Japan	135

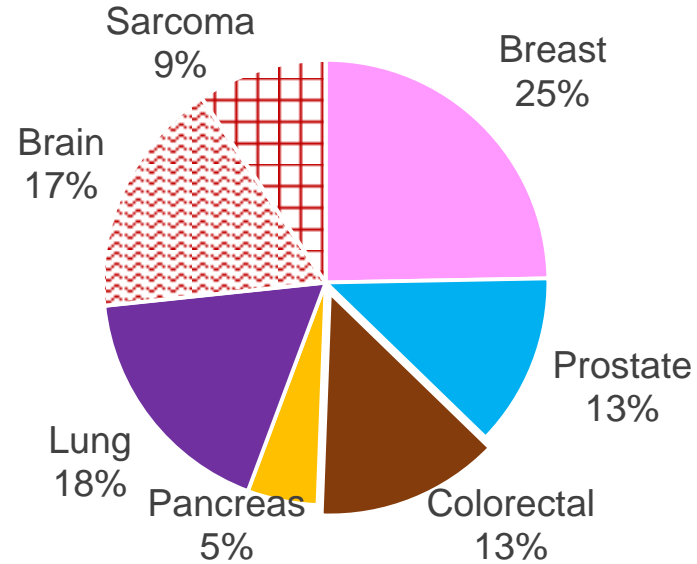
# One-page Questionnaire

Is PE/PPI occurring or planned in your study? ?	No	Considered	Informed or consulted	Actively involved	Co-creation / Partnership	Not yet started
1. Research Priorities including defining patient-relevant added value and outcomes	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
2. Fundraising for research	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
3. Protocol design / end points/ study activities	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
4. Informed Consent, Patient Information, and other Information to Trial Participants	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
5. Ethical review	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
6. Investigators Meetings	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
7. Study reporting (incl. dissemination, communication, publishing)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
8. Co-applicant (i.e involved in the regulatory dossier set up for Regulatory Authorities or for Funding Organisations)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Other(s) - if others, please describe below	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

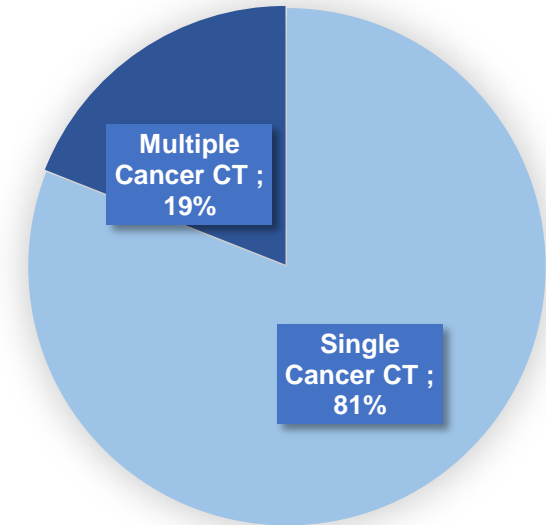


# Landscape of academic cancer research

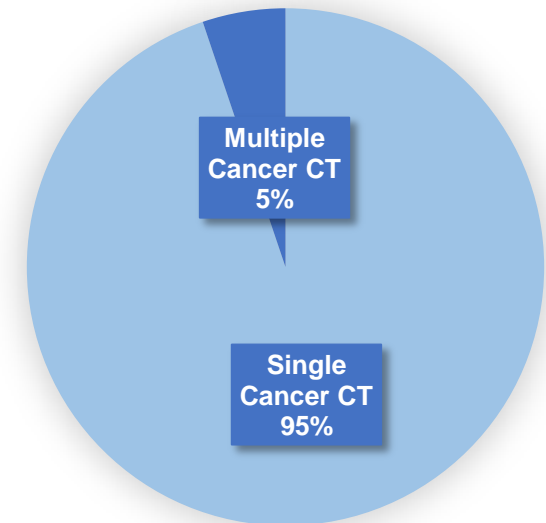
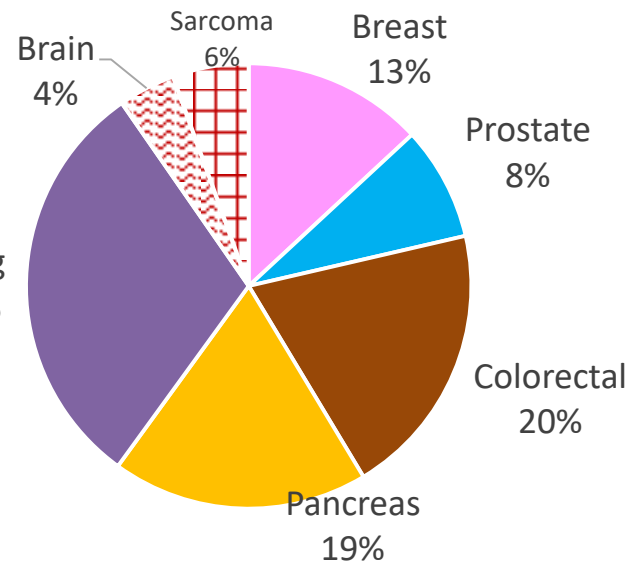
## By cancer types



## By single versus multiple cancers



**Europe**  
BE, DE, FR, UK



**Japan**

# Interim results – 12<sup>th</sup> June 2023

**Japan:** 135 questionnaires sent,  
69 (**51%**) valid responses

**COMPLETED - Closed**

Cancer Centers, University Hospitals, Prefectural Hospitals, Municipal Hospitals, City Hospitals etc

**EU:** out of 126 sent questionnaires,  
only **39 (31%) responses**  
79 questionnaires still to be sent

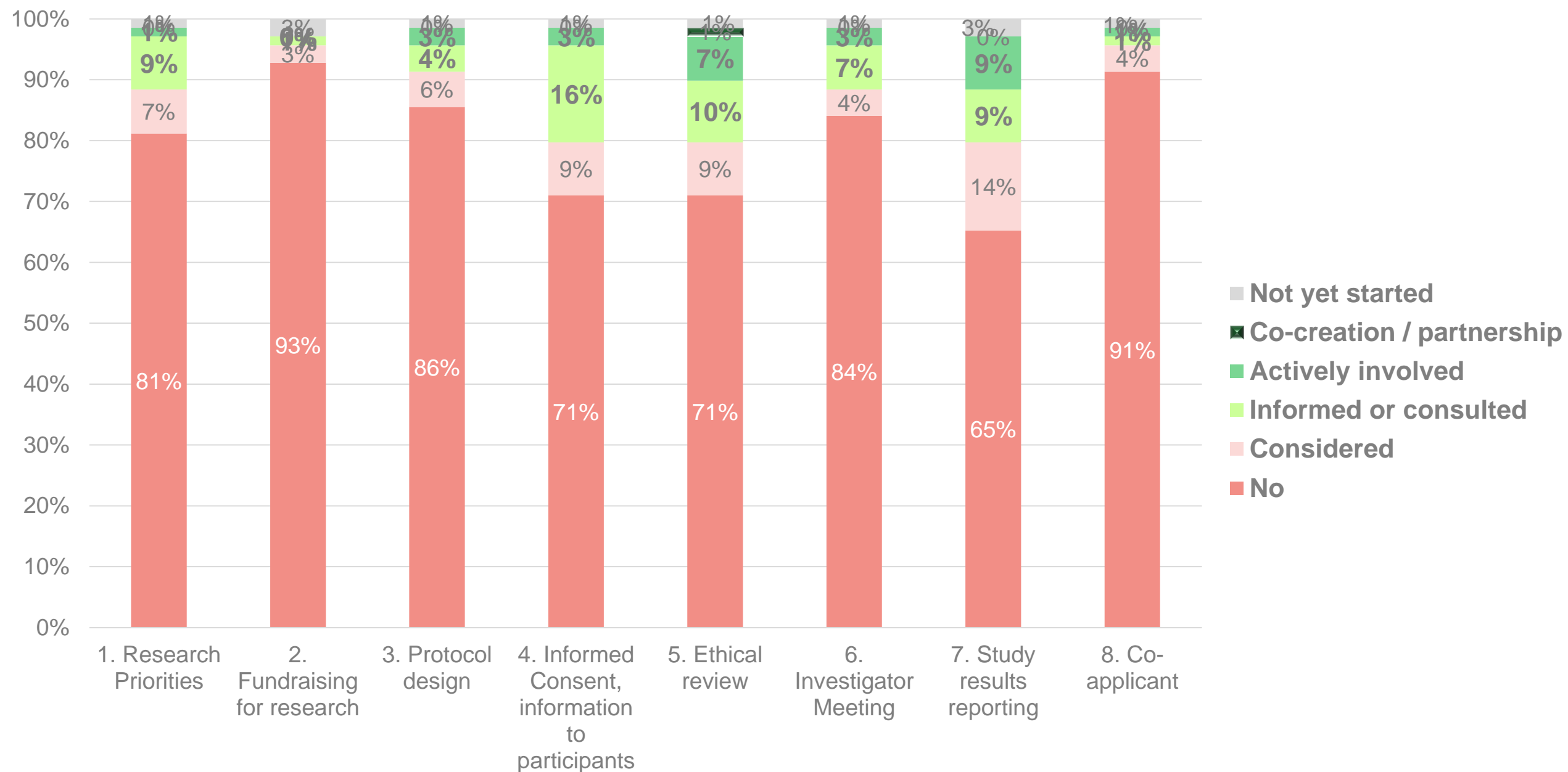
EORTC (12)  
UNICANCER (15)  
Centre Léon Bérard (6)  
Centre Eugene Marquis (1)  
NCT Dresden / TU Dresden (1)  
Deutsches Krebsforschungszentrum (1)  
Centre François Baclesse (1)  
DKFZ (1)  
Centre Antoine Lacassagne (1)

EU Patient Organisations :  
11 responses,

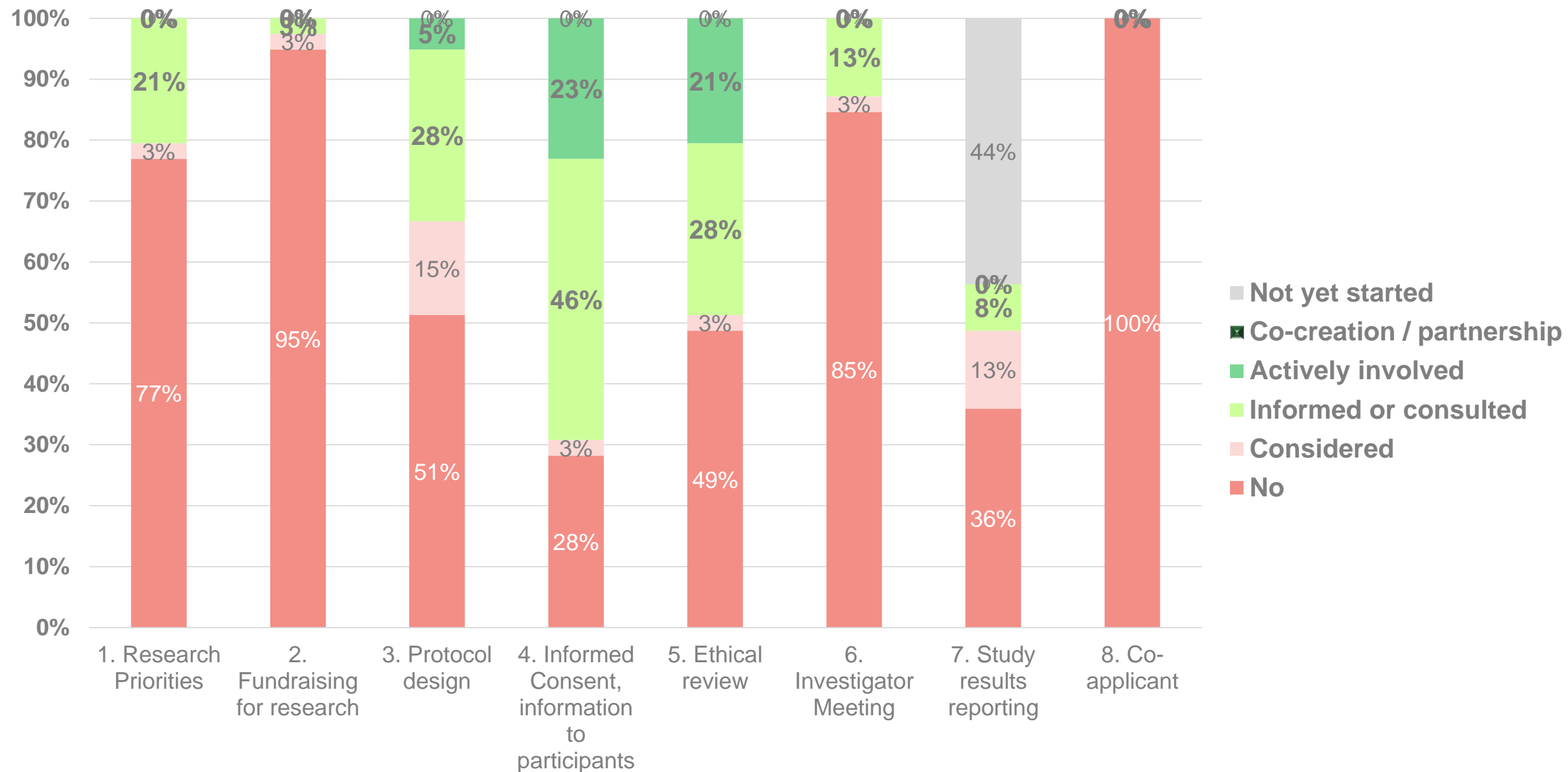
Digestive Cancers Europe  
Europa DONNA  
EuropaUOMO  
European Cancer Patient Coalition  
POLA  
NET en MEN Kanker Belgie  
Europacolón Portugal



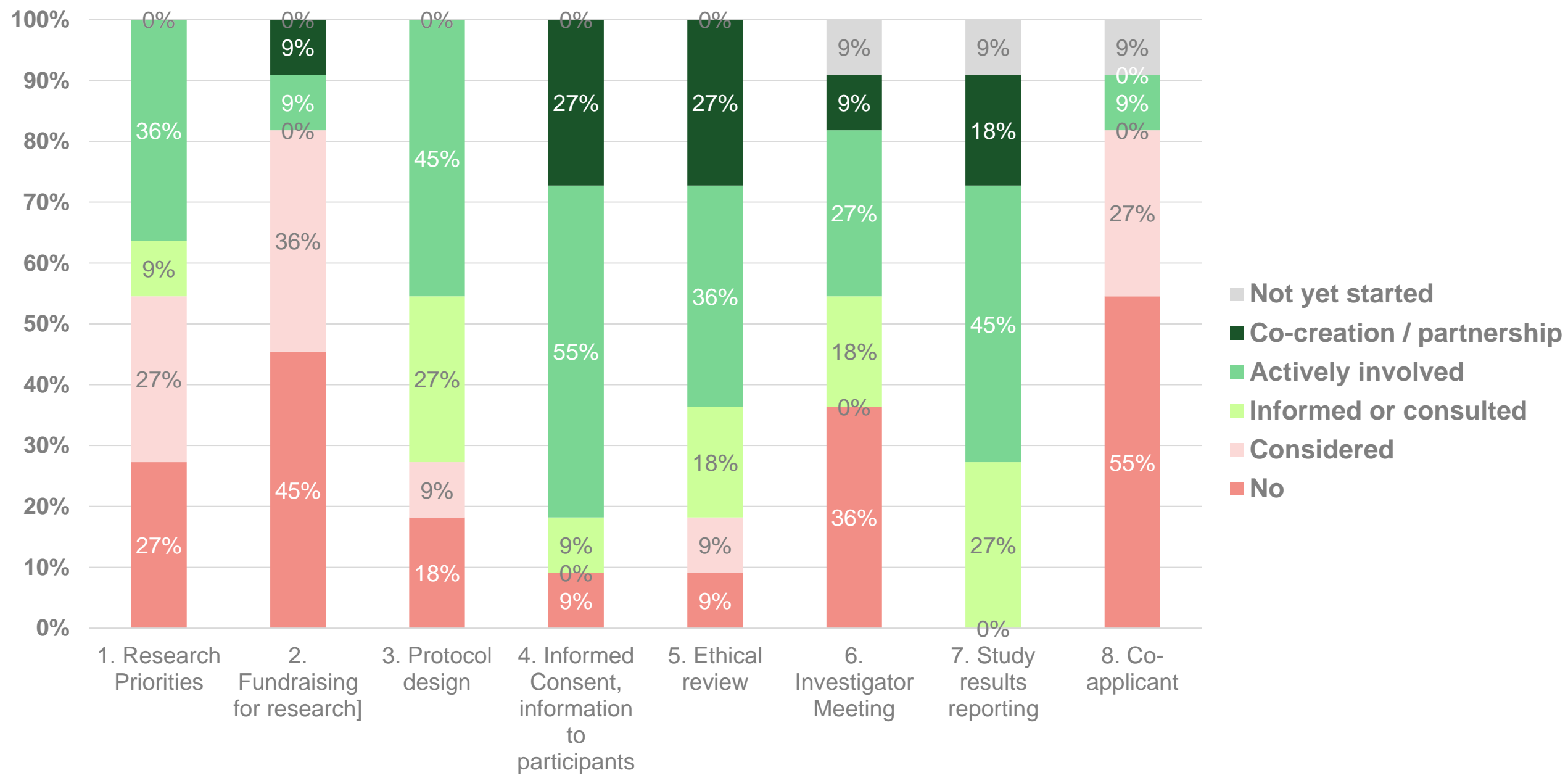
# Responses from Japanese Principal Investigators (n=69, 51%) - FINAL



# Responses from EU Principal Investigators (n=39, 19%) - INTERIM



# As reference, responses from EU Patient representatives (n=11)



## KEY Upcoming Milestones

- **Today** - Jun: OECl Oncology Days – Oral session
- Jun. : sending remaining questionnaires and follow up
- Jul. – Sep.: meeting with the representatives of “best cases”
- Aug : meeting with key stakeholders in Europe
- Sep : Japan Cancer Association: Poster session (tbc)
- Oct : ESMO: attendance (tbc)
- Q4: finalisation of survey data collection and analysis.
- Q1 2024: Confirming results, draft recommendations and report writing

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Thank You!

**EORTC (12) UNICANCER (15)**

**Centre Léon Bérard (6)**

Centre Eugene Marquis (1)

NCT Dresden / TU Dresden (1)

Deutsches Krebsforschungszentrum (DKFZ) (2)

Centre François Baclesse (1)

Centre Antoine Lacassagne (1)

Next actions: Joint email with

**Prof. Bertrand Tombal**, MD, PhD, past president of EORTC to the contact point of remaining studies, asking to answer the short survey.



PAST PRESIDENT

Bertrand Tombal

Cliniques Universitaires Saint-Luc

Brussels, Belgium

EU Patient Organisation  
11 responses,





39

<b>EudraCT Number:</b> 2017-000155-21		<b>Sponsor Protocol Number:</b> UC-0160/1702		<b>Start Date</b> * : 2019-06-04	
<b>Sponsor Name:</b> UNICANCER					
<b>Full Title:</b> An open label, randomized, phase III study, evaluating the efficacy of a Combination of Apalutamide with Radiotherapy and LHRH Agonist in high-risk postprostatectomy biochemically relapsed prostate...					
<b>Medical condition:</b> High-risk biochemically-relapsed prostate adenocarcinoma following radical prostatectomy.					
<b>Disease:</b>	<b>Version</b>	<b>SOC Term</b>	<b>Classification Code</b>	<b>Term</b>	<b>Level</b>
	20.0	10029104 - Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10060862	Prostate cancer	PT
<b>Population Age:</b> Adults, Elderly			<b>Gender:</b> Male		
<b>Trial protocol:</b> <a href="#">FR</a> (Ongoing)					
<b>Trial results:</b> (No results available)					
<b>B.5.6</b>	<b>E-mail</b>				<a href="mailto:getug-afu33@unicancer.fr">getug-afu33@unicancer.fr</a>



Emails on their ways to other institutions

- Other institutions

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OECI Members

- APHP (6)
- Centre Léon Bérard (still 4)
- Charité Universitätsmedizin Berlin (3)
- Hôpital Erasme (1)
- Gustave Roussy (3)
- Institut Jules Bordet (5)
- Paoli Calmettes (1)
- Inst. Reg du Cancer Montpellier (5)
- The Christie Hospital NHS (1)
- UZ Brussel (3)

# We need your support !

Further discussions or details needed ?  
Don't hesitate to come to us 😊 !



Let's contribute to  
improve lives of  
cancer patients in  
both regions

Laureline Gatellier ガテリエ・ローリン

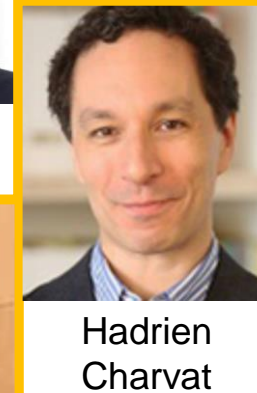
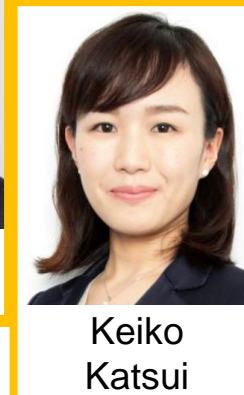
[lgatelli@ncc.go.jp](mailto:lgatelli@ncc.go.jp)

[beatrice.serckx@gmail.com](mailto:beatrice.serckx@gmail.com)

# Project members

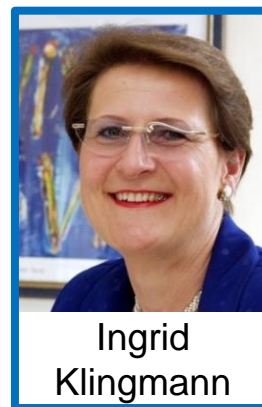
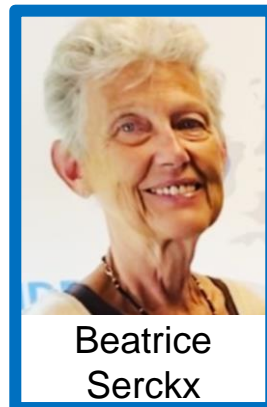
## In Japan

- Laureline Gatellier, National Cancer Center Japan (NCC), Patient representative
- Tomohiro Matsuda, NCC
- Kenichi Nakamura, NCC, Japan Clinical Oncology Group (JCOG)
- Keiko Katsui, AMED, St. Marianna University
- Yoshiyuki Majima, Rare Cancers Japan, Patient Representative
- Jin Higashijima, PPI Japan, Chiba University
- Hadrien Charvat, Juntendo University
- Kazuyuki Suzuki, Novartis Japan



## In EU

- Ingrid Klingmann, EFGCP
- Beatrice Serckx, Consultant



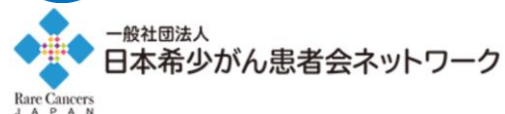
Special support from



PAST PRESIDENT  
Bertrand Tombal  
Cliniques Universitaires Saint-Luc  
Brussels, Belgium

<https://www.eortc.org/governance/board/>

# Thank you!



Back up

# Project Brief

- **Executive summary**

Patient engagement / Patient-Public-Involvement (PE/PPI) around the world is an active and rapidly progressing field. An objective evaluation and comparison among continents is still limited.

This study focuses on the comparison of PE/PPI in **clinical research in the cancer field between Japan and Europe** with the goal to clarify the current PE/PPI activities (*etat des lieux*) during the drug development process in both regions and develop proposals for improving PE/PPI activities.

- **Background**

PE/PPI has started in Japan later than EU and US (around 2015) with a steep increase such as the creation the PPI guidebook, the establishment of a PPI department at AMED and PMDA, the implementation and Japanese translation of EUPATI training programs in Japan.

An objective comparison of PE/PPI in EU and Japan would allow to better understand the differences and perspectives of each region.

- **Problem statement**

The evaluation and comparison of PE in clinical research is limited, making it difficult to objectively compare PE/PPI in EU and Japan.

- **Methodology**

- Survey launched with principal investigators of academia-led clinical trials / clinical research (through e-mails and by visiting scientific congresses)
- Meet with experts such as EMA / PMDA, key HCP and funding organisations to better understand blocking points, vision and landscape.

- **Risks**

- Biases (low response rate, self-assessment, cultural differences, responders' profile)
- Limited motivation of responders to participate to this study  
Resulting in a limited view of non-representative figures



# Survey – Key elements

## EUPATI Scheme

### Patient involvement in medicines R&D

