HMA/EMA Joint Task Force on big data - Survey for Pharmaceutical Industry

Fields marked with * are mandatory.

Background

This survey forms part of the work of the Heads of Medicines Agencies/European Medicines Agency (HMA /EMA) Joint Task Force on big data whose mandate[1] is to explore a number of issues regarding the emerging challenges presented by big data in the regulation of medicinal products for human use.

The term "big data" refers to extremely large sets of information, which require specialised computational tools to enable their analysis and exploitation.
These data might come from:
- data derived from clinical practice: e.g. electronic medical records, claims data, registries;
- “omics” data: e.g. genomics, proteomics, metabolomics;
- social media, m-health and other innovative and novel datasets;
- clinical trials;
- reports on spontaneous adverse reactions.

In the context of Medicines Regulation, the revolution in data and associated analytical tools could mean the submission of data in large amounts or of a complex nature supplementing more traditional analysed and structured data. Alternatively, it could exist as data lying underneath the regulatory submissions, for which it would be crucial to understand their presence and the robustness by which they were generated in order to make a competent evaluation of the submission as a whole.
While the evidence derived from big data sets has the potential to add significantly to the development of medicinal products over their entire life cycle, it is recognised there are also substantial challenges in the use of these data.

The objective of this survey is to ascertain the current landscape in terms of application of big data by Industry across the drug development pathway (human medicines only). The results are important to develop a future big data strategy and identify the future needs of the European Medicines Regulatory Network in this context. A synopsis of the results will be available as a public output of the HMA/EMA Joint Task Force.

[1] HMA/EMA Joint Task Force on big bata Mandate: http://www.ema.europa.eu/docs/en_GB/document_library/Other/2017/03 /WC500224262.pdf and http://www.hma.eu/506.html

How to complete the survey

The survey is open to Companies, SMEs and interested stakeholder organisations until the **20th October 2017**. It is customised to the respondent's profile and can only be submitted electronically. Any question marked with an asterisk (*) require an answer in order to progress through the survey. Free text boxes are allowed for further comments.
If you have any questions, you should contact the Secretariat of the HMA/EMA Joint Task Force on big data directly at tse@dkma.dk.

This survey aims to collect only aggregated and anonymous data. It does not require you to disclose your personal identity. We will collect and analyse the responses provided and use the analyses in public documents but we will not link them to any other personal information you may provide. Collected data will be kept one year and then destroyed. For security reasons, the survey platform will record IP addresses for every server request accessing the questionnaire.

Questions

*** 1. Please indicate the size of your company:**

- ○ Company (>250 employees)
- ○ SME (< 250 employees)
- ○ SME (<50 employees)
- ○ SME (< 10 employees)
- ○ On behalf of an organisation. Note that only one response per organisation will be taken into account.

*** 2. What is your organisation's profile?**

- ☐ Development, production or marketing of pharmaceuticals
- ☐ Development, production or marketing of medical devices
- ☐ Service provider to pharmaceutical industry
- ☐ Industry, trade association or chamber of commerce
- ☐ Non governmental organisation (NGO) or association of NGOs
- ☐ Other private sector (please specify in the comments field below)

Any comments (including any contact details if desired)

250 character(s) maximum

*** 3. Does your company have medicines for human use on the market within EU?**

- ○ Yes
- ○ No

* **4. Please indicate up to five key areas where you believe big data will have the greatest impact:**

- ☐ Target identification
- ☐ Defining molecular mechanisms of action
- ☐ Understanding disease prevalence
- ☐ Disease stratification
- ☐ Patient stratification/personalised medicine
- ☐ Biomarker identification
- ☐ Understanding current clinical care/patient pathway and unmet need
- ☐ Clinical trial design
- ☐ Outcome identification
- ☐ Informing on patient reported outcomes
- ☐ Safety surveillance
- ☐ Signal validation
- ☐ Defining benefit in high risk populations
- ☐ Determining the impact of label changes
- ☐ Resource utilisation
- ☐ HTA assessments

* Any comments - ***Please indicate the datasets applicable to the areas you have ticked above.***

500 character(s) maximum

* **5. In any of the above areas, please provide up to 3 examples where big Ddta has been used to drive decision making across any of your products' lifecycle:**

250 character(s) maximum

6. What would be your level of concern regarding the validity of the following big datasets on a scale of 1 to 5, where 1 corresponds to the lowest concern and 5 the biggest:

	1	2	3	4	5
* Genomics	○	○	○	○	○
* Proteomics	○	○	○	○	○
* Metabolomics	○	○	○	○	○
* Lipidomics	○	○	○	○	○
* Clinical trial data (via data sharing platforms)	○	○	○	○	○
* Adverse Drug Reaction data	○	○	○	○	○
* Patient registries	○	○	○	○	○
* Electronic health records	○	○	○	○	○
* Administrative claims data	○	○	○	○	○
* Social media data (e.g. twitter data)	○	○	○	○	○
* Imaging datasets (functional MRI, PET etc.)	○	○	○	○	○

Any comments

500 character(s) maximum

7. For your company, what are the key challenges in the use of big data? Please prioritise your choices on a scale of 1 to 5 where 1 corresponds to the lowest challenge and 5 the biggest:

	1	2	3	4	5
* Data access					
* Data privacy/legislation on data protection					
* Data security					
* Data quality					
* Data harmonization across Europe					
* Integration of multiple data sets					
* Data validation					
* Data reproducibility					
* Challenges of recruiting the relevant expertise					
* Information Technology challenges					
* Other *(please specify in the comments field below)*					

Any comments

500 character(s) maximum

***8. In your opinion, what measures could the regulatory network introduce to address these challenges?**

500 character(s) maximum

***9. In your view, what are the greatest international challenges? Please highlight specific examples if available.**

500 character(s) maximum

***10. If you have any further comments, please include them here.**

250 character(s) maximum