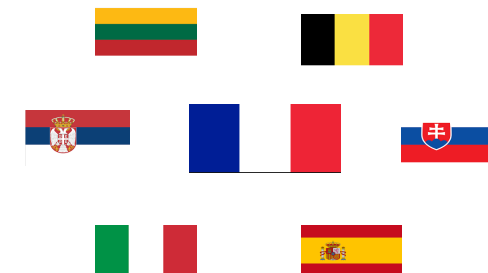




iPAAC
INNOVATIVE PARTNERSHIP
FOR ACTION AGAINST CANCER



WP9 - INNOVATIVE THERAPIES AGAINST CANCER

Dr Muriel DAHAN, Head of the Clinical Guidelines and Medicines Direction

Dr Hélène DENIS, Project manager, Medicines Department

French National Cancer Institute (INCa) – France



Co-funded by
the Health Programme
of the European Union

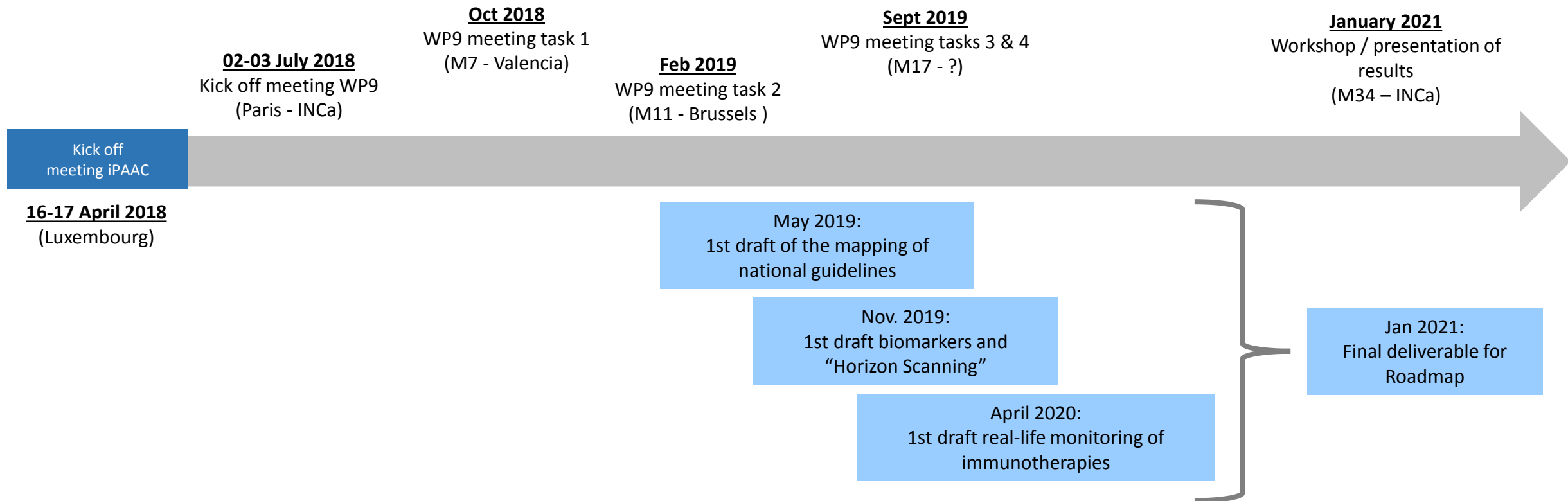


WP9 OBJECTIVES







INNOVATIVE THERAPIES IN CANCER - IMMUNOTHERAPIES

- 1) Map existing **guidelines** and reference frameworks regarding the use of immunotherapies in clinical practices and identify potential off-label use
 - ➔ Promote the proper use of these innovative treatments
 - ➔ Spur coordination across institutions, professionals and Member States
- 2) Identify and validate predictive **biomarkers** for response, resistance or toxicity
 - ➔ Better identify responders or non responders
- 3) Identify and predict impact of forthcoming innovative treatments (**horizon scanning** activities)
 - ➔ Anticipation of new therapies, their associated costs and their place in the therapeutic strategy
- 4) Identify tools that could be implemented in Europe for **real-life monitoring** of innovative treatments
 - ➔ Provide guidance regarding the assessment of innovative therapies in real-life setting

WP9 - GENERAL ORGANIZATION



PARTNERS & TASKS ALLOCATION

		Tasks				
		9.1	9.2	9.3	9.4	9.5
Associated partners						
	Belgium	Scientific Institute of Public Health (WIV-ISP)				
		X	X	X	X	X
	Italy	CRO-Aviano (in collaboration with ISS)				
			X		X	X
	Lithuania	National Centre of Pathology, Affiliate of Vilnius University Hospital Santaros Klinikos (VuHSK)				
			X	X		X
	Serbia	Clinical Center of Kragujevac CCK (in collaboration with IPHS)				
		X		X	X	X
	Slovakia	Biomedical Research Center (BMC SAS)				
		X		X		X
Collaborative partners						
	Spain	INCLIVA	X	X		X
		CIBERONC	X	X		X



iPAAC
INNOVATIVE PARTNERSHIP
FOR ACTION AGAINST CANCER



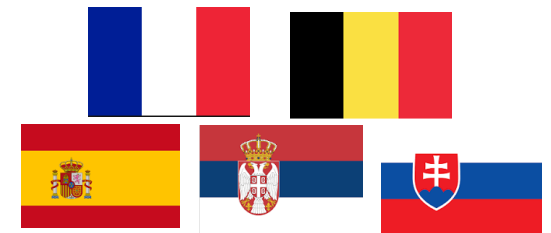
TASK 9.1



GUIDELINES AND CLINICAL PRACTICES REFERENCE FRAMEWORK

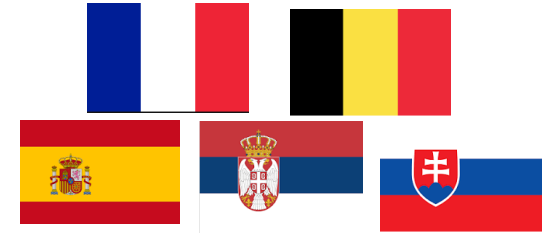


Co-funded by
the Health Programme
of the European Union



TASK 9.1 - Guidelines and clinical practices reference framework

- Participants: France, Belgium, Serbia, Slovakia – Spain
- Main goals:
 - Provide current status regarding national guidelines & reference frameworks of clinical practices on innovative therapies;
 - Identify potential off-label use in the guidelines.
- Milestones: May 2019 - First draft of the mapping of national guidelines and reference frameworks of clinical practices with regards to innovative therapies
- Internal deliverable: September 2019 - Mapping of national guidelines and clinical practices reference frameworks regarding innovative therapies



TASK 9.1 - METHODOLOGY

Literature review

Selection of key words and languages to be used



Inclusion & exclusion criteria to be defined



Identification of guidelines and reference framework



Brief presentation of each guideline
(year of publication, authors, scope, key recommendations, biomarkers, ...)



Assessment of guidelines (including off label use)



Questionnaire

Development of relevant questions



Identification of survey responders (Stakeholders, Learned societies, National health authorities, public health institutions...)



Survey dissemination
(online format)



TASK 9.1 – LITERATURE SEARCH TO IDENTIFY GUIDELINES

- Focus on innovative immunotherapies:
 - Checkpoints inhibitors (anti-PD-1, anti-PD-L1, anti-CTLA-4)
 - CAR-T cells
 - Potential new targets (IDO, LAG3, ...)
- Key words:
 - Immunotherapy, checkpoint inhibitors, anti-PD-1, anti-PD-L1, anti-CTLA-4, CAR-T cells
 - Already approved medications: Ipilimumab, nivolumab, pembrolizumab, avelumab, atezolizumab
 - Cancer localizations

Languages to be used:

INCa: English and French; Belgium: Dutch, German; Serbia: Serbian; Spain: Castilian, Catalan; Slovakia: Slovakian



iPAAC
INNOVATIVE PARTNERSHIP
FOR ACTION AGAINST CANCER



TASK 9.2

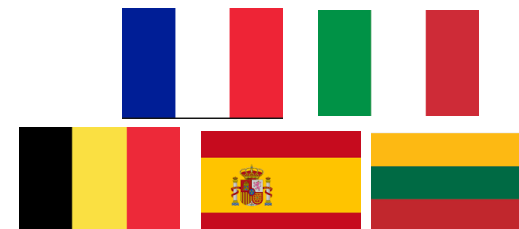


BIOMARKERS:

Predictive parameters for immunotherapies response and/or toxicity



Co-funded by
the Health Programme
of the European Union



TASK 9.2 - BIOMARKERS

- Participants: France, Italy, Belgium, Lithuania - Spain
- Main goals:
 - Analysis of biomarkers for innovative therapies as predictive parameters of response and/or side effects
 - Map existing guidelines in order to have an overview of the use of biomarkers for immunotherapies in clinical routine
 - Identify parameters specific to biomarkers to be included in a Horizon scanning to anticipate the use of predictive biomarkers in clinical routine
- Milestones: November 2019 -First draft of mapping of existing national guidelines with biomarkers used in clinical routine
- Internal deliverable: January 2020 - Biomarkers: current use in clinical practices in Europe and early detection in Horizon scanning



TASK 9.2 - METHODOLOGY

IDENTIFICATION OF BIOMARKERS USED IN CLINICAL ROUTINE

Similar method as for task 1

- Literature search
- Questionnaire
- Analysis of guidelines

ANTICIPATION OF NEW BIOMARKERS

Similar method as for task 3

- Review of existing Horizon scanning systems
- Identification of specificities for biomarkers



TASK 9.3

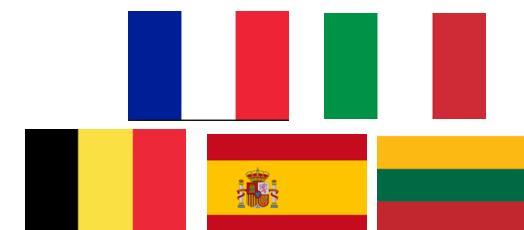


HORIZON SCANNING :
A tool to anticipate innovative therapies



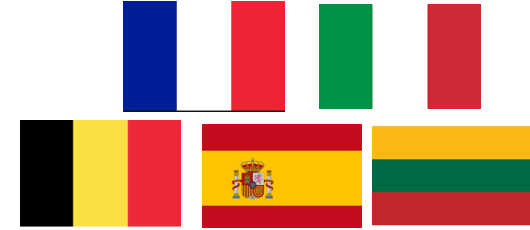
Co-funded by
the Health Programme
of the European Union

iPAAC kick-off meeting, Luxembourg, April 2018

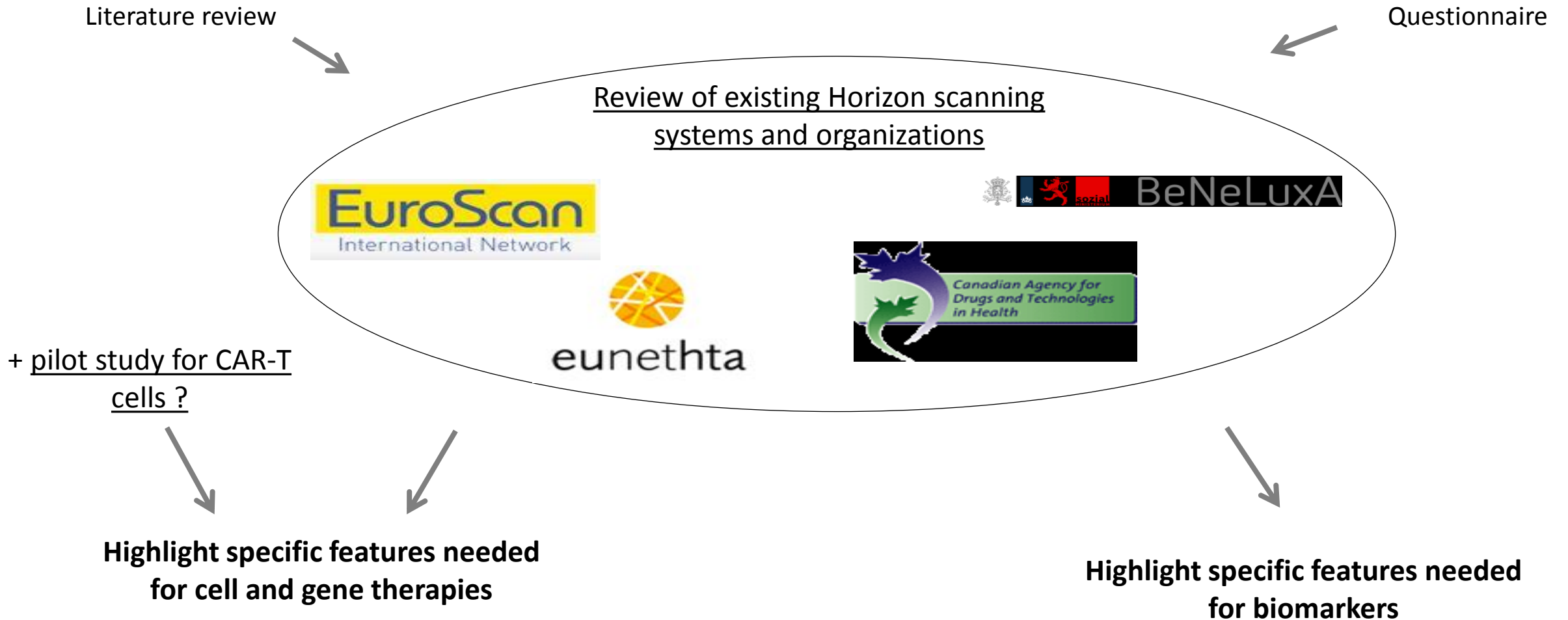


TASK 9.3 – HORIZON SCANNING

- Participants: France, Belgium, Serbia, Slovakia, Lithuania
- Main goals:
 - Anticipation of market approval of incoming new therapies and rising costs
 - Identify uses and services provided by Horizon scanning systems
 - Identify special Horizon scanning features to be considered for:
 - Gene and cells therapies (CAR-T cells as an example?)
 - Biomarkers
- Internal deliverable: April 2020 – Horizon scanning in Europe: existing systems, new trends, implementation in Member states



TASK 9.3 - METHODOLOGY





iPAAC
INNOVATIVE PARTNERSHIP
FOR ACTION AGAINST CANCER



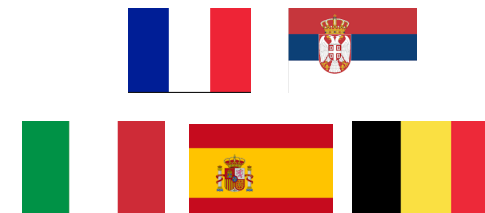
TASK 9.4



REAL LIFE MONITORING OF INNOVATIVE THERAPIES



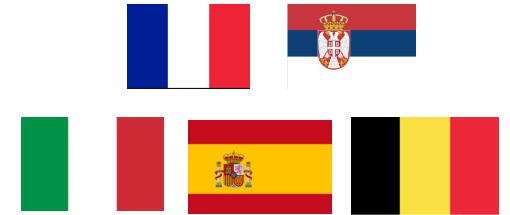
Co-funded by
the Health Programme
of the European Union



TASK 9.4 – REAL LIFE MONITORING OF INNOVATIVE THERAPIES



- Participants: France, Italy, Belgium, Serbia - Spain
- Main goals:
 - Provide guidance and model for the assessment of innovative therapies in real-life setting
 - Identify the following information:
 - ➔ What are the relevant data to be collected?
 - ➔ How can we collect and analyze these data?
 - ➔ Why do we need to collect these data, especially for the patients benefice ?
 - ➔ How can we use these data to improve evidence-based medicine level of proof?
- Milestones: April 2020 - First draft of common European tools for a real-life monitoring of selected immunotherapies
- Internal deliverable: December 2020 - European tools for real-life monitoring of selected immunotherapies



TASK 9.4 - METHODOLOGY

Literature review



Identification of system in place for real-life monitoring of
immunotherapies
(CancerLinq, AIFA, ENCEPP, GPRD, ...)



Questionnaire



Classification of identified system according to the goal of each
system



Appraisal: strength and weakness of each system



Provide recommendations for Member states for implementation
of real-life monitoring systems

If possible, implementation of real-life pilot study post-authorization to help positioning
medicines in real-life setting



iPAAC
INNOVATIVE PARTNERSHIP
FOR ACTION AGAINST CANCER



TASK 9.5

DRAFTING THE ROADMAP ON IMPLEMENTATION AND
SUSTAINABILITY OF CANCER CONTROL ACTIONS IN THE FIELD
OF INNOVATIVE CANCER THERAPIES

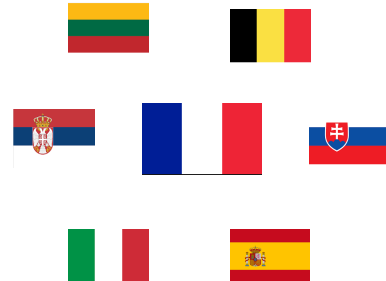


Co-funded by
the Health Programme
of the European Union



TASK 9.5 DRAFTING THE ROADMAP

- Participants: all WP9 partners
- Deliverable: Roadmap on Implementation and Sustainability of Cancer Control Actions in the field of innovative cancer therapies (January 2021)
- Description: Preparation of the summary of the activities with recommendations and strategies for implementation for policymakers for each topic.
- To be done in accordance with instructions set up by the WP4.



IDENTIFIED RISKS AND CONTINGENCY PLANNING

Identified Risk	Likelihood	Impact	Contingency planning
Coordination difficulties between all institutions, professionals and member states	Medium	High	Strong initial commitment from partners, discussions will take place before and during the JA in order to improve coordination
Delay or failure of a partner to deliver work as agreed	Low	Medium	Strong initial commitment from partners, experienced WP9 staff members will detect problem early (close monitoring of work progress) and propose new deadlines; if that fails: redistribution of work to other partners after discussion and decision by WP9 leader
Low response rate to questionnaires	Low	High	Strong initial commitment from partners, reminders will be sent to all partners, some delay will be proposed to partners in answering the proposed questionnaires
Difficulties in coordination implementation of Horizon Scanning and real life monitoring in participating countries	Medium	High	Preparatory discussions will take place before the start of the JA with the participating countries, specific data will be selected to foster coordinated implementation in participating countries

NEXT STEPS

- WP9 kick-off meeting on 02-03 July in France at the INCa
- Reconfirm dates and location for future WP9 meetings

To contact us:

mdahan@institutcancer.fr

hdenis@institutcancer.fr



INCA PARTICIPANTS

WP number	WP title	Lead beneficiary	Person-months	INCa participants	Person-months INCa
WP1	Coordination	1 - NIJZ Slovenia	147.00	Thomas Dubois Hélène Denis	2.00
WP2	Dissemination	6 - UZIS Czech Republic	68.50	Thomas Dubois Hélène Denis	2.00
WP3	Evaluation	4 - CIPH Croatia	66.70	Thomas Dubois Hélène Denis	2.00
WP4	Integration in National Policies and Sustainability	2 - WIV-ISP Belgium	74.80	Muriel Dahan Claudia Ferrari Thomas Dubois Hélène Denis	5.80
WP5	Cancer Prevention	7 - THL Finland	86.03	Jérôme Foucaud Christine Chomienne	1.39
WP6	Genomics in Cancer Control and Care	2 - WIV-ISP Belgium	95.34	Frédérique Nowak	2.8
WP7	Cancer Information and Registries	13 - ISS Italy	198.45		
WP8	Challenges in Cancer Care	23 - ICO Spain	67.32		
WP9	Innovative Therapies in Cancer	8 - INCa France	55.50	Muriel Dahan Christine Chomienne Thomas Dubois Frédérique Nowak Sophie Negellen Hélène Denis Elisabeth Bermudez	40.7
WP10	Governance of Integrated and Comprehensive Cancer Care	9 - BMG Germany	121.4		

INCA STAFF



Pr Norbert IFRAH
President of INCa



Thierry BRETON
General Manager, INCa



Dr Muriel DAHAN
Director of clinical guidelines
and medicines Direction



Pr Christine CHOMIENNE
Director of the Research
Division



Dr. Claudia FERRARI
Head of the Organisation and
cancer care pathway department



Sophie NEGELLEN
Head of the medicines
department



Elisabeth BERMUDEZ
Project manager,
Medicines department



Helene DENIS
Project manager
Medicines department



Frédérique NOWAK
Head of the department Biology,
Transfer and innovation



Thomas DUBOIS
Head of the international
affairs department



Jérôme FOUCAUD
Head of department research for
Humanities and social sciences,
epidemiology and public health



iPAAC
INNOVATIVE PARTNERSHIP
FOR ACTION AGAINST CANCER

THANK YOU FOR YOUR ATTENTION



Co-funded by
the Health Programme
of the European Union

