IMPORTANT

Horizon Project IMPORTANT

IMPlementing geriatric assessment for dose Optimization of CDK 4/6-inhibitors in older bReasT cAncer patieNTs

Research and Innovation Action
HORIZON-MISS-2020-CANCER-01
GA 101104589

Duration: 60 months
Start date: 01/05/2023

Deliverable ID.:	**D6.7**	
Deliverable title:	**First policy brief formulating recommendations based on the research and innovation strand of the 'Diagnosis and treatment' annual cluster meeting**	
Planned delivery date:	**31 October 2024**	
Actual delivery date:	**27 November 2024**	
Deliverable leader:	**ORB**	
Contributing partners:		
Dissemination Level:	**X**	**PU = Public**
		CO = Confidential
		Cl = Classified

This project has received funding from the European Union's Horizon Europe research and innovation program under grant agreement No 101104589. The UK participant in Horizon Europe Project IMPORTANT is supported by UKRI grant number 10072029 (Care Across Ltd). This deliverable reflects only the author's view and the Commission is not responsible for any use that may be made of the information it contains.

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8	Circular Economy Foundation	CEF	BE
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Revision History

Date	Ver.	Author(s)	Summary of main changes
27.11.2024	1.1	Mukhrizah Othman	Initial version
27.11.2024	2.0	Antonios Valachis	Final version approved

- **Introduction:**

  The Diagnosis and Treatment Cluster is composed of 12 projects revolving around Pragmatic Clinical Trials participating in the EU Cancer Mission program. There is a real stake in these projects to identify what are the challenges faced by these research programs as well as what is innovation.

- **Overview**

  The project leaders exchanged during annual meeting and through a survey (11 out of 12 projects participated), we obtained the following points:

  Before initiating their project, the main challenges faced were (ranked in order of priority):

  1. **Budget estimate exceeding the funding opportunities**
  2. **Lack of academic network in European Countries**
  3. **Lack of access to innovative techniques across the countries**
  4. Budget disparities between countries
  5. Product reimbursement disparities between countries
  6. Other honorable mentions: preparation of agreements, funding for phase III trials overall, adding new countries and the need to draft a clinical trial before having all the elements to evaluate feasibility and challenges of management.

  Until now while implementing their projects, the main challenges currently faced are (ranked in order of priority):

  1. **CTIS Part I Submission and CTIS Part II Submission**
  2. **Budget disparities between countries**
  3. **Product reimbursement disparities between countries**
  4. Insufficient budget
  5. Partners could not deliver the anticipated task
  6. Contract processes (amendment, negotiations)

  In the future, the main challenges the projects anticipate are (ranked in order of priority):

  1. **Insufficient enrollment rates**
  2. **CTIS Part I and Part II Submission**
  3. **Delay in respecting deadlines**
  4. Insufficient budget
  5. Product reimbursement disparities between countries
  6. Partner could not deliver the anticipated task
  7. Amendment process for budget reallocation
  8. Implementing new techniques in different countries
  9. Other honorable mentions: Coordination between partners and contract negotiations

Second aspect of the discussion covered the question of innovation.

Investigators were asked to indicate what they consider as innovation in their pragmatic clinical trials:

- Trial design
- De-escalating treatment
- Use of innovating applications for patient reported outcomes
- Implementing new biomarkers

Additionally, investigators were asked to define potential common innovation between all these trials (ranked in order of priority):

1. **Implementation of pragmatic procedures/aspects in a clinical trial**
2. **New biomarkers**
3. **Automatized Data Extraction**
4. Use of Digital Patient Reported Outcome tools
5. Use of AI tools
6. Remote monitoring
7. Other honorable mentions: new surgical techniques, collaboration and knowledge exchange

- **Analysis**

While preparing the projects, the main challenges in research are restricted funding or lack of access to academic network, treatment (reimbursement) and innovative technologies for academic projects. We find these challenges all throughout the life of the project and at the time of implementation, regulatory and bureaucratic steps are limiting in the launch of the trials. However, these trials bring about innovation in the research field by proposing new study designs (biomarkers, surgical techniques, de-escalation) and new tools (AI, Automated Data Extraction, Digital Patient Reported Outcome, Remote Monitoring) to the medical field and answer to important patient-care questions.

- **Recommendations**

Based on the above discussion and survey, we came up with the following recommendations:

Recommendations to EU:

- Discussion with relevant authorities on making the European regulatory landscape including the Clinical Trial Regulation supportive towards academic clinical research and especially for pragmatic clinical trials. There is currently a real risk of preventing clinical research from happening in Europe.
- Budget transfer flexibility among partners for clinical trials related-costs (current amendment process is inducing important delay)
- Facilitate addition of new partners/countries to meet enrolment ambitions with an appropriate budget for them

Ongoing Project Investigators:

- Sharing of biomarkers implementation at the local level versus centralized to demonstrate feasibility
- Sharing automatized data extraction program
- Sharing uptake of patient digital monitoring

Future Project Investigators:

- Anticipate administrative time for CTIS submission and timelines, and major delay in patient enrolment
- Anticipate regulatory experts' staff for CTIS submission across countries
- Assess carefully feasibility of national coordination and allocated costs

- **Conclusions**

Common challenges have been reviewed to provide feedback both to EU and to Investigator's, as well as identifying common elements of innovation. The policy brief's will be updated annually following each Annual Cluster Meetings.