SECTION A

Terms & Definition of Observational Studies:

Numbers of terms and definitions are used in the field of non-interventional / observational studies. For this questionnaire we voluntary limited definitions to:

- the latest EU regulation (No 536/2014, 16 April 2014) [i]
- the ENCePP position paper (22 November 2011) [ii]

[i] REGULATION (EU) N° 536/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/reg_2014_536/reg_2014_536_en.pdf

[ii] ENCePP considerations on the definition of non-interventional trials under the current legislative framework ("Clinical Trials Directive" 2001/20/EC) (22 November 2011) http://www.encepp.eu/publications/documents/ENCePPinterpretationofnoninterventionalstudies.pdf

[iii] The European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP). Guide on Methodological Standards in Pharmacoepidemiology (Revision 6). EMA/95098/2010.
Available at http://www.encepp.eu/standards_and_guidances

* 1. **Please enter your Country:**

* 2. **Does your country have a specific regulation for Observational Studies?**

- ◯ Yes
- ◯ No

If not, please specify:

3. **Does your local definition of Observational studies fully comply with the below quoted definition?**

Please consider the following definition given by EU for Non-Interventional Study (NIS):

»`Non-interventional study' means a clinical study other than a clinical trial;

» Means any investigation in relation to humans intended: (a) to discover or verify the clinical, pharmacological or other pharmacodynamic effects of one or more medicinal products; (b) to identify any adverse reactions to one or more medicinal products; or (c) to study the absorption, distribution, metabolism and excretion of one or more medicinal products; with the objective of ascertaining the safety and/or efficacy of those medicinal products;

» DOES NOT fulfils any of the following conditions: (a) the assignment of the subject to a particular therapeutic strategy is decided in advance and does not fall within normal clinical practice of the Member State concerned; (b) the decision to prescribe the investigational medicinal products is taken together with the decision to include the subject in the clinical study; or (c) diagnostic or monitoring procedures in addition to normal clinical practice are applied to the subjects.

- ◯ Yes
- ◯ No

If not, please specify:

* 4. **Does a specific regulation/local guidelines exist in your country in order to conduct observational studies with “additional diagnostic or monitoring procedures”?**

- ◯ Yes
- ◯ No

If yes, please specify how your regulation regulates these type of studies

* 5. **According to ENCEPP interpretation certain additional diagnostic and monitoring procedures are acceptable in observational studies.**
Is this acceptable in your local regulation?

- ◯ Yes
- ◯ No

If not, please specify:

* 6. **Does your local regulation comply with the ENCePP "Guide on Methodological Standards in Pharmacoepidemiology" (EMA/95098/2010) [iii]"?**

- ◯ Yes
- ◯ No

If not, please specify:

* 7. **Does your country regulation/local guidelines clearly refer to any of the following directives/principles?**

	Please select
Data Protection or GDPR (current regulation in force in your country) *EU*	
PASS/PAES - 2010/84/EC *EU*	
Medical Device current regulation (2007/47/CE/ MDR 2017/745) *EU*	
ISPE (www.ispe.org) *Scientific* / *Good Practice*	
ENCePP guidelines (www.encepp.eu) *Scientific* / *Good Practice*	
STROBE initiative (www.strobe-statement.org) *Scientific* / *Good Practice*	
Good Clinical Data Management Practices, 10/2010 *Scientific* / *Good Practice*	

* 8. **In your country the following observational studies follow a specific regulation?**

	Please select
Pure retrospective studies *(e.g. data base analysis or Medical Chart Review)*	
Registries	
Studies conducted with children/newborn (Pediatric sites)	
Studies conducted upon EMA request (PASS/PAES)	
Studies including use of validated PRO (Patient reported Outcomes)	
Studies including use of interview or questionnaire (not validated PRO)	
Studies including new analysis of already drawn blood samples	
Studies involving public sites	
Studies on Medical Device	
Studies on Cosmetics	
Studies on Food	

Other(s) (please specify)

SECTION B

Please complete section below regarding the non-interventional / observational studies Authorization Processes and Physician fees in your Country

* 9. **What is the duration for the Authorization Process in your country?**

Please reply considering a prospective observational study in oncology following 300 patients during 2 years period (5 visits) by 50 sites (For example 20 public sites + 30 private sites).

Minimum of (weeks)	
Average of (weeks)	
Maximum of (weeks)	

* 10. **What are the total estimated costs for the Authorization Process in your country?**

Please reply considering a prospective observational study in oncology following 300 patients during 2 years period (5 visits) by 50 sites (For example 20 public sites + 30 private sites)

Minimum of (Euros)	
Average of (Euros)	
Maximum of (Euros)	

* 11. **What are the estimate fees per patient in your country?**

Please reply considering a prospective observational study in oncology following 300 patients during 2 years period (5 visits) by 50 sites (For example 20 public sites + 30 private sites) and estimated time to complete CRF 2 hours

Minimum of (Euros)	
Average of (Euros)	
Maximum of (Euros)	

* 12. **According to your local experience which factors are perceived to be obstacles and which advantages in attractive investments for running observational studies in your country:**

	Please select
Cost of the authorization process	
Cost for patients' fees	
Duration of the authorization process	
Legislation/legal framework	
Investigators' experience and compliance *(Good Epidemiological standards, ENCePP standards,..)*	

Other (please specify)

13. **In your country how would you rate the investigators' engagement with observational research (1= poor to 10= excellent)?**

14. **In your country how do payers and decision makers rate the importance of providing Real World Data (RWD) for establishing the value of the product (1 = poor to 10 = excellent)?**

15. **In your perspective in the past 5 years the interest in RWD studies increased or decreased?**

- Increased
- Decreased

16. **In your perspective in the next 5 years the interest in RWD studies will increase or decrease?**

- Increase
- Decrease