Opening and Setting the Scene

Session 1
13:00–14:15

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Introduction to the SIMPLERAD project

Bernd J. Krause

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The SIMPLERAD consortium

- **EIBIR**

  Krause, Bernd – scientific coordinator, WP4 lead, WP5 co-lead
  Hierath, Monika – project manager, WP5 lead, WP4 co-lead

  EIBIR project office
  Peld, Nathan D

- **EFOMP**

  Bardiès, Manuel – WP1 lead, WP3 co-lead
  Peters, Steffie – WP2 co-lead
  Stokke, Caroline – WP4 co-lead (also EANM)

- **EANM Forschungs GmbH**

  Herrmann, Ken – WP2 co-lead
  Verburg, Frederik – WP3 lead
  Gear, Jonathan – WP2 lead
  Laßmann, Michael – WP1/3 co-lead
  Stokke, Caroline – WP4 co-lead
  Covens, Peter
  Decristoforo, Clemens
  Patt, Marianne
  Schulze, Rico – WP1 co-lead

  EANM project office
  Zieglmeier, Moritz
  De Martini, Amélie

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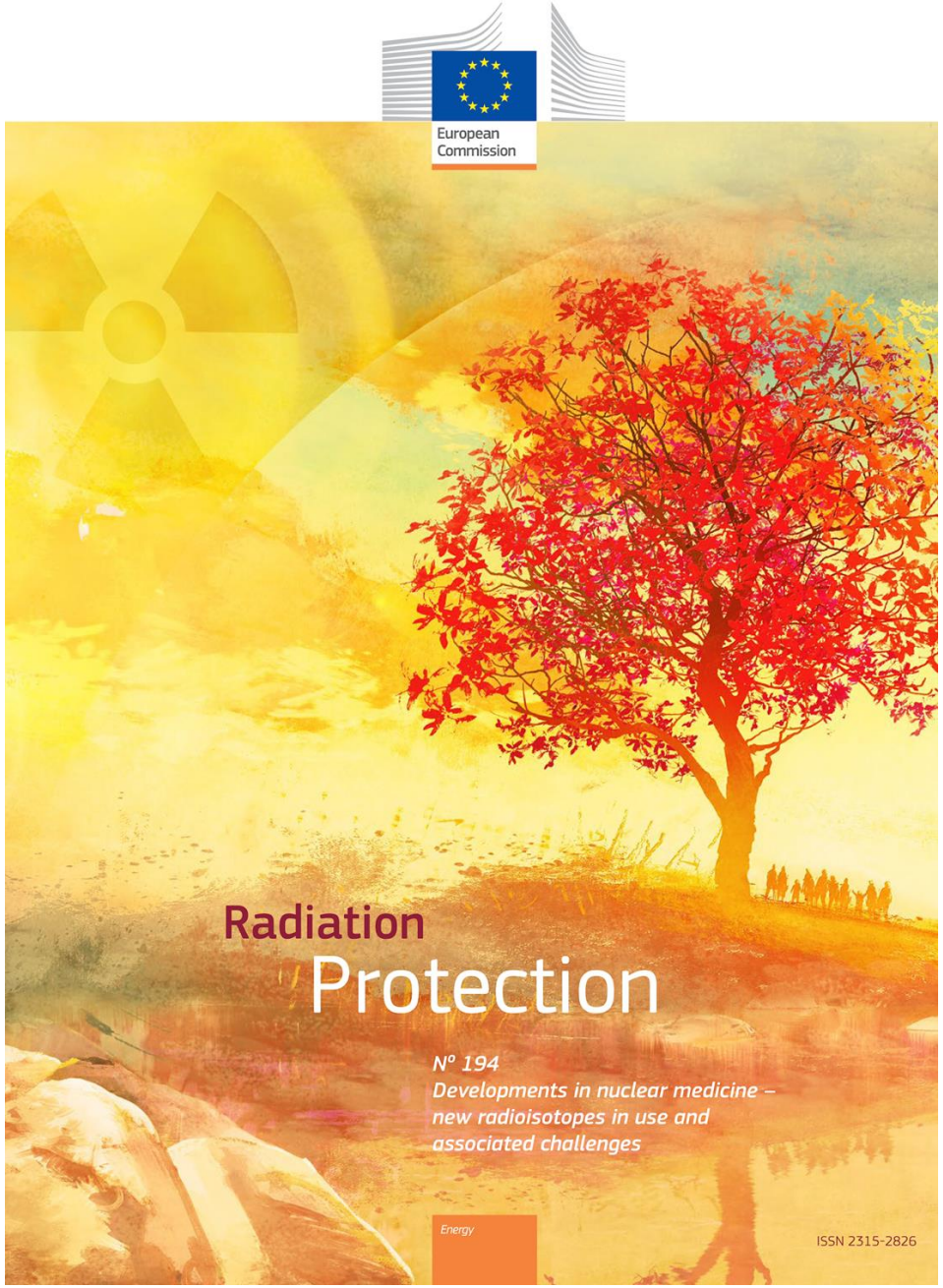
Workshop November 2019

Organised by the Working Party on Research Implications on Health and Safety Standards of the Article 31 Group of Experts

RP 194
Developments in Nuclear Medicine – New Radioisotopes in Use and Associated Challenges



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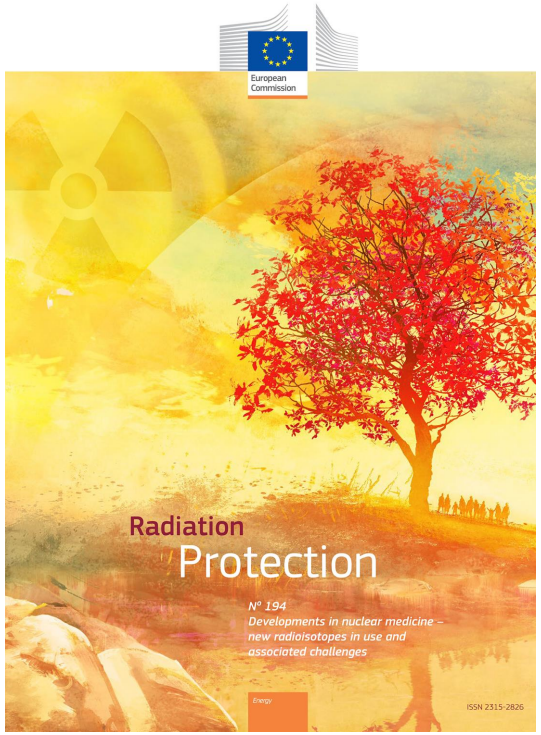
Main topic



Compliance with article 56 of the BSSD requires treatment planning and verification of the absorbed dose delivered

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Issues to be tackled

- Compliance with article 56 of the BSSD requires treatment planning and verification of the absorbed dose delivered
- Lack of European guidance for implementing BSSD, pertaining to the specific difficulties faced in nuclear medicine
- Lack of consideration in EMA guidance regarding marketing authorisation concerning safety of radionuclides
- Confusion between the requirement for optimisation stipulated in the BSSD and the need to follow the posology of the product used for marketing authorisation
- Lack of clarity re. qualitative assessment of delivery verification or a requirement for quantitative analysis based on dosimetry indices
- Lack of medical-physics expertise and physicians' knowledge on dosimetry in many nuclear medicine centres
- Divergent interpretation within the EU regarding the definition of standardised therapeutic procedures
- Lack of data to make dosimetric comparison for treatment verification
- Lack of guidance for the establishment of appropriate dose constraints
- Lack of harmonisation regarding criteria for patient release from hospitals and management of radioactive waste
- Lack of clarity of the level of optimisation required to comply with European directives on, e.g., patient selection, imaging, dosimetry

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Background and challenges addressed

- Therapeutic nuclear medicine and use of radiopharmaceuticals have heralded a paradigm shift towards personalised cancer care
- Crucial to ensure high standards in quality and safety
- Challenges due to a complex and fragmented regulatory framework regarding preparation and use of therapeutic radiopharmaceuticals
  - EU pharmaceutical legislation, currently undergoing revision
  - Euratom radiation protection legislation
- SAMIRA Action Plan provides a welcome framework for the professional community to analyse and address these challenges to ensure high quality of care and safety to Europe's patients and foster further innovation in the field

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SIMPLERAD project attributes

- Timespan: May 2022 – April 2024
- Kickoff meeting with European Commission on 23 May 2022
- Consortium
  - EANM – EANM Forschungs GmbH
  - EFOMP – European Federation of Organisations in Medical Physics
  - EIBIR – European Institute for Biomedical Imaging Research as project management partner

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SIMPLERAD general objectives

SIMPLERAD aims to:

- Improve the understanding of the links and interdependencies between the European pharmaceutical legislations and Euratom radiation protection requirements
- Highlight potential barriers to implementation
- Propose practical guidance and recommendations to advance a coherent implementation of these requirements with respect to the therapeutic use of radiopharmaceuticals
- Address quality and safety issues related to the current use and introduction of novel therapeutic radiopharmaceuticals into clinical practice, including requirements for dosimetry, the role of MPEs, release of patients from hospital, and management of radioactive waste

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SIMPLERAD specific objectives

- Analyse the interrelations between EU pharmaceutical legislation and Council Directive 2013/59/Euratom's requirements for therapeutic nuclear medicine (WP1)
- Implement a survey on the implementation of the relevant European legal requirements with respect to therapeutic nuclear medicine (WP2)
- Recommend actions to advance the coherent implementation of the European legal requirements with respect to therapeutic nuclear medicine (WP3)
- Organise a project workshop (WP4)

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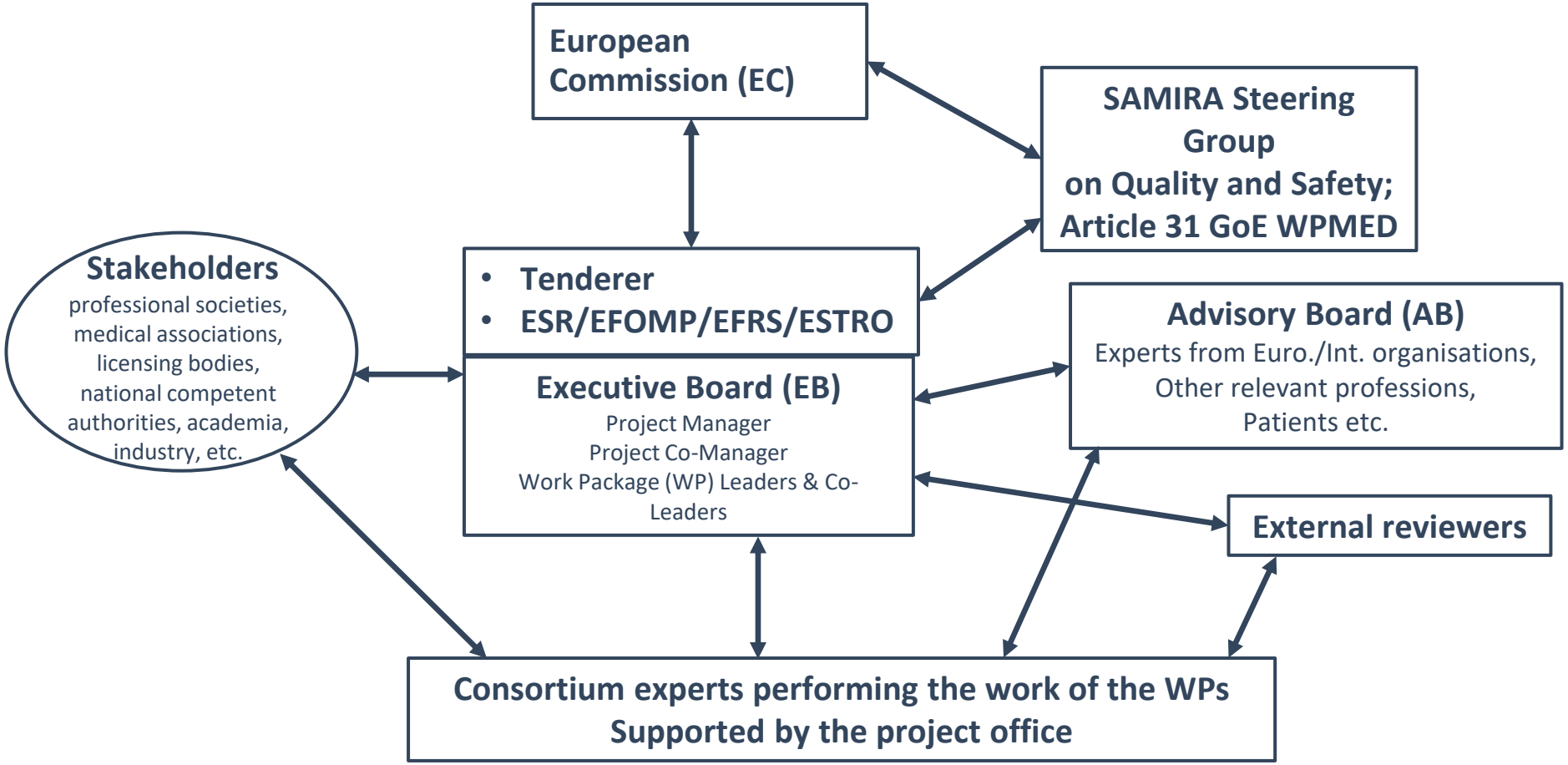
SIMPLERAD organisational chart



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SIMPLERAD Advisory Board

- Strong involvement of stakeholders to ensure high quality project work and acceptance within the communities
- Reviewed deliverables and provided first consultation on draft guidelines/recommendations
- Representatives from relevant international organizations and stakeholders from the UK, as well as regulators, industry stakeholders, patients and other stakeholders not otherwise represented in the project

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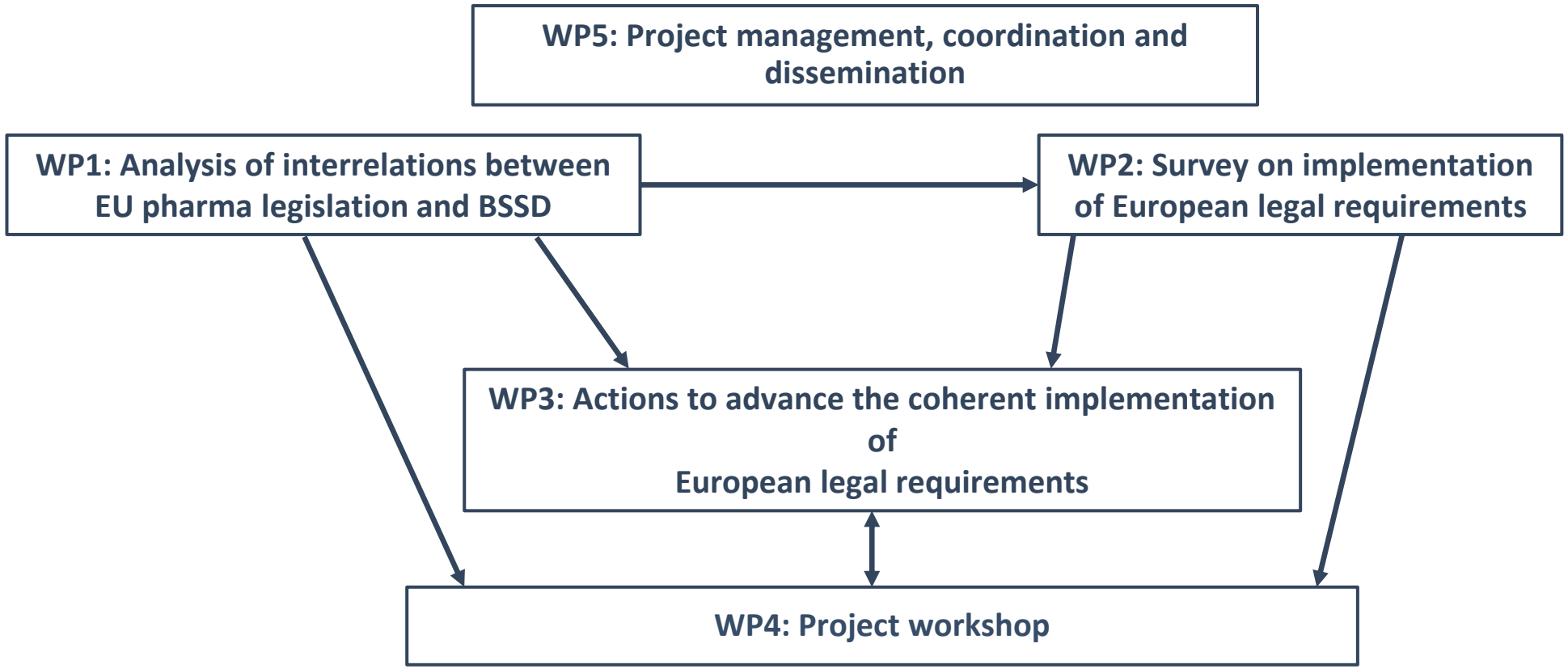
Work package structure and interrelations



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SIMPLERAD work packages

WP1 – Analysis of the interrelations between EU pharmaceutical legislation and Council Directive 2013/59/Euratom	**M1-M7**	**Lead** - M. Bardiès **Co-leads** – M. Lassmann, R Schulze
WP2 – Survey and analysis of the implementation of relevant European legal requirements for therapeutic nuclear medicine	**M1-M14**	**Lead** – J. Gear **Co-leads** – K. Herrmann, S. Peters
WP3 – Advancing coherent implementation of European legal requirements for therapeutic nuclear medicine	**M4-M24**	**Lead** – F. Verburg **Co-leads** – M. Lassmann, M. Bardiès
WP4 – Organisation of a European workshop	**M12-M24**	**Lead** – B.J. Krause **Co-leads** – M. Hierath, C. Stokke
WP5 – Project management, coordination, dissemination	**M1-M24**	**Lead** – M. Hierath **Co-lead** – B.J. Krause

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Project timeline

Deliverable numbers in bold	Year 1												Year 2											
	Q1			Q2			Q3			Q4			Q1			Q2			Q3			Q4		
	2022												2023									2024		
	May	Jun	Jul	Aug	Sept	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sept	Oct	Nov	Dec	Jan	Feb	Mar	Apr
WP1 Analysis of the interrelations between EU pharmaceutical legislation and Council Directive 2013/59/Euratom																								
T1.1 Literature review and further activities																								
T1.2 Comparative analysis of the regulatory frameworks in the EU, UK and USA																								
T1.3 Report of the analyses and findings of Tasks 1.1 and 1.2	**1.1**					**1.2**																		
WP2 Survey and analysis of implementation of relevant European legal requirements for therapeutic nuclear medicine																								
T2.1 Contact database for questionnaires and expert interviews																								
T2.2 Development, implementation and analysis of questionnaires	**2.1**																							
T2.3 Design, implementation and summarisation of expert interviews																								
T2.4 Summary report, including results of questionnaire replies and expert interviews						**2.2**						**2.3**												
WP3 Advancing coherent implementation of European legal requirements for therapeutic nuclear medicine																								
T3.1 Development of a list of additional actions to address current issues																								
T3.2 Development of a list of 10 highest ranked priorities from WP1 and WP2 results																								
T3.3 Development of a table of contents for a guidance document and draft WP3 report											**3.1**							**3.2**						
T3.4 Stakeholder consultation for WP4 workshop																								
T3.5 Processing of stakeholder feedback and prepare WP3 final report																						**3.3**		**3.4**
WP4 Organisation of a European workshop																								
T4.1 Establishment of programme structure and organisation of invitations and dissemination																		**4.1**						
T4.2 Organisational arrangements: meeting room, catering, registration, online streaming, reimbursements																				**4.2**				
T4.3 Preparation of the workshop proceedings, including session summaries, conclusions and recommendations																						**4.3**		
WP5 Project management, coordination and dissemination																								
T5.1 Organisation and chairing of kickoff, Executive Board, and European Commission progress meetings		**5.2**						**5.5**						**5.7**						**5.9**			**5.11**	
T5.2 Financial administration																								
T5.3 Monitoring of ongoing project work and achievement of deliverables, quality assurance and risk management																								
T5.4 Reporting to the European Commission according to tender specifications	**5.1**	**5.1**				**5.4**	**5.4**					**5.6**	**5.6**					**5.8**	**5.8**			**5.10**		**5.12**
T5.5 Internal/external communication and dissemination			**5.3**																					

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