## EFPIA position on EDPB Opinion 3/2019 and the Commission Questions and Answers (Q&A) addressing the interplay between the Clinical Trials Regulation (CTR) and the General Data Protection Regulation (GDPR) under Art. 70(1)(b) GDPR

EFPIA broadly welcomes the two documents which seek to provide clarity regarding the interaction between the two Regulations. In particular, the documents:

- confirm that the GDPR is applicable to clinical research and that both Regulations apply simultaneously;
- make a distinction between primary and secondary use of data which better aligns these concepts with the reality of clinical research;
- confirm that the consent provisions of the two regulations relate to different concepts of consent, namely that informed consent under the CTR is consent in an ethical sense to participation in the clinical trial, different from consent to processing of personal data under the GDPR;
- state that *GDPR consent* will not be the appropriate legal basis for processing personal data for scientific research purposes in most cases and explain why this is the case
- Clarify that the processing of personal health data must conform both to the general standards of lawfulness under Art. 6 GDPR and the specific derogations for processing special categories of personal data under Art. 9(2) GDPR.
- States (in question 2 of the Commission Q&A) that clinical trial sites are controllers under GDPR (though it should be noted that the Q&A and opinion do not address all questions related to this issue)

EFPIA also notes a number of areas within the scope of the Q&A in which further guidance or discussion will be required:

- In the Opinion, the Board describes the primary use of the data as "all processing operations related to a specific clinical trial protocol during its whole lifecycle, from the starting of the trial to deletion at the end of the archiving period". This definition appears to exclude specific research activities that formed part of the planned further development of the medicine at the time that the trial was initiated but which go beyond the immediate trial. Researchers will need to reflect on how to ensure that relevant data is preserved during the longer-term development of the medicine.

- The Opinion distinguishes between processing activities which are legal obligations under the CTR (for example processing for reliability and safety purposes and data retention) and those that are considered research activities. While legal bases exist for both, it is likely that more detailed guidance for industry will need to be developed to clarify the applicable legal base, acknowledging that there will be many processing activities where it will be impossible to separate the two, also taking into consideration the term "clinical study" as defined in Art. 2(2) CTR

- Further elaboration of the scope of the relevant articles will also be needed in relation to situations where the lawful processing of personal health data under Art. 6 GDPR and the specific derogations for processing special categories of personal data under Art. 9 GDPR propose distinct legal grounds. In the Opinion (para. 10 and 13) data processing activities for reliability and safety purposes are firstly necessary for compliance with a legal obligation to which the controller is subject (Art. 6(1)(c) GDPR) and second for reasons of public interest in the area of public health (Art. 9(2)(i) GDPR). At the same time, processing operations purely related to *research* activities in a clinical trial may fall under the legitimate interests of the controller in conjunction with Art. 9(2)(i) GDPR which also postulates a public interest ground. This suggests it will be necessary to articulate the scope of the public interest but also the conditions under which a sponsor acts simultaneously under his legitimate interests and reasons of public interests.

- The EFPIA raises concerns as to the Board's consideration that a "freely given" consent may be unlikely in a clinical trial. Although this statement (para. 17. and 18) refers to the GDPR consent in the first place, the alleged "imbalance of power", when referred to the CTR consent, could have an impact on the long-established ethical principles of the Declaration of Helsinki.

It would be useful for the Commission to confirm that, notwithstanding that the CTR has yet to enter into effect, this guidance should be taken into consideration immediately by relevant authorities

<u>Several important questions that require clarification lie outside the defined scope of the Opinion and Q&A</u>

- The Opinion is much less informative regarding secondary use of data and the Board acknowledges that this is a subject to which they will return. EFPIA welcomes the emphasis that the Opinion places on the provisions of Art. 5(1)(b) GDPR and the protections given under Art. 89 GDPR which provide for processing for scientific research purposes for secondary purposes. In EFPIA's view, this is a key element of the GDPR. When undertaking the further review of this issue, EFPIA believes it will be important for regulators to focus on the balance between securing the flexibilities to re-use data for scientific purposes, which are pivotal to realising the societal benefits, with the need to elaborate the safeguards needed to protect individual interests.

- The Opinion and the Commission's Questions and Answers only deal with interventional clinical trials and secondary use of data collected in such trials. However, non-interventional studies are a key part of sponsors' research activities and where such studies involve the processing of patients' personal data it is important that there is clarity as to the applicability of the derogations under Art. 9 of the GDPR.