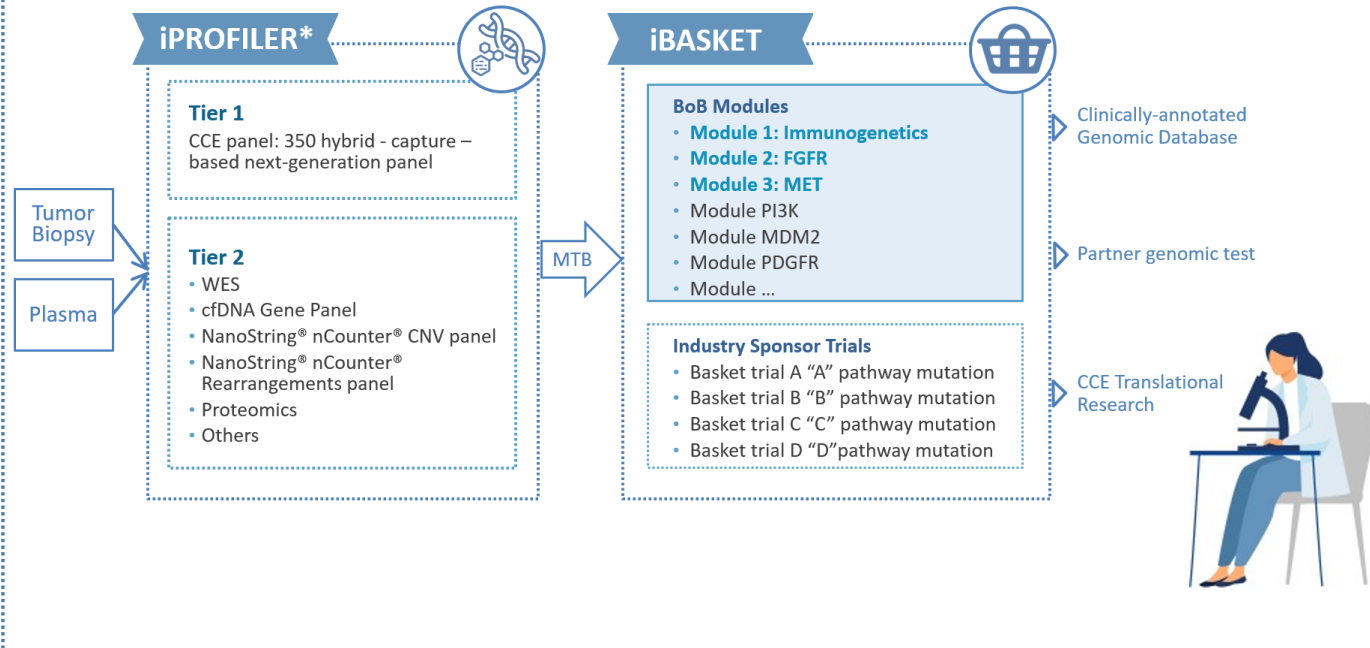


CCE\_DART

BUILDING DATA RICH CLINICAL TRIALS



# Where do we come from?



# CCE\_DART objectives

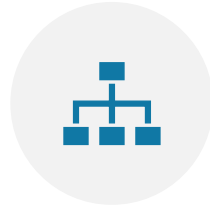


The main objective of the project is to deliver novel methods for the design and implementation of newer, more efficient and effective clinical trials in oncology by:

- Developing digital **tools** to facilitate the trial management and clinical-decision-making
- Using a more efficient **clinical trial methodology** with new statistical designs
- Incorporating a more accurate, integrated and dynamic **imaging and molecular markers** of tumor drug response to treatment into the design and implementation of clinical trials
- Empowering and engaging **patients** in the overall research process



# CCE\_DART Lump Sum



MANAGEMENT  
STRUCTURE



PROPOSAL BUDGET



GRANT AGREEMENT  
PREPARATION



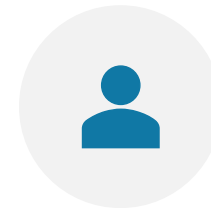
REPORTING



REVIEW MEETING



AMENDMENTS

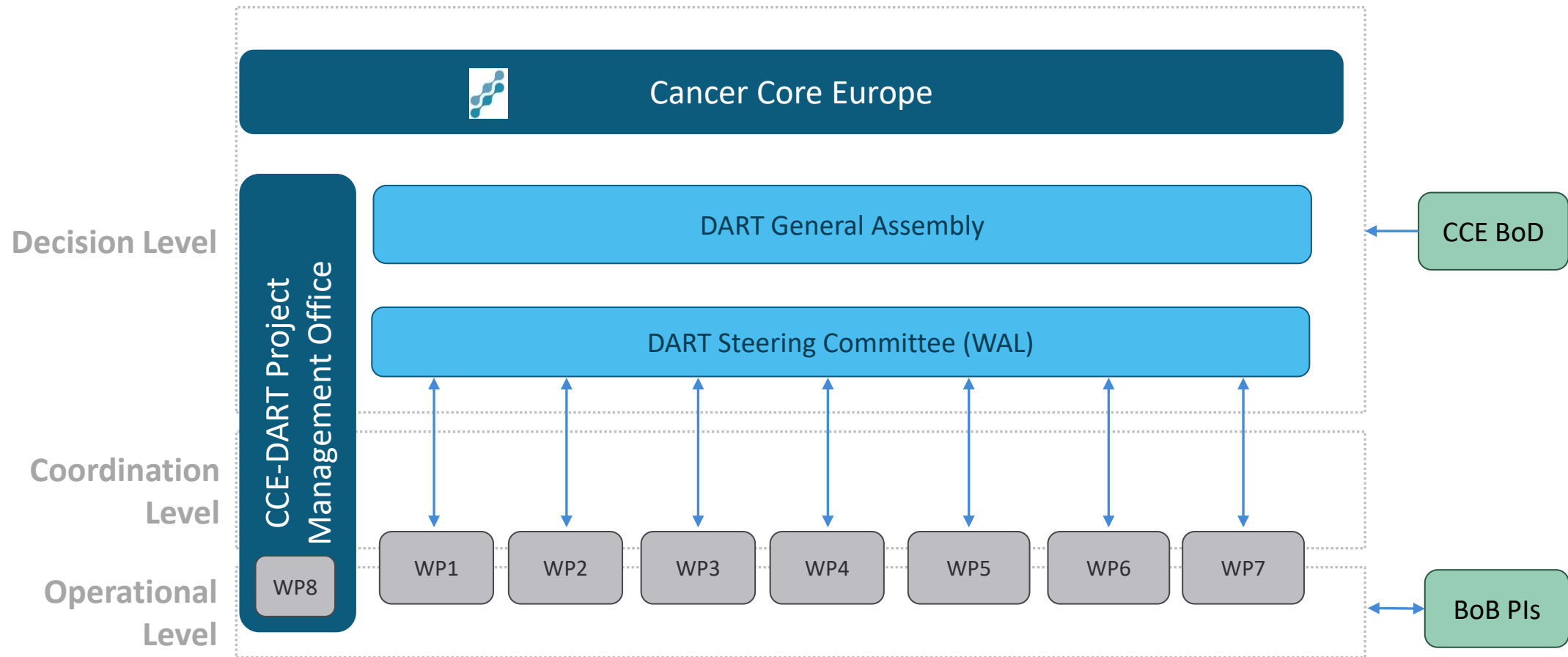


PROJECT MANAGER

# CCE\_DART Management structure



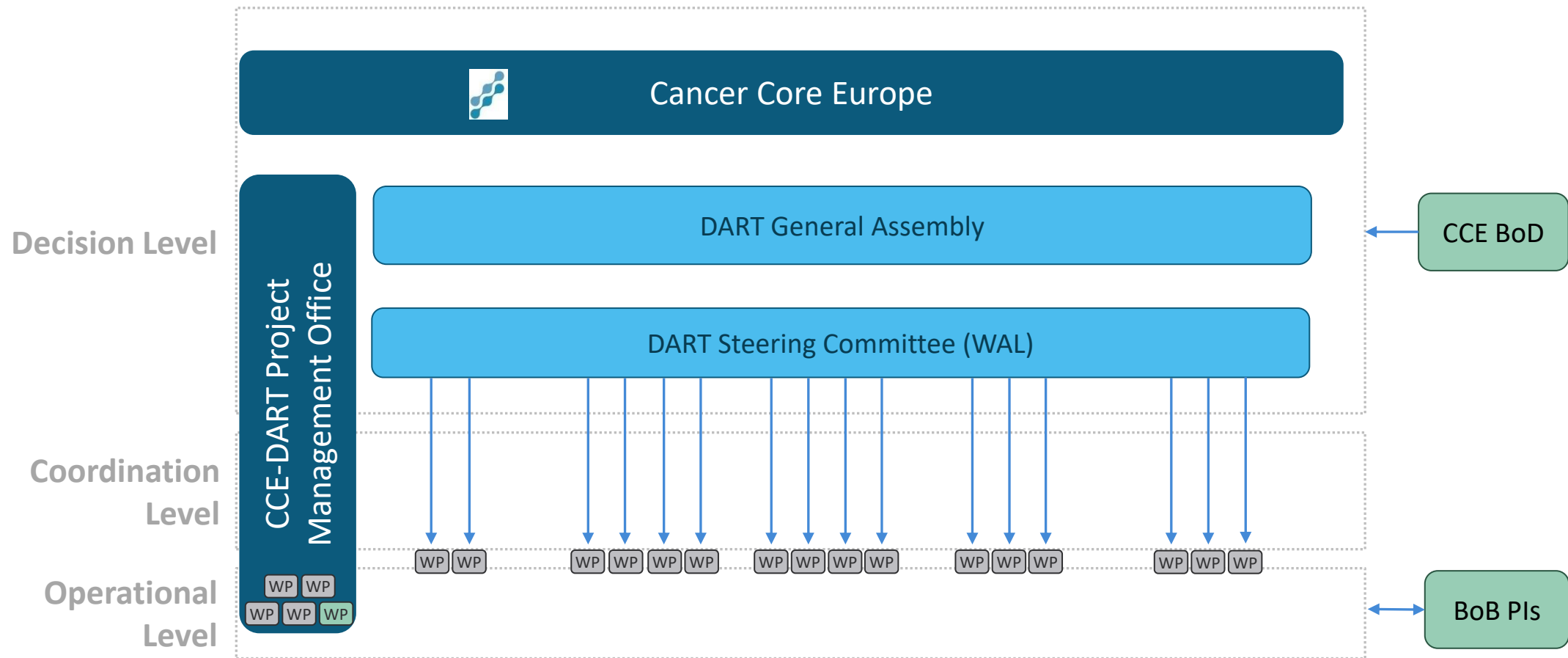
## Standard proposal



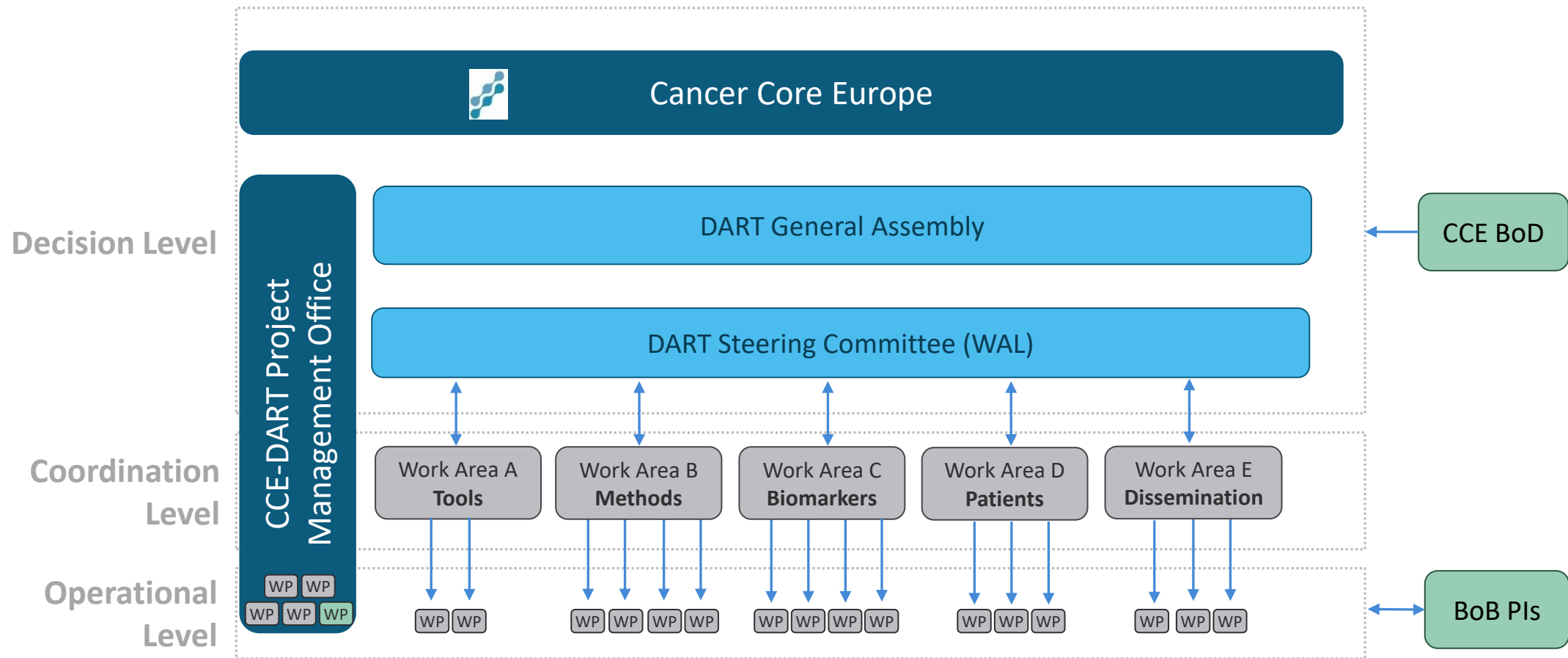
# CCE\_DART Management structure



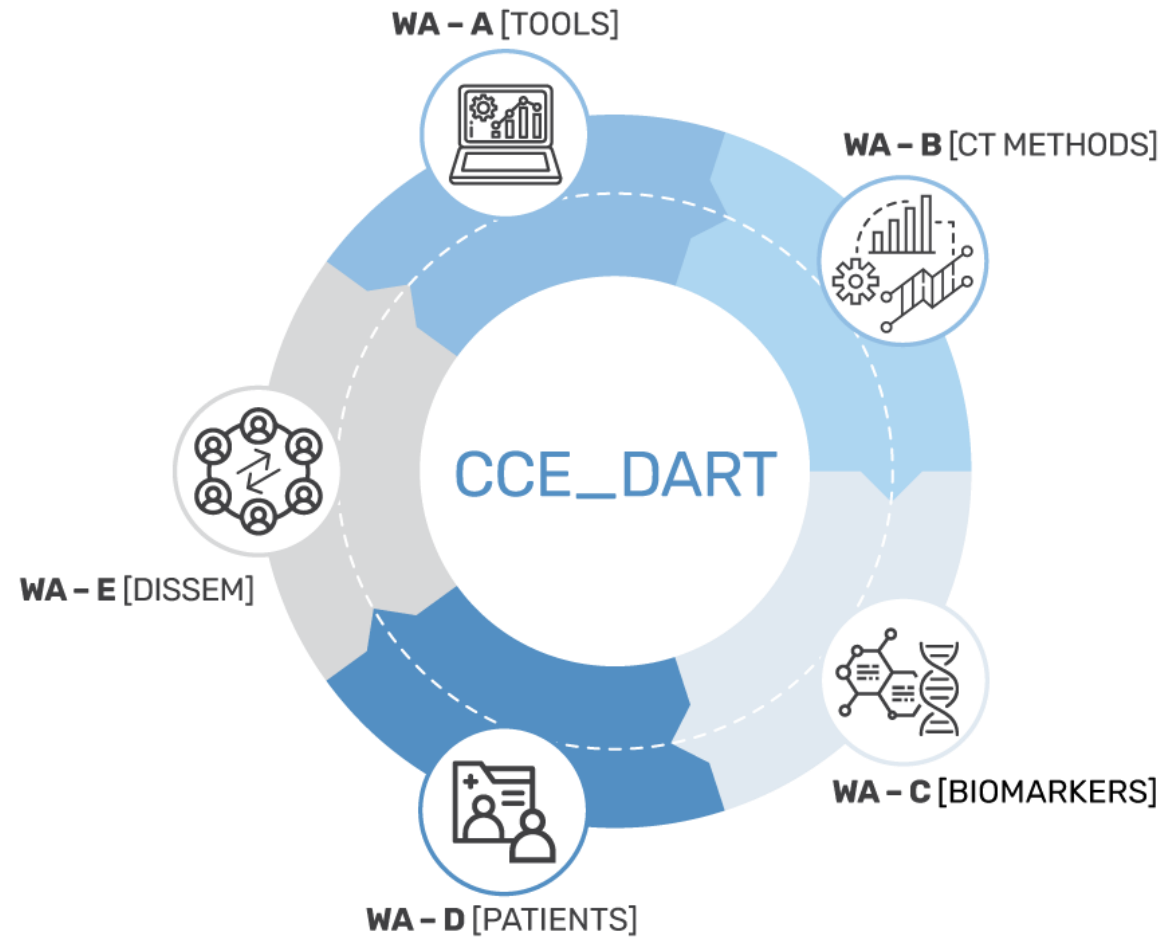
## Lump Sum proposal



# CCE\_DART Management structure



# CCE\_DART implementation



CCE\_DART is composed by the following Working Areas:

- WA-A: Development of new tools
- WA-B: Novel Clinical Trials Designs
- WA-C: New Cancer Biomarkers
- WA-D: Patient involvement through information and partnership
- WA-E: Communication, Dissemination, Valorisation and Sustainability of CCE-DART Model



# Proposal budget



# Budget



COST CATEGORY	BE1 name		
	UNITS	COST PER UNIT	BE TOTAL COSTS
<b>COSTS WORK PACKAGE 1: WP1 name</b>			
<b>A. DIRECT PERSONNEL COSTS</b>			
<b>A.1 Employees (or equivalent)</b>			
SENIOR SCIENTISTS (or equivalent in the private sector)			0,00
JUNIOR SCIENTISTS (or equivalent in the private sector)			0,00
TECHNICAL PERSONNEL (or equivalent in the private sector)			0,00
ADMINISTRATIVE PERSONNEL (or equivalent in the private sector)			0,00
OTHERS			0,00
<b>A.2 Natural Persons under direct contract</b>			0,00
<b>A.3 Seconded Persons</b>			0,00
<b>A.4 SME owners and natural person beneficiaries</b>		5.080,00	0,00
<b>B. DIRECT SUBCONTRACTING COSTS</b>			0,00
<b>C. DIRECT PURCHASE COSTS</b>			
<b>C.1 Travel and subsistence</b>			0,00
<b>C.2 Equipment (complete 'Depreciation costs' sheet)</b>			
<i>Equipment</i>			0,00
<i>Infrastructure</i>			0,00
<i>Other assets</i>			0,00
<b>C.3 Other goods, works and services</b>			
<i>Consumables</i>			0,00
<i>Services for meetings, seminars</i>			0,00
<i>Services for dissemination activities (including website)</i>			0,00
<i>Publication fees</i>			0,00
<i>Other (shipment, insurance, translation, etc.)</i>			0,00
<b>D. OTHER COST CATEGORIES</b>			
<b>D.1 Financial support to third parties (if applicable in the topic specific conditions)</b>			0,00
<b>D.2 Internally invoiced goods and services</b>			0,00
<b>D.3 Transnational access to research infrastructure unit costs (if mentioned as eligible in the topic specific conditions)</b>			0,00
<b>D.4 Virtual access to research infrastructure unit costs (if mentioned as eligible in the topic specific conditions)</b>			0,00
<b>D.5 PCP/PPI procurement costs (if mentioned as eligible in the topic specific conditions)</b>			0,00
<b>TOTAL DIRECT PERSONNEL COSTS AND PURCHASE COSTS (A+C)</b>			0,00
<b>TOTAL DIRECT COSTS (A+B+C+D)</b>			0,00
<b>E. INDIRECT COSTS (25% * (A+C))</b>			0,00
<b>F. TOTAL COSTS (A+B+C+D+E)</b>			0,00

# Proposal budget – day to day control



TOTAL FOR ALL BENEFICIARIES PER WP																						
	WP1	WP2	WP3	WP4	WP5	WP6	WP7	WP8	WP9	WP10	WP11	WP12	WP13	WP14	WP15	WP16	WP17	WP18	WP19	WP20	Totals	
BENEFICIARIES	Scientific coordination and clinical counseling	Biorepository of BoB trials data and multi-layer visualization	CT Manag Tool development and optim.	Development of new tumor response markers - established	Development of new tumor response markers - emerging tech	Data sharing platform	Discovery of multi-layer complex biomarkers	New CT Design: "Seamless"	Nwe CT Design "Dynamyc"	Basket trial validation	Online Pharmaeconomics	development of online tools for PRO	Patient centered model for info and engagement in	Promoting patient participation	RP1 Coord and manag	RP2 Coord and manag	RP3 Coord and manag	Communication and dissemination	Maximize the impact of results and exploitation	Develop academic/ pharma / regulatory consensus around		
VHIO																					- €	
KI																						- €
UCAM																						- €
DKFZ																						- €
NKI																						- €
INT																						- €
Mario Negri																						- €
IGR																						- €
MAN																						- €
The HYVE																						- €
DataRiver																						- €
FormVision																						- €
Totals	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €
Pct:																						

TOTAL PERSON/MONTHS FOR ALL BENEFICIARIES (INCLUDED LINKED PARTIES) PER WP													
WORK PACKAGES	VHIO	KI	UCAM	DKFZ	NKI	IT	IGR	MAN	HYVE	DR	FV	TOTALS	
1 Scientific coordination and clinical counseling													
2 Biorepository of BoB trials data and multi-layer visualization													
3 CT Manag Tool development and optim.													
4 Development of new tumor response markers - established tech													
5 Development of new tumor response markers - emerging tech													
6 Data sharing platform													
7 Discovery of multi-layer complex biomarkers													
8 New CT Design: "Seamless"													
9 Nwe CT Design "Dynamyc"													
10 Basket trial validation													
11 Online Pharmaeconomics													
12 development of online tools for PRO													
13 Patient centered model for info and engagement in PM													
14 Promoting patient participation													
15 RP1 Coord and manag													
16 RP2 Coord and manag													
17 RP3 Coord and manag													
18 Communication and dissemination													
19 Maximize the impact of results and exploitation													
20 Develop academic/ pharma / regulatory consensus around CT													
<b>TOTALS</b>	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00
Pct:													

- Invitation letter
- Proposal evaluation Form
- Ethics Summary Report
- Preliminary comments in view of first submission of GA Data
  - All beneficiaries with PLSIGN Role and validated in the Beneficiary Register (PDM)
  - All beneficiaries to sign DoH
  - Deliverables/Milestones (to update dates and to add milestones)
  - Third parties (to confirm involvement)
  - **Budget redistribution**
  - Table History of changes



Funding & tender opportunities  
Single Electronic Data Interchange Area (SEDIA)

Home | SEARCH FUNDING & TENDERS | HOW TO PARTICIPATE | PROJECTS & RESULTS | WORK AS AN EXPERT | SUPPORT

## Lump sum funding in Horizon Europe

- Overview
- Guidance
- Events
- Opportunities
- Background



Lump Sum funding in Horizon Europe: How does it work and what are the next steps?

**Lump sum funding in Horizon Europe: How does it work and what are the next steps?**

Ver en YouTube

## Reporting process — Lump sum

### Table of contents

- Process description and steps
  - Step 1: All beneficiaries receive a notification and log on to the Funding & Tenders Portal
  - Step 2: All beneficiaries complete their contribution to the Technical Part of the Periodic Report and Lock for Review their Technical Part once completed
    - A. Completing your contribution to the Technical Part
    - B. Locking the Technical Part for Review
    - C. Reviewing the Technical Part and accepting and including it for submission to the EU
  - Step 3: The Coordinator completes the Status of Work Packages and Locks & Includes them
    - A. Completing the Status of Work Packages
    - B. Locking and Including the Status of Work Packages
  - Step 4: The Coordinator receives a notification that the Financial Statement for all beneficiaries is ready to be signed
    - A. Locking for Review the Financial Part
    - B. Signing the Financial Part
  - Step 5: The Coordinator reviews the elements of the Periodic Report & submits to the EU
  - Step 6: The EU reviews the submitted Periodic Report and accepts, requests additional information or rejects it
  - Step 7: Interim Payment

# Reporting



**Periodic Reporting and Payment - Lump Sums**  
REP-237556-1 - period  
01/03/2021 > 28/02/2022

01 Mar 2022

Draft Submitted Observations Paid

- Technical Part contribution locking...
- Status of Work Packages contribution Lock & Include
- Periodic Report composition Submit to EU

Process documents

Process communications

Process history

---

- Financial Part TELIA [PIC 922460301] Lock for review

# Reporting



237556 (237556 SURDULI ...) InnovFun... Status Of WP 

Period No: 1 Duration (months): 12  
Reporting Period : [01 Mar 2021 - 28 Feb 2022]

## Status of completion

 SAVE







Number	Title	Lead Beneficiary	Status of Completion	Completion %
WP1	wp1	AST GmbH	Partially Completed	60.00
WP2	wp2	AAA	Completed	100.00
WP3	wp3	AST GmbH	Partially Completed	50.00
WP4	wp4	AAA	Not Completed	0.00
WP5	wp5	AST GmbH	Not Completed	0.00



# Reporting



Periodic Reporting and Payment - Lump Sums Composition [Period No: 1 (11 Apr 2021 - 10 Jul 2022), Project No: 245724]

Report Item	Status	Action
▼ Technical report		
  Technical Part of Periodic Report	Included	<b>Redo</b>
▼ Status of Work Packages		
  Status of Work Packages	Included	<b>Redo</b>
▼ Financial report		
1 (1/1)   Financial Statement TELIA[PIC 922460301]	Included	

All signed !

Suspension of the payment deadline

Review Meeting

# Review Meeting

## Before the meeting

- Proposed dates: within 2-3 weeks
- Two external experts (to declare no Col)

## Meeting

- Agenda

## After the meeting

- Review report

Topic	Responsible	Time
Introduction – meeting purpose and planning	Project Officer – Experts Monitors	xx-xx
Tour de table	All participants	xx-xx
<b>Overview of the Reporting Period:</b> <ul style="list-style-type: none"> <li>• Project management</li> <li>• Next steps planned</li> <li>• Key general comments</li> </ul>	Coordinator	xx-xx
<b>Q&amp;A</b>		xx-xx
<b>Reporting on objectives &amp; work-plan (Work Packages):</b> <ul style="list-style-type: none"> <li>• Work done and results</li> <li>• Problems encountered</li> <li>• Next steps planned</li> </ul>	WP leaders	xx-xx
<b>Q&amp;A</b>		xx-xx
<b>Other implementation aspects:</b> <ul style="list-style-type: none"> <li>• Impact, including impact to SMEs</li> <li>• Dissemination, communication, exploitation</li> <li>• Data Management Plan</li> <li>• Gender balance aspects</li> <li>• Ethics issues</li> <li>• Resources</li> </ul>	Coordinator and/or WP leaders	xx-xx
<b>Q&amp;A</b>		xx-xx
<b>Closing the Review Meeting</b> <ul style="list-style-type: none"> <li>• Preliminary conclusions (PO - Monitors)</li> <li>• Next steps - review finalisation and Interim / final project payment (PO)</li> </ul>	Project Officer – Experts Monitors	xx-xx

# Review Meeting



## GENERAL PROJECT REVIEW CONSOLIDATED REPORT

- Overall assessment
  - General comments
  - Recommendations concerning the period covered by the report
  - Recommendations concerning future work
- Objectives and workplan
- Impact
- Implementation
- Resources
- Expert opinion on deliverables
- Expert opinion on milestones

# Amendment #1



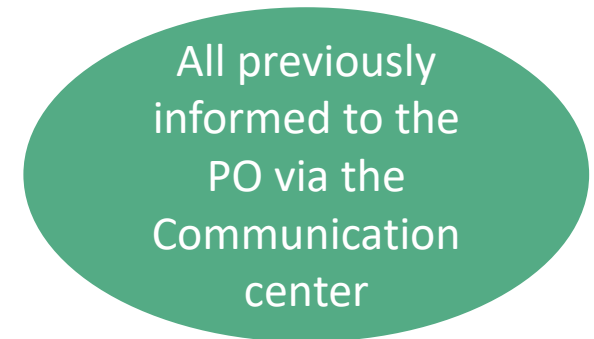
## Changes involving beneficiaries

- Deletion of a beneficiary whose participation has been terminated
- Change of the leader in some tasks
- New PI for a beneficiary
- Other changes in the beneficiaries' details



## Changes in the description of action (annex I)

- Update of project timeline (timelines, deliverables & milestones due dates)
- Reorganization of the working areas (WAs)
- Update of the SAB members' names
- Minor WPs updates
- Correction of clerical errors and clarifications



# Amendment #1



## Changes in the budget (annex II)

- Budget redistribution

TOTAL FOR ALL BENEFICIARIES PER WP - AMENDMENT																					
	WP1	WP2	WP3	WP4	WP5	WP6	WP7	WP8	WP9	WP10	WP11	WP12	WP13	WP14	WP15	WP16	WP17	WP18	WP19	WP20	Totals
BENEFICIARIES	Scientific coordination and clinical counseling	Biorepository of BoB trials data and multi-layer visualization	CT Manag Tool development and optim.	Development of new tumor response markers - established tech	Development of new tumor response markers - emerging tech	Data sharing platform	Discovery of multi-layer complex biomarkers	New CT Design: "Seamless"	New CT Design "Dynamyc"	Basket trial validation	Online Pharmacoeconomics	development of online tools for PRO	Patient centered model for info and engagement in PM	Promoting patient participation	RP1 Coord and manag	RP2 Coord and manag	RP3 Coord and manag	Communication and dissemination	Maximize the impact of results and exploitation	Develop academic/ pharma / regulatory consensus around CT	
VHIO	xx €	xx €	xx €	xx €	xx €	xx €	xx €	xx €	xx €	xx €	xx €	xx €	xx €	xx €	xx €	xx €	xx €	xx €	xx €	xx €	xx €
KI	xx €	xx €	xx €	xx €	xx €	xx €	xx €	xx €	xx €	- €	- €	- €	- €	- €	- €	xx €	xx €	xx €	xx €	- €	xx €
UCAM	xx €	xx €	- €	xx €	xx €	xx €	- €	xx €	xx €	xx €	- €	xx €	- €	- €	xx €	xx €	xx €	xx €	xx €	- €	xx €
DKFZ	xx €	xx €	- €	xx €	xx €	xx €	xx €	xx €	- €	- €	xx €	xx €	- €	- €	xx €	xx €	xx €	xx €	xx €	- €	- €
NKI	xx €	xx €	- €	xx €	xx €	xx €	- €	xx €	xx €	- €	- €	xx €	- €	- €	xx €	xx €	xx €	xx €	xx €	- €	- €
INT	xx €	xx €	- €	- €	- €	xx €	xx €	xx €	- €	xx €	- €	xx €	xx €	xx €	xx €	xx €	xx €	xx €	xx €	- €	- €
Mario Negri	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	xx €	xx €	- €	- €	- €	- €	- €	- €	- €
IGR	xx €	xx €	- €	- €	- €	xx €	- €	xx €	- €	xx €	- €	- €	- €	- €	xx €	xx €	xx €	xx €	xx €	- €	- €
MAN	- €	- €	- €	- €	- €	- €	xx €	- €	- €	- €	- €	xx €	- €	- €	xx €	xx €	xx €	xx €	xx €	xx €	- €
The HYVE	- €	xx €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	xx €	xx €	xx €	- €	xx €	- €	xx €
DataRiver	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	xx €	xx €	xx €	xx €	xx €	- €	xx €	- €	- €
FormVision	- €	- €	xx €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	xx €	- €	- €	- €	- €	- €	- €
Totals	xx €	xx €	xx €	xx €	xx €	xx €	xx €	xx €	xx €	xx €	xx €	xx €	xx €	xx €	xx €	xx €	xx €	xx €	xx €	xx €	- €



# Amendment #2

## Changes in the description of action (annex I)

- Change in the duration (12 months extension)
  - Includes update of project timeline (timelines, deliverables & milestones due dates)



# Project manager



Imagen de Freepik

# Other questions?

One partner  
delaying a WP



Amendment  
process



Reporting  
WPs



Budget  
redistribution



Follow up from  
the PO



Elena Chavarria  
[echavarria@vhio.net](mailto:echavarria@vhio.net)







This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 965397