31 October 2019
EMA/499786/2019

Workshop on the role of registries in the monitoring of cancer therapies based on genetic and molecular features

29 November 2019, 09:00 to 17:00 CET, EMA conference room 0-C

Welcome room: 0-C, European Medicines Agency, Spark Building, Orlyplein 24, 1043 DP Amsterdam, The Netherlands

Chair: Dr Peter Mol, College ter Beoordeling van Geneesmiddelen, Co-Chair of the Scientific Advise Working Party and Co-Chair of the Patient Registry Initiative Task Force.

The main objectives of the workshop are to agree on:

- Core data elements: minimum data elements that should be collected in cancer registries to support regulatory assessment of long term safety and effectiveness of new cancer treatments; the feasibility of collecting the core data elements;
- Quality assurance: measures necessary to ensure registry data are of suitable quality to support regulatory assessments and to permit registries interoperability; conduct of data analysis;
- Governance: practical considerations for accessing/sharing data to be used for regulatory purposes; clarify roles of all involved stakeholders.

Health and safety information

In accordance with Agency policy, delegates are to be shown a slide show with health and safety and emergency information and procedures. This is to be displayed at the start of this meeting using the Crestron system as delegates are entering the meeting room. In addition, the chairperson or meeting secretariat is to draw the delegates' attention to the slideshow and indicate where the nearest fire exit(s) to the meeting room are. Should there be an evacuation during the meeting, staff will guide delegates out of the building via the nearest fire exit, and assist anyone with mobility impairment.

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Item	Topic	Speaker	Time
1.	Welcome, introduction, expected outcomes of the workshop	P. Mol[1]	09:00
2.	Regulators view on the role of registries for generating data on cancer therapies	F. Josephson[2]	09:10
3.	Current situation for the monitoring of new cancer therapies through existing registries: o European Network of Cancer Registries (ENCR) o Registries for European Reference Networks (ERNs)	O. Visser[3]; H. Le-Borgne[4]	09:30
4.	Experience from a registry holder: Public Health England	A. Turnbull[5]	09:55
5.	Explanation of the Group-work breakout sessions	K. Plueschke[6]	10:20
Break - Coffee / Tea – 10:25 to 10:50			
Group-work breakout sessions (Rooms 0-C, 0-D, 0-E)			
6.	**Group 1:** Discussion on core data elements to be collected by cancer registries to support regulatory assessment, feasibility of data collection; **Group 2:** Measures necessary to ensure registry data is of suitable quality to support regulatory assessments and to permit registries interoperability; **Group 3:** Governance - practical considerations for accessing/sharing data to be used for regulatory purposes, roles of all involved stakeholders.		10:50 to 13:00
Lunch – 13:00 to 13:45			
7.	Discussion on recommendations: each group agrees on & prepares a summary (slides / poster) of its recommendations for discussion with all the workshop participants	Discussion within each group	13:45
8.	Presentations of the groups' recommendations to all the participants, and discussion towards consensus	1 presenter from each group (20 minutes each)	15:30
9.	Conclusions and next steps	P. Mol[1]	16:30
End of the workshop – 17:00			

[1] College ter Beoordeling van Geneesmiddelen, The Netherlands
[2] Läkemedelsverket, Sweden
[3] Integraal Kankercentrum Nederland (IKNL), The Netherlands
[4] European Commission, Belgium
[5] Public Health England, United Kingdom
[6] European Medicines Agency, The Netherlands