



Federaal Kenniscentrum voor de Gezondheidszorg
Centre Fédéral d'Expertise des Soins de Santé
Belgian Health Care Knowledge Centre

Experiences with patient involvement in KCE Trials Funding Programme

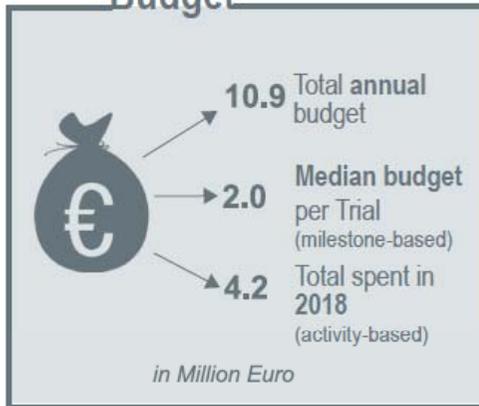
France Vrijens, Head KCE Trials

Symposium FAGG/AFMPS

“Collaborating with and for the patient”, Brussels,
December 10 2019



Budget



Specificities

- ✓ Pragmatic & practice oriented
- ✓ Comparative effectiveness (drugs, devices, other...)
- ✓ Non-commercial
- ✓ Data sharing
- ✓ Potential for return on investment

Quality support



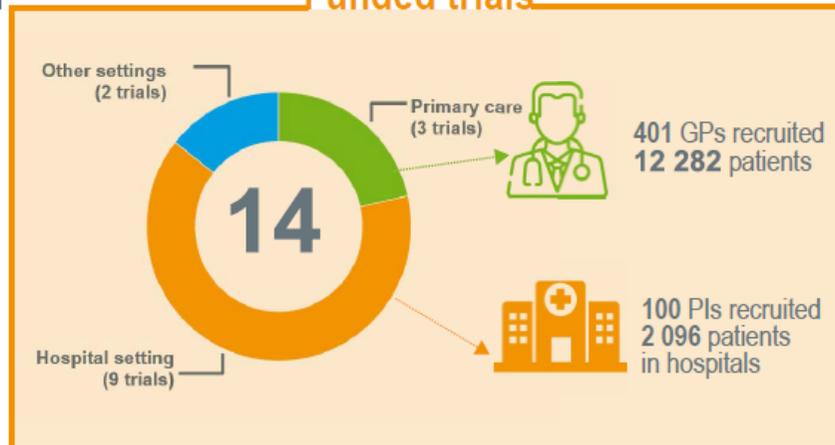
Selection process



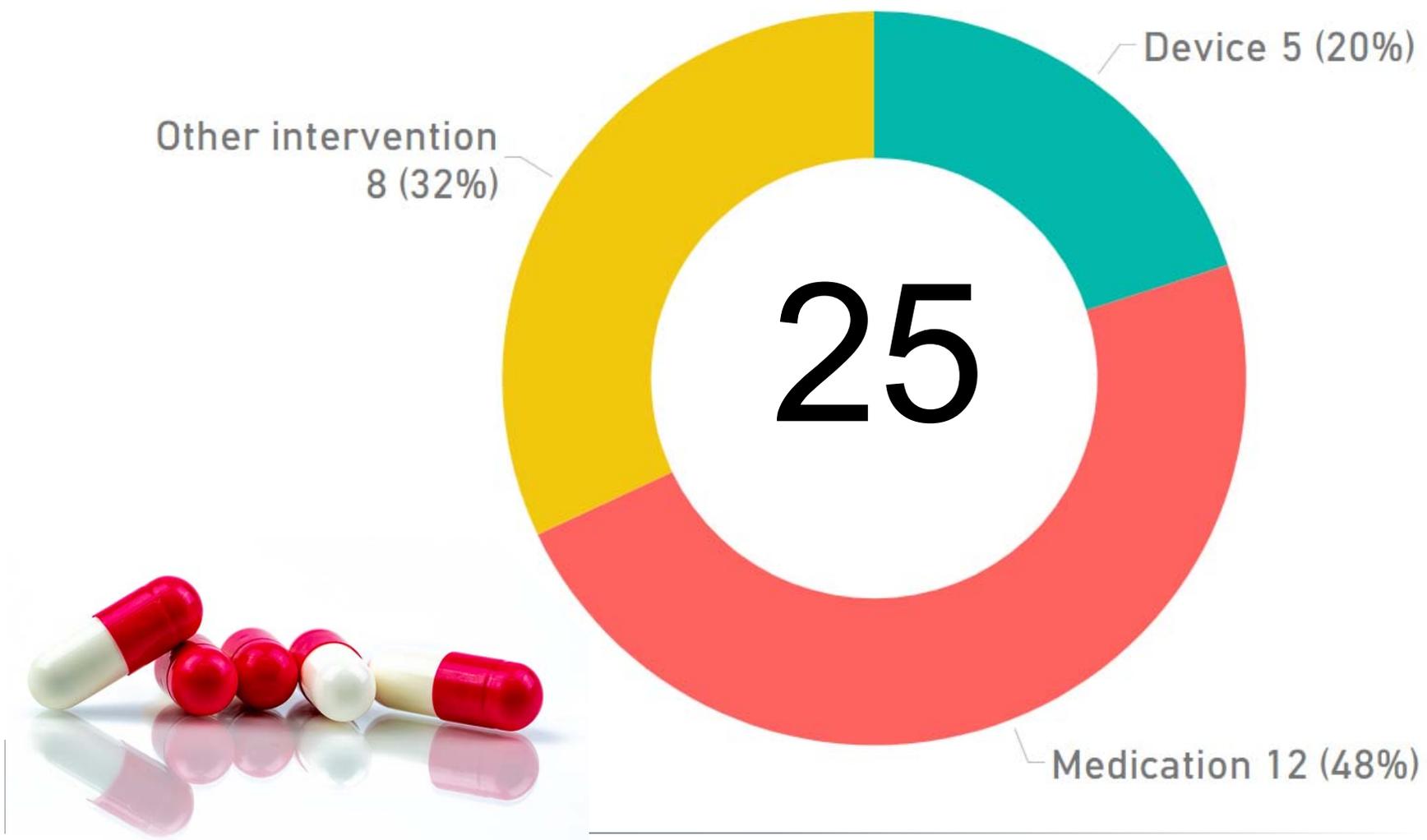
Calls for studies



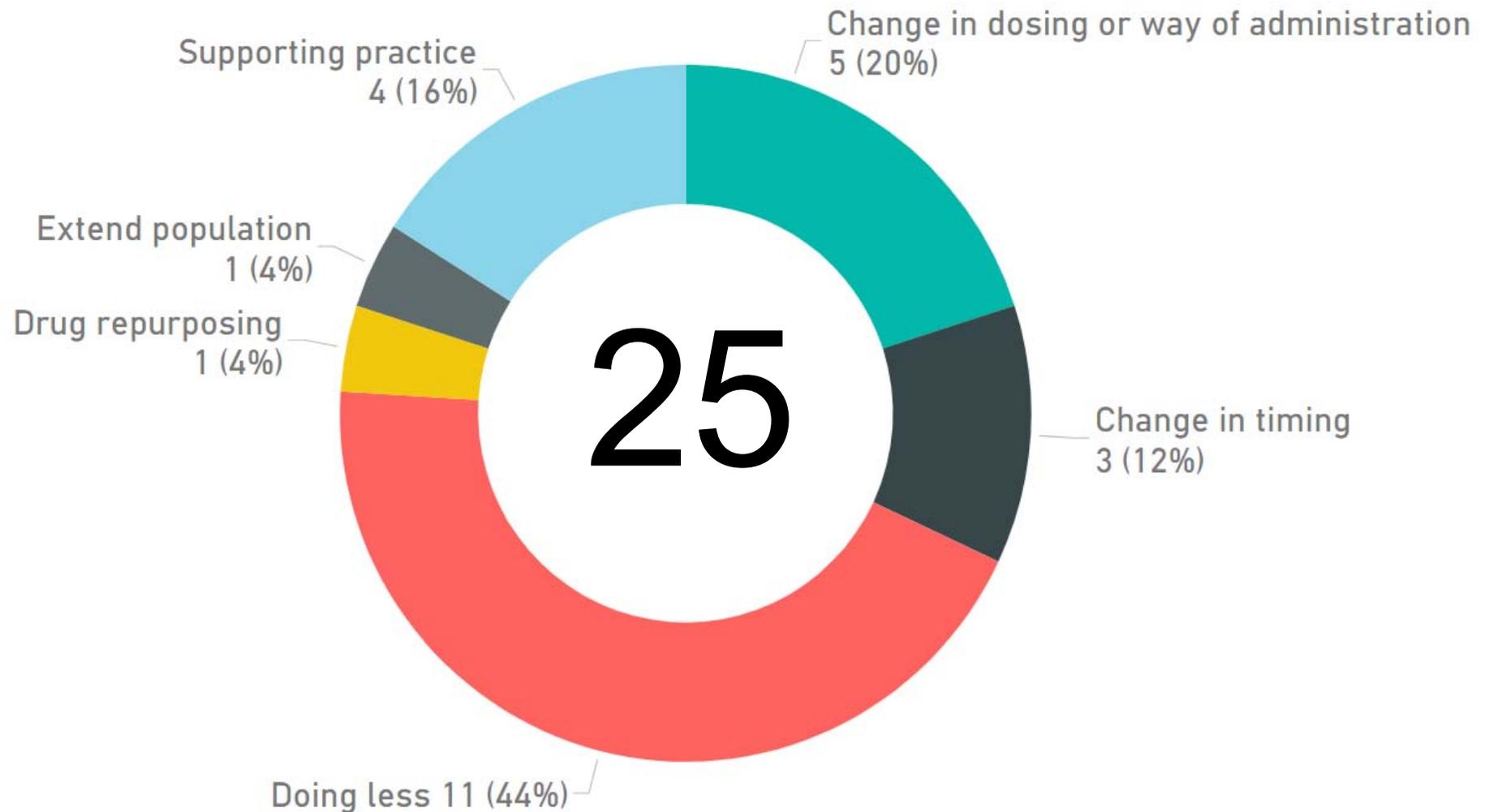
Funded trials



KCE Trials Portfolio: studies by *Intervention*



KCE Trials Portfolio: studies by *Aim of study*



Dynamic Dashboards on KCE Trials website

Hospitals recruiting patients in a KCE Trials funded study (Dashboard 1/3)

How many hospitals ?

41



Last update 06 December 2019
Updated every Friday



Project Short title	Project site name	Principal Investigator	Project site status	Recruited (total)
ADVOR	OLV Ziekenhuis Campus Aalst	Dierckx, Dr Riet	Open	17
Renomet	OLV Ziekenhuis Campus Aalst	Van Vlem, Bruno	Expression of interest	0
ADVOR	AZ Delta	Deceunick, Dr Michel	Open	7
PELICAN	AZ Delta	Decoster, Dr Olivier	Open	0
Renomet	AZ Delta	Maes, Bart	Expression of interest	0
ADVOR	AZ Glorieux	Van Durme, Dr Frederik	Open	3
ADVOR	AZ Groeninge	Derthoo, Dr David	Open	10
CareRA2020	AZ Herentals	,	Expression of interest	0
Total				536

Dynamic Dashboards on KCE Trials website

Recruitment Status for studies funded by KCE Trials Programme, by Recruiting Site (Dashboard 2/3)

Project Short title

- Select all
- ADVOR
- AGNOHSTIC
- Beneductus
- BLING III
- CareRA2020
- PELICAN
- Renomet

Project site status

- Select all
- Open

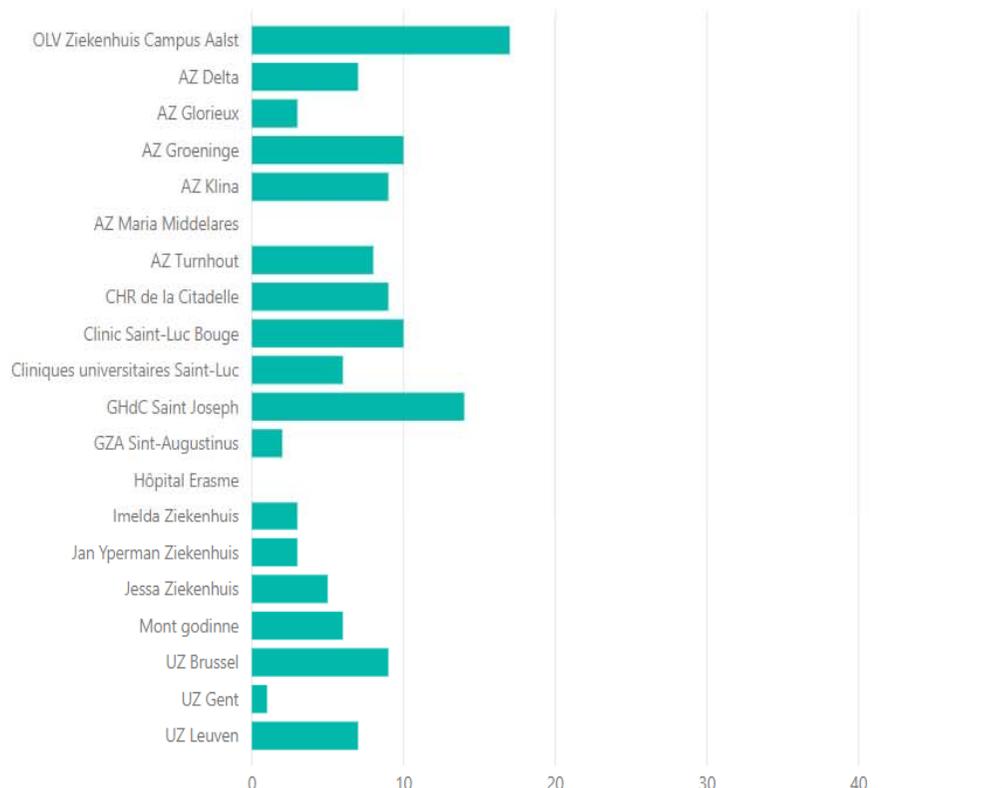
Total patients recruited

193

Recruiting Sites

24

Recruited (total) by Project site name



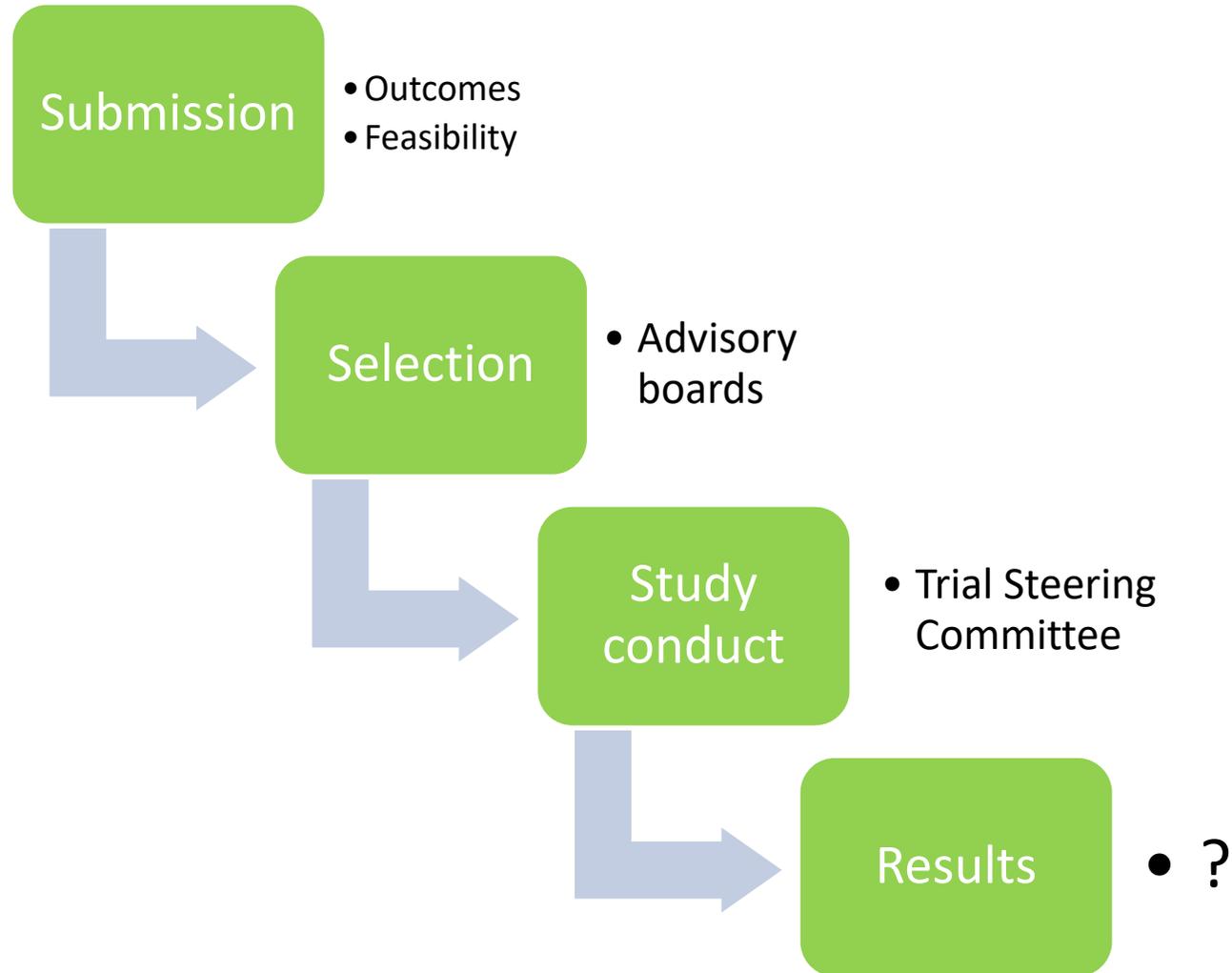
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Project Short title	Project site name	Principal Investigator	Project site status	Recruited (total)	First site patient recruited (any)	Last site patient recruited (any)
ADVOR	AZ Klina	,	Open	9	27-Mar-19	28/11/2019
ADVOR	Clinic Saint-Luc Bouge	,	Open	10	20-Feb-19	15/11/2019
ADVOR	GHdC Saint Joseph	,	Open	14	22-Mar-19	18/11/2019
ADVOR	GZA Sint-Augustinus	,	Open	2	18-Apr-19	25/09/2019
ADVOR	UZ Gent	De Pauw, Dr Michel	Open	1	04-Jun-19	4/06/2019
ADVOR	AZ Delta	Deceunick, Dr Michel	Open	7	20-Feb-19	10/10/2019
ADVOR	AZ Groeninge	Derthoo, Dr David	Open	10	19-Dec-18	8/10/2019
ADVOR	OLV Ziekenhuis Campus Aalst	Dierckx, Dr Riet	Open	17	06-Feb-19	27/11/2019
ADVOR	UZ Leuven	Droogne, Prof Walter	Open	7	10-Dec-18	28/02/2019
Total				193		

Where are patients involved ?



Submission stage – question on PPI

The KCE Trials programme strongly recommends to have patients and public actively involved in the design of the study.

Please briefly describe how patient and public involvement has informed and/or influenced the development of the application and how they will contribute during the lifecycle of the project. **This can include, for example, involvement in the choice of the research topic, choice of the outcomes, assisting in the design, advising on the feasibility of the research project etc.**

Initiatives to facilitate patient recruitment are not to be mentioned here, only patient involvement in the design.

Submission stage

– Specific section in budget for PPI

10 Patient and Public Involvement									
10a	Patient involvement in study project design and set-up	mtg	1	FX	€ 2 000,00	€ 2 000,00	€ 2 000,00	€ 2 340,00	up to € 5000 with justification
10b	Patient involvement in Trial Steering Committee Meetings	mtg	2	FX	€ 200,00	€ 400,00	€ 400,00	€ 468,00	2 patients to attend each TSC
10c	Other activities for patient involvement (if applicable)	oth							
					€ 2 200,00	€ 2 400,00	€ 2 400,00	€ 2 808,00	

+ 1 day of training for CTUs and investigators on patient involvement in clinical trials (speakers from UK)

Selection via 3 advisory groups

Prioritisation Group (PG)

- 4x/ year
- Take/prepare decisions
- Delegated by KCE CA/RvB + 7 universities
 - + Patients

Panel

- 1x / year (once per call)
- ranking of all proposals in scope
- 30 health professionals
 - + Patients

Trials Board (TB)

- 4x/ year (max 6/call)
- improve design (resubmissions)
- 25 experts in methods CT
 - + Patients

Which patient organisations ?

- **Umbrella patient associations**
 - **LUSS**
 - **Vlaams Patiëntenplatform (VPP)**
 - **European Cancer Patient Coalition**
- **Disease specific patient association**
 - **Hodgkin vzw**
 - **Net-Men kanker vzw**
 - **Wij Ook vzw (Prostate Cancer)**
- **Individual patients**
- **Test-gezondheid / Test-santé**

Panel - Participation

- **Participation Patients representatives :**
 - **Call 2016: 0 / 71 (0%)**
 - **Call 2019: 6 / 30 (20%)**
 - **BeneFit: 2 from BE, 2 from NL (total +- 30)**
- **Same voting rights as other experts**
- **For patients representatives, KCE Trials offers to pay costs of online general training on clinical trials (« patient expert »)**

Panel - Questions

Panel Meeting Review - INV19-1246

Panel 20191122 Call 2019

Meeting Date

2019-11-22 08:00

DOWNLOAD DOCUMENTS

REVIEWER COMMENTS

Is the research relevant from the perspective of the patients concerned?

Consider:

- the fulfilment of wishes and needs from patients;
- improvement of patients' health;
- improvement of the quality of life of patients;
- improvement of social participation and independence of patients;
- improvement of care in general;
- relevance of the selected outcome measures for patients.

Good ▼

Please explain your score



Panel - Questions

Is the plan of action feasible from the perspective of the patient?

Consider:

- the burden for the patient (e.g. undergoing treatment/diagnostics, completing questionnaires);
- duration of the investigation;
- possible objections of patients to participating (e.g. because of a preference for a particular treatment).

Are patient organisations or experience experts sufficiently involved in the design and implementation of the study?

Consider:

- to what extent the experience experts are representative for the patient group;
- the degree of involvement of the experience experts (e.g. informative, advisory etc);
- the steps in which they are involved (for instance the design/execution of the project plan, research and implementation).

Insufficient ▼

Please explain your score

Recommendations

What recommendations would you like to give to the applicants in order to further optimize the proposal from the patients' perspective?



RESULTS

- **3 Studies (Call 2016) with results in 2020**
- **Open Access & Dissemination**
- **Data sharing**
- **KCE HTA reports based on trial data**
- **Impact & Implementation**



- **Future calls for proposals**
 - Investigator-led call
 - Commissioned call ?
 - Themed call ?
- **International collaboration**
- **Research agendas**



Priority Setting Partnerships

Home

About the JLA

The PSPs

Top 10s

JLA Guidebook

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You are in: Home

The James Lind Alliance

The [James Lind Alliance \(JLA\)](#) is a non-profit making initiative established in 2004. It brings patients, carers and clinicians together in [Priority Setting Partnerships \(PSPs\)](#) to identify and prioritise the [Top 10 unanswered questions](#) or evidence uncertainties that they agree are the most important.

The aim of this is to make sure that health research funders are aware of the issues that matter most to the people who need to use the research in their everyday lives.



The PSPs

Find out about the areas in which Priority Setting Partnerships identify the uncertainties which really matter.



Top 10s

See the top priorities for future research, agreed by patients, carers and health professionals working with Priority Setting Partnerships.



The JLA Guidebook

Read a step-by-step guide to the processes involved in a Priority Setting Partnership.



COLLABORATION

Funders
Hospitals
Stakeholders

Researchers & Sponsors
Clinical Trials Units
Advisory Groups
Patients representatives