ERA PerMed

**How to implement the joint call:
ERA PerMed – ERA Net on Personalised Medicine**

Katja Kuhlmann, DLR-PT, Germany; Joint Call Secretariat 2020
ISCIII, Spain (Coordinator; JCS2018)
ANR, France (JCS2019)
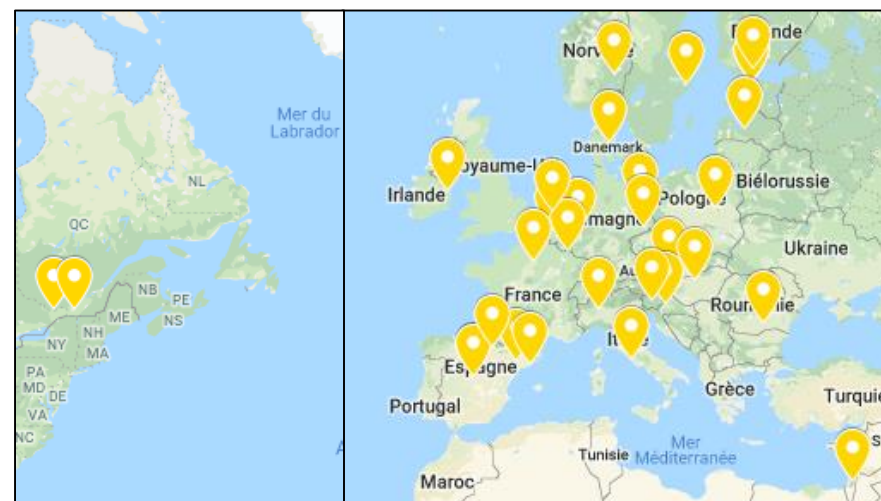
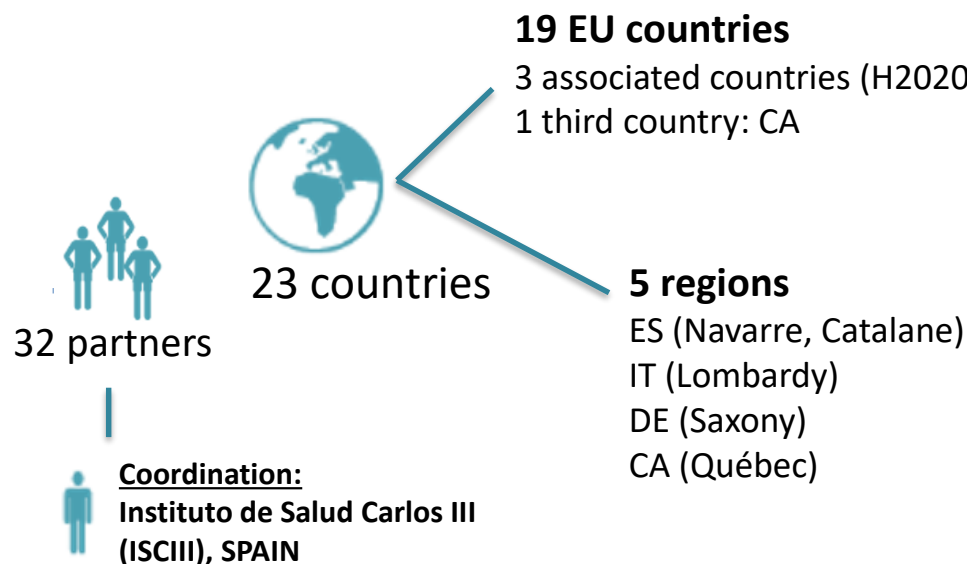ERA-LEARN Workshop, December 16, 2020

Content

- **About ERA PerMed**
- Funding mode and funding commitment
- Scope of call
- Timing of the call
- The evaluation process
- Proposal management tools
- The ranking list
- Top-up funding: Filling the gaps

ERA PerMed – ERA NET on Personalised Medicine

- **Time frame**: 1 December 2017 – 30 November 2022

- **Consortium**: 32 funding organisations from 23 countries (AT, BE, CA, DE, DK, **ES**, EE, FI, FR, HR, HU, IE, IL, IT, LV, LU, NL, NO, PL, RO, SE, SI, TR)

The biggest ERA Net in health

19 EU countries
3 associated countries (H2020) : IL, NO, TR
1 third country: CA

23 countries

32 partners

5 regions
ES (Navarre, Catalane)
IT (Lombardy)
DE (Saxony)
CA (Québec)

Coordination:
Instituto de Salud Carlos III (ISCIII), SPAIN
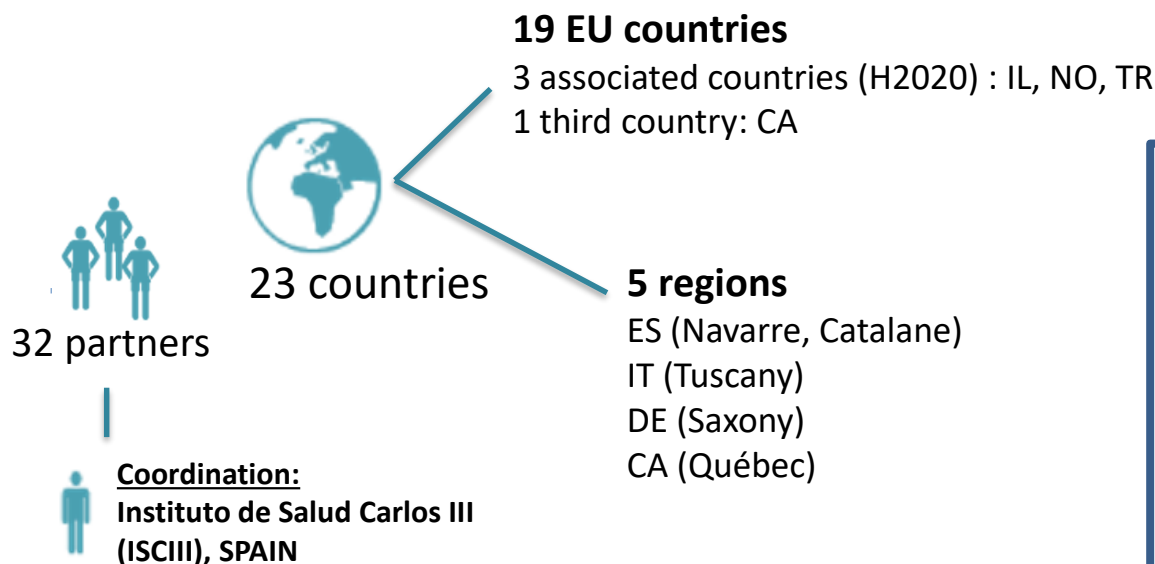

Joint Transnational Calls (JTCs)
1 Call cofunded by the EC➔ 2018
3 Calls non-cofunded : 2019, **2020**, 2021

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ERA PerMed and **ICPerMed**
are closely connected.

➔ ICPerMed Action Plan and SRIA are consulted during the preparation of the calls

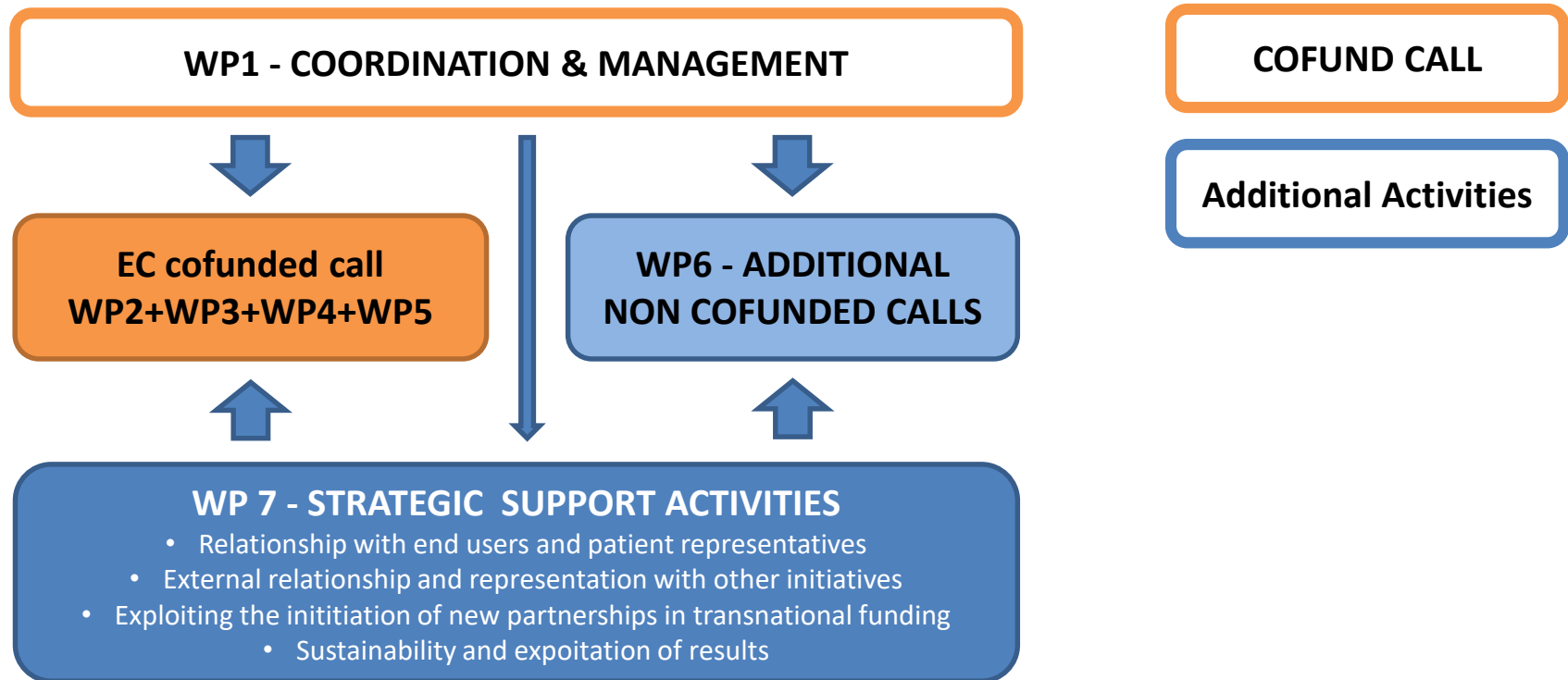https://www.icpermed.eu/

www.erapermed.eu

Joint Transnational Calls (JTCs)
1 Call cofunded by the EC➔ 2018
3 Calls non-cofunded : 2019, **2020**, 2021

ERA PerMed - structure

WP1 - COORDINATION & MANAGEMENT

COFUND CALL

Additional Activities

EC cofunded call WP2+WP3+WP4+WP5

WP6 - ADDITIONAL NON COFUNDED CALLS

WP 7 - STRATEGIC SUPPORT ACTIVITIES
- Relationship with end users and patient representatives
- External relationship and representation with other initiatives
- Exploiting the inititiation of new partnerships in transnational funding
- Sustainability and expoitation of results

1. Description of the cofund call already in the ERA-Net proposal
2. Agreement on the administrative procedures amongst funders in the CA

Joint Transnational Call 2018 – Co-funded call

19 EU countries

3 associated countries (to Horizon 2020)
Turkey, Norway, Israel

1 third country (Canada)

5 regions

31 Partners

23 Countries

Joint Call Secretariat:
INSTITUTO DE SALUD CARLOS III (ISCIII)

Initial budget
27 Mio€ (approx.)

Two step procedure
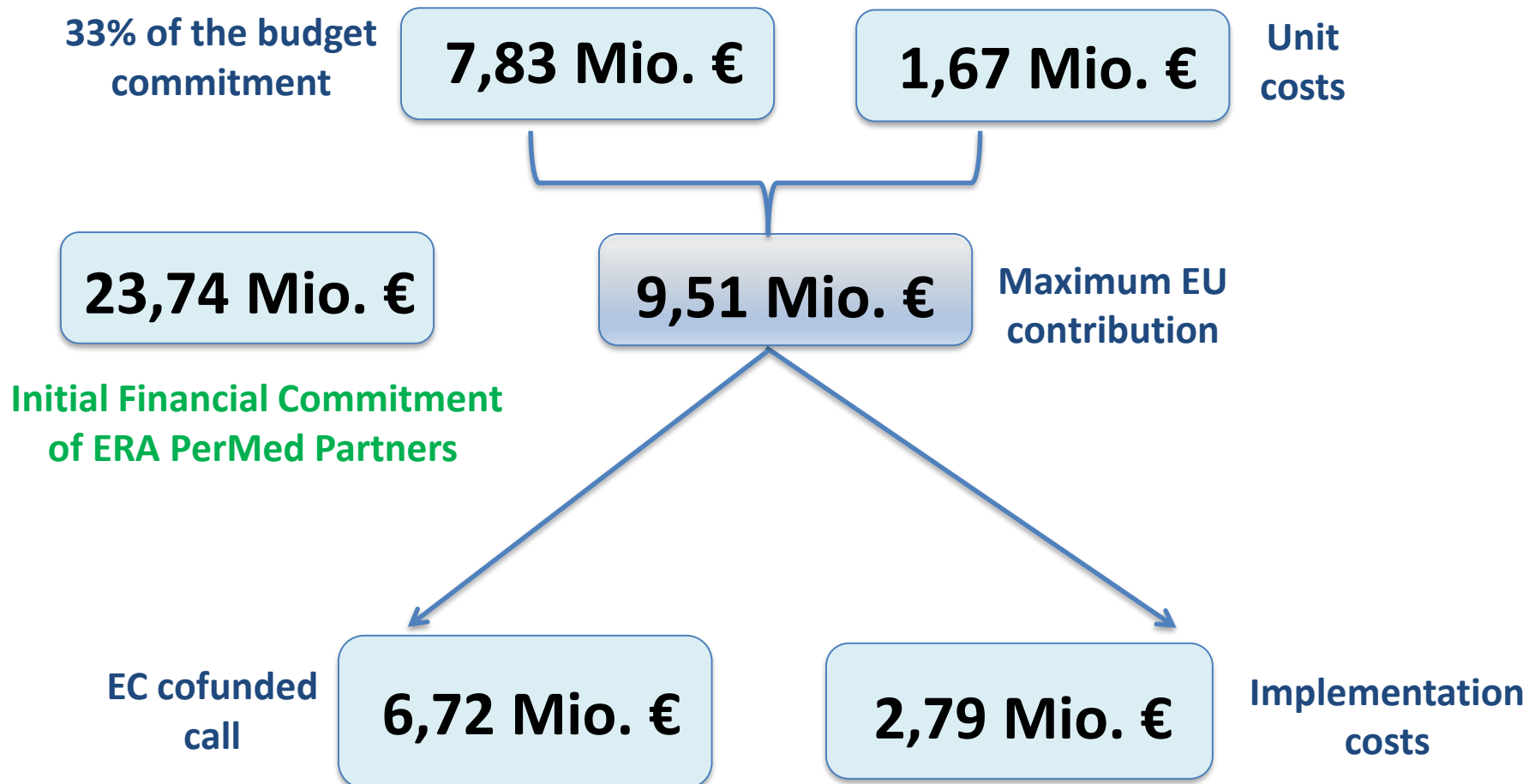
Launch: February 2018

Timeline: **Submission deadline of Pre-proposals: April 2018**

Submission deadline of Full-proposals: June 2018

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ERA PerMed – cofunding scheme

33% of the budget commitment

7,83 Mio. €

1,67 Mio. €

Unit costs

23,74 Mio. €

9,51 Mio. €

Maximum EU contribution

Initial Financial Commitment of ERA PerMed Partners

EC cofunded call

6,72 Mio. €

2,79 Mio. €

Implementation costs

Virtual common pot model

- Central application procedure coordinated by the Joint Call Secretariat

- However: Each funding organisation funds only their own applicants with national or regional budget

- "funding gaps" can occur if dedicated budget of participating funders is too low
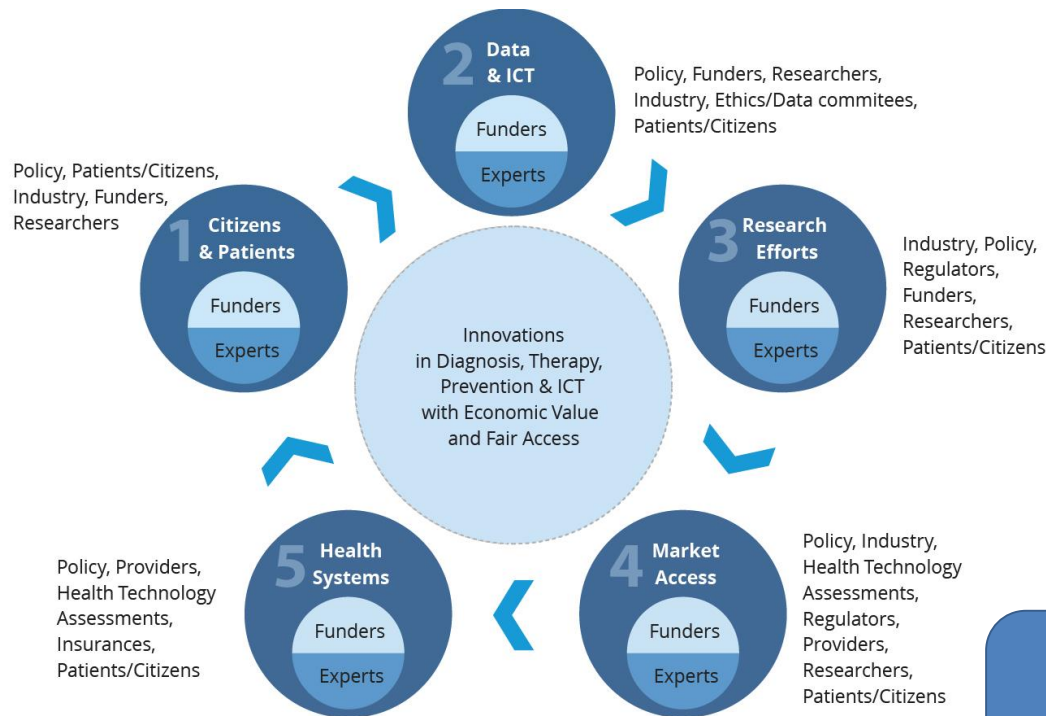
Co-Funded call:

- EC contribution depends on project money spent by the funding organisations

- Co-funded call: Top-up money can in part be used to fill funding gaps

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Development of the scope for the cofund call

Policy, Patients/Citizens, Industry, Funders, Researchers

1 Citizens & Patients
Funders
Experts

2 Data & ICT
Funders
Experts

Policy, Funders, Researchers, Industry, Ethics/Data commitees, Patients/Citizens

3 Research Efforts
Funders
Experts

Industry, Policy, Regulators, Funders, Researchers, Patients/Citizens

Innovations in Diagnosis, Therapy, Prevention & ICT with Economic Value and Fair Access

Policy, Providers, Health Technology Assessments, Insurances, Patients/Citizens

5 Health Systems
Funders
Experts

4 Market Access
Funders
Experts

Policy, Industry, Health Technology Assessments, Regulators, Providers, Researchers, Patients/Citizens

SRIA 2015

PerMed
Shaping Europe's Vision for Personalised Medicine
Strategic Research and Innovation Agenda (SRIA)

http://www.permed2020.eu/_media/PerMed_SRIA.pdf

ICPerMed Action Plan 2017

ICPerMed
Action Plan

http://www.icpermed.eu/media/content/ICPerMed_Actionplan_2017_web.pdf

Recommendation of PerMed2020:
Only by including the whole value chain, we can move forward in Personalised Medicine.

1

General concept developed for all calls: The cofund call and all additional calls

➔ **JTC2018 topics already defined in the ERA PerMed proposal**

Development of the scope for the cofund call

- Consultation of experts during the ICPerMed workshop in June 2017

- Internal survey within ERA PerMed amongst participating funding organisations

- Establishment/consultation of the Call Advisory Board

- **Approval of the last version, at least 30 days before the expected date of publication**

2 Refinement of the concept of the call

3 Feedback of each funder
➔ Feasibility of call and topics

4 Refinement of the scope

5 Validation/approval of the call text by the EC

JTC2018

Joint Transnational Call for Proposals (2018) for

"Research projects on personalised medicine – smart combination of pre-clinical and clinical research with data and ICT solutions"

Research Area 1
Validation, pre-clinical and clinical biomedical research –"Translating Basic to Clinical Research and Beyond".

Module 1A: Preclinical Research

Module 1B: Clinical Research

+

Research Area 2
Data analysis, management and protection, including ethical, legal and social implications –"Integrating Big Data and ICT Solutions".

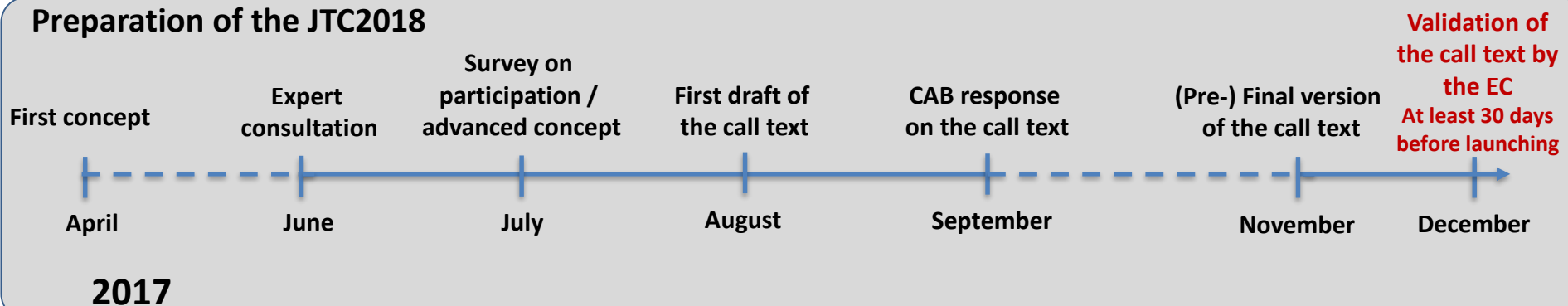Module 2A: Data and ICT – Enabling Technology

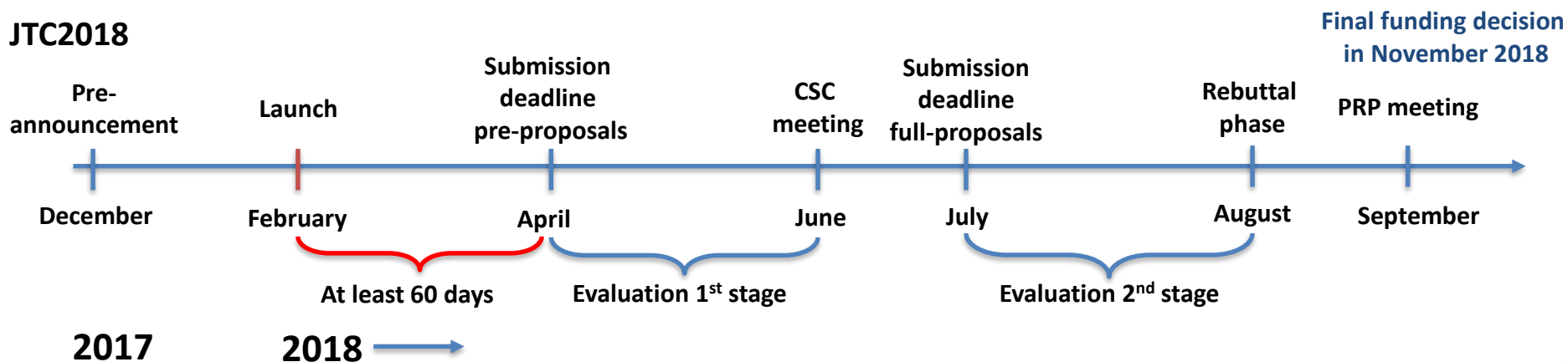Module 2B: Data and ICT - Towards application in health care

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Call calendar

Preparation of the JTC2018

First concept

Expert consultation

Survey on participation / advanced concept

First draft of the call text

CAB response on the call text

(Pre-) Final version of the call text

Validation of the call text by the EC
At least 30 days before launching

April | June | July | August | September | November | December

2017

JTC2018

Pre-announcement

Launch

Submission deadline pre-proposals

CSC meeting

Submission deadline full-proposals

Rebuttal phase

PRP meeting

Final funding decision in November 2018

December | February | April | June | July | August | September

At least 60 days

Evaluation 1st stage

Evaluation 2nd stage

2017 | **2018** →

Recommendation:
Restricted time for the call ➜ Early launch of the call enables the ERA Net to adapt the call calendar, if needed.
At least 60 days for the pre-proposal submission are requested by the commission.
Publication of the call via ERA Learn: https://www.era-learn.eu/network-information/call-calendar
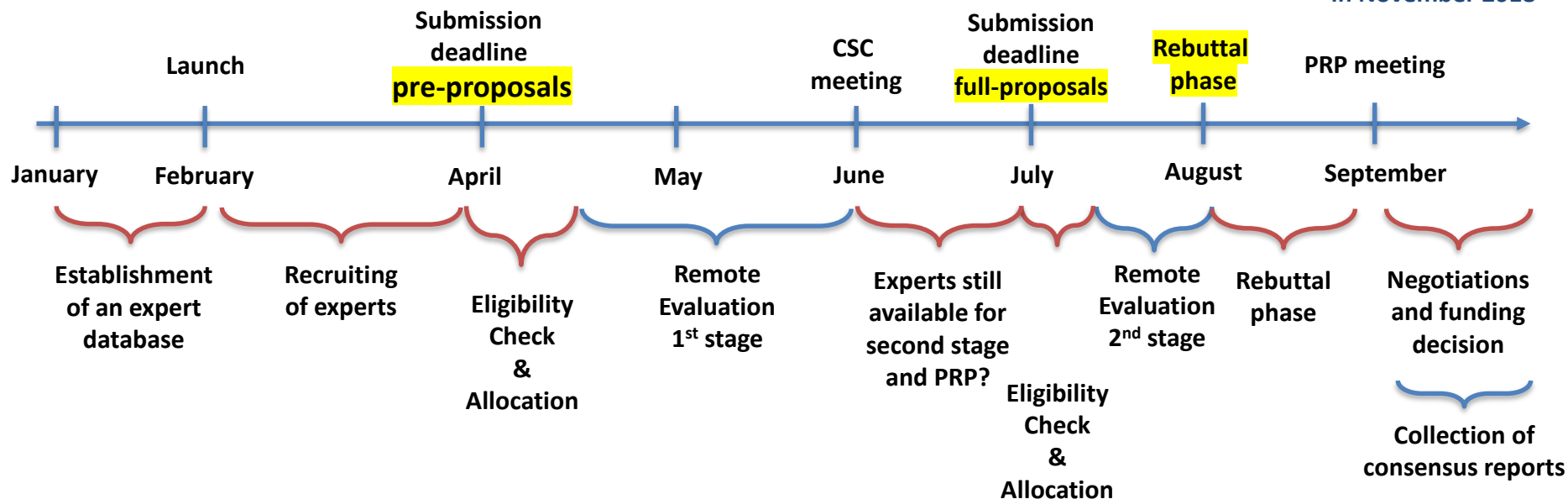
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The evaluation process

JTC2018

Final funding decision in November 2018

Launch

Submission deadline pre-proposals

CSC meeting

Submission deadline full-proposals

Rebuttal phase

PRP meeting

January — February — April — May — June — July — August — September

Establishment of an expert database

Recruiting of experts

Eligibility Check & Allocation

Remote Evaluation 1st stage

Experts still available for second stage and PRP?

Eligibility Check & Allocation

Remote Evaluation 2nd stage

Rebuttal phase

Negotiations and funding decision

Collection of consensus reports

Comment:
Central eligibility check: Joint Call Secretariat
Regional/national eligibility check by the respective funding organisations
For allocating projects to reviewers, a working group can be formed
Inclusion of an **independent observer** in the call – latest at the full-proposal phase ➔ requested by the commission

Finding experts and telling them what to do

- **ERA PerMed had to establish its expert database:**
  - Input came from ERA PerMed partners (regional/national FOs)
  - Collection of / requirements for experts:
    - Corresponding to the different topics in the scope
    - Request to propose also experts from outside the consortium

- **Recommendation:**
  - Provide experts with guidelines for the evaluation
    - Background around the funding programme and the call
    - Conflict of interest and confidentiality,
    - Steps of the evaluation (first, second, rebuttal, PRP meeting)
    - Expectations and correct wording for the written evaluation
  - Be clear in evaluation deadlines and the date for the PRP meeting

Finding experts and telling them what to do

- **Difficulty:**
  - Availability of reviewers for the entire process (full-proposal evaluation is in the summer period);
  - ERA PerMed provides no remuneration of experts;
  - Our experiences – just to keep in mind:
    - 60% no answer
    - 20% NO participation
    - 20% YES for participation (thereof you might loose around 3% when finally contacting as selected evaluator)
    - Keeping in contact with reviewers (e.g. by sending reminders) is important

The evaluation process

General principles for the remote evaluation (pre- and full-proposal):

- 3 reviewers per proposal,
- 3 evaluation criteria: Excellence, Impact and Implementation,
- Scoring system from 0 to 5,
  - Threshold: score of 3 for each criteria.

For the Peer Review Panel Meeting:

- One rapporteur introducing each proposal,
- Two reviewers challenging each rapporteur.

Consensus Report

- Prepared by the rapporteur.

Experts/Reviewers – evaluation

Criterion 1

Excellence of the proposal:

a. Clarity and pertinence of the objectives; b. Scientific quality of the proposed approach and methodology; c. Soundness of the concept; d. Novelty of the concept; e. Feasibility of the project (adequate requested resources, time schedule); f. Quality of the project consortium: international competitiveness of participants in the field(s), previous work and expertise of the participants, added value of the transnational collaboration.

Criterion 2

Impact of the proposal:

a. Added value of the transnational collaboration; sharing of resources (registries, diagnosis, biobanks, models, databases, diagnostic and informatics tools, etc.), platforms/infrastructures, harmonisation of data and sharing of specific know-how; b. Potential impact of the expected results on clinical and other health related applications; c. Involvement of pertinent patient organisations, patient representatives (if available/applicable); d. Involvement of private partners (SME and/or industry, if available/applicable); e. Innovative potential; f. Consideration of sex aspects and underrepresented populations in research teams. Inclusion of sex and/or gender analysis and underrepresented populations in the research, if applicable.

Criterion 3

Quality and efficiency of the implementation

a. Quality of the project plan; b. Adequateness of the work package structure and work plan (tasks, matching events, time schedule); c. Balanced participation of project partners and integration of workload in the different work packages, quality and efficiency of the coordination and scientific management; d. Scientific justification and adequateness of the requested budget (rational distribution of resources in relation to the project's activities, partner responsibilities and time frame); e. Risk assessment, regulatory and ethics issues properly addressed (when necessary); f. Coherent integration and combination of Research Areas and Modules in the proposal.

Experts/Reviewers – evaluation

Scoring system:

0: Failure. The proposal fails to address the criterion in question, or cannot be judged because of missing or incomplete information.

1: Poor. The proposal shows serious weaknesses in relation to the criterion in question.

2: Fair. The proposal generally addresses the criterion, but there are significant weaknesses that need corrections.

3: Good. The proposal addresses the criterion in question well, but certain improvements are necessary.

4: Very good. The proposal addresses the criterion very well, but small improvements are possible.

5: Excellent. The proposal successfully addresses all aspects of the criterion in question.

Total Score = sum of scores for each criterion – best total score = 15
Threshold 3 for each criterion (mean of 3 experts), 9 for the total score.
Additional question in pre-proposal step: **Within scop**e of the call?

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Proposal Management Tools

Number of proposals in ERA PerMed calls:

Call	# pre-proposals	# full proposals	Funded projects
JTC2018	143	50	25
JTC2019	196	56	22
JTC2020	188	56	18

➢ The use Electronic tools is recommended for handling high numbers of proposals and/or written reviews

➢ ERA PerMed used an electronic tool for collecting proposals and for managing the evaluation process

➢ In addition, a platform for sharing proposals, reports etc. between funding organizations (e.g. sharepoint) is very helpful

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The ranking list

Rules for the Call Steering Committee:

Follow the ranking list strictly as long as EU Top-Up is used.

Additional consensus on the establishment of the funding decision:

Ranking in blocks; e.g.:

- A++: excellent proposals, recommended for funding (no informal ranking needed);
- A+: very good proposals, which are funded depending on the available budget from the funding organizations (informal ranking remains and is used as a tool for guidance);
- …add further blocks as needed
- B: Proposals that are not prioritized for funding (no informal ranking needed).

Proposals within each block (ca. 5-6 max.) are considered of equal scientific quality.

The ranking list

Hypothetical example

ERA PerMed's aims:
➢ Fund the best projects
➢ Fund as many projects as possible
➢ Do not fund low quality projects

Akronym	Final Score	Rank-ing	Category
AFK	14.8	1	A++
BBIAB	14.7	2	A++
BBL	14.7	3	A++
BBS	14.5	4	A++
BEG	14	5	A+
BRB	13.9	6	A+
BTW	13.9	7	A+
...	...		...
ROFL	9.5	98	B
YOLO	7	99	B

Recommended for funding.
Several groups; equal scientific quality within each group

Not recommended for funding.

Informal ranking remains and is used as a tool for guidance.

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- **Top-up funding: Filling the gaps**
- Project monitoring and reporting

Funding negotiations and funding gaps

Hypothetical example

Acronym	Category	**Dedicated budget** 600,000 € Funder 1	1,800,000 € Funder 2	1,500,000 € Funder 3	300,000 € Funder 4	900,000 € Funder 5	1,200,000 € Funder 6
AFK	A++	300,000 €		300,000 €		300,000 €	300,000 €
BBIAB	A++		300,000 €	600,000 €		600,000 €	600,000 €
BBL	A++					900,000 €	
BBS	A++		600,000 €				900,000 €
BEG	A+		900,000 €		300,000 €		1,200,000 €
BRB	A+			900,000 €		1,200,000 €	1,500,000 €
BTW	A+	600,000 €	1,200,000 €	1,200,000 €			
…	A+						
ROFL	B	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
YOLO	B	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.

Flexibility in the funding decision within one group, e.g. in the case of funding gaps

Trying to avoid funding gaps

First evaluation step:

1. the total budget of all selected pre-proposals should not exceed the proposed total budget of the JTC by more than 3 times,

2. Each FO must establish a responsible approach to avoid an unbalance between the committed national/regional budgets and the requested funding,

3. If the initial national/regional oversubscription after pre-proposal submission exceeds a factor of approximately 3 (or 2, respectively, for third countries not eligible for EC contribution) **each funding organization is responsible to implement the most suitable mechanisms to comply with this requirement**.

JTC2018: **50 out of 143 eligible pre-proposals were invited to the full-proposal stage**.

Filling the gaps – top up funding

Optimizing both the regional/national and the EU contributions:

1. explore all funding solutions to unblock situations at the regional/national level, e.g. by increasing their budget).

2. Following this step, the final distribution of the EC contribution will be discussed and agreed by the CSC.

   ➔ the further rules might be revised, if needed:

   I.   **Reimbursement**: 50%-70% of the EU Top-Up for just-retour reimbursement.

   II. **Gap filling**: 30%-50% of the EU Top-Up for Gap filling.

   III. Max. 20% of the EU Top-Up total budget per FO.

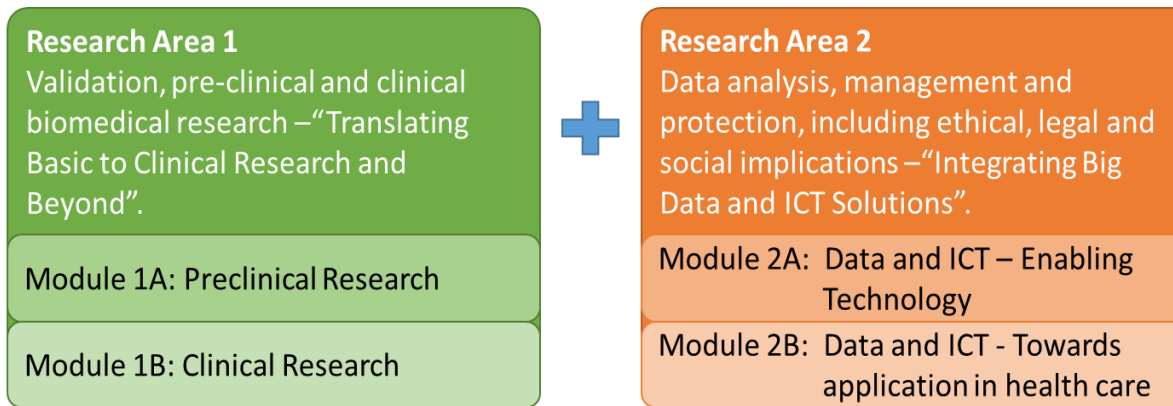   IV. Max. EU Top-Up: respective national/regional contribution

   ➢ **Aim: Optimise use of funds; fund as many (excellent) projects as possible**

Funding negotiations

- Question of negotiation amongst the participating FOs

  ➔ Requests time and the need to develop funding scenarios

  ➔ includes most probably several TelCos (CSC and bilateral) and mail exchanges

- To be considered:

  1. Regional/national decision committee meetings,

     ➔ requirement and mechanisms to get the funding decision might vary a lot between the different funders

  2. Different deadlines for the publication of results.

  To combine both requirements might be challenging.

Outcome of the Co-Funded JTC2018

Research Area 1
Validation, pre-clinical and clinical biomedical research – "Translating Basic to Clinical Research and Beyond".

Module 1A: Preclinical Research

Module 1B: Clinical Research

Research Area 2
Data analysis, management and protection, including ethical, legal and social implications – "Integrating Big Data and ICT Solutions".

Module 2A: Data and ICT – Enabling Technology

Module 2B: Data and ICT - Towards application in health care

- 159 pre-proposals submitted, 143 eligible pre-proposals
- 50 proposals invited to full-proposal submission
- **25 funded projects with a total budget of 28.3 Mio. Euro**

ERA PerMed newsletter - information about all 25 funded projects:
http://www.erapermed.eu/wp-content/uploads/2019/01/ERAPerMed-9-1-19-HR.pdf

Questions?

www.erapermed.eu