



News from Brussels and London regarding EU Regulation and EU Portal

EUREC-Meeting, Prague March 25, 2019

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Col – Statement and Caveat

- **There are no conflict of interests to declare.**
- **The views expressed here do not necessarily represent exactly those of AKEK Germany.**

EU Portal

- **There are still major problems with the EU Portal and the related data bases.**
- **There is again a change of the contractor (move from Athens to Sevilla).**
- **EMA and COM are not willing to share forecasts beyond three months.**
- **It seems that an internal deadline has been set.**
- **I expect the EU Portal not to be ready before 2021, if at all.**

Background

The CTR 536/2014 requires that many existing guidelines have to be updated and many new ones have to be written and consented, e.g.

- **Ethical Considerations on clinical trials with minors**
- **Note for Guidance re lay summary of results of a clinical trial**
- **Note for Guidance re emergency trials**
- **Paper for transitional period**
- **Note for Guidance re informed consent**
- **Thus new working parties had to be established.**

Clinical Trial vs. Clinical Study: Article 2 2. - Working Party

‘Clinical trial’ means a clinical study which 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.

Clinical Trial: Article 2 2. - Working Party

Problem: Uniform standards in the EU are lost once a study is considered a clinical trial in one MS whereas the same study qualifies as a clinical study in another MS.

Task: to provide a definition of 'normal clinical practice' which is uniformly applicable in all EU MS.

Cave: The term 'normal clinical practice' is used in Art. 8 2. too," a MS concerned may disagree with the conclusion of the reporting MS as regards Part I of the assessment report only on the following grounds: (a) when it considers that participation in the clinical trial would lead to a subject receiving an inferior treatment than in *normal clinical practice* in the MS concerned; → I expect another Working Party.

What is the meaning of ‚Condition‘: Article 8 1. - Working Party

“Each Member State concerned shall notify the sponsor through the EU portal as to whether the clinical trial is authorised, whether it is authorised subject to *conditions*, or whether authorisation is refused.

An authorisation of a clinical trial subject to *conditions* is restricted to *conditions* which by their nature cannot be fulfilled at the time of that authorisation.”

Question: What is a condition according to this specification! Nobody knows.

My initial idea: e.g. the presentation of a valid insurance contract as many insurers insure authorized clinical trials only.

What is the meaning of ,Condition': Article 8 1. - Working Party

Now there is a strong trend to accept as condition the integration of all agreed modifications re Part I in the trial protocol, etc.

Thus neither the NCA nor the EC sees and crosschecks the final version of the trial protocol before the trial starts!

Rationale: The time slot permitted by the CTR is too short to allow the proper modifications of the trial protocol, etc.

COM comment: this can be done by the GCP-inspectors of the MS.

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Interplay of EU GDPR and CTR

Background: There are a couple of contradictions and inconsistencies between GDPR and CTR.

COM sent a Q & A draft to the EDPB in Oct. 2018.
Response arrived end of Jan 2019 (Opinion 3/2019)

Major result:

The EDPB considers that as an alternative to data subject's consent, the lawful grounds of processing provided under Article 6(1)(e) or 6(1)(f) are more appropriate.

Interplay of EU GDPR and CTR

Major result:

To conclude, the EDPB recommends modifying the Q&A when discussing the lawful grounds for processing to distinguish the processing activities related to reliability and safety that can be directly derived from legal obligations of the controller and which fall within the legal basis of Article 6(1)(c) in conjunction with Article 9(1)(i) of GDPR.

Interplay of EU GDPR and CTR

Major result:

For all other processing activities... purely related to research activities, there are three alternative legal bases, depending on the whole circumstances attached to a specific clinical trial:

- a task carried out in the public interest under Article 6(1)(e) in conjunction with Article 9(2), (i) or (j) of the GDPR; or**

Interplay of EU GDPR and CTR

Major result:

- the legitimate interests of the controller under Article 6(1)(f) in conjunction with Article 9(2)(j) of the GDPR; or
 - under specific circumstances, when all conditions are met, data subject's explicit consent under Article 6(1)(a) and 9(2)(a) of the GDPR.
- In CTs no individual IC for data processing is needed !

Interplay of EU GDPR and CTR

Consequences

- In CTs no individual IC for data processing is needed. Individual IC is considered the least appropriate option only. Rationale: WP29, Guidelines on consent under Regulation 2016/679, 28 November 2017, WP259
- There are different legal bases for processing data of CTs depending to the non-disjunct purposes.
- There will be a working party to develop a template for IC for dp in CTs.

Interplay of EU GDPR and CTR

Consequences

- **the use of different legal bases lead to the different rights of the data subjects.**

Many MS disagreed with Opinion 03/2019 and one may doubt that it contributes to a uniform application of the GDPR in the MS.

Final remarks

- It may happen that the CTR will never enter into force.
- The occasional vagueness of the wording of the CTR in the context with the different cultural backgrounds in the EU MS create serious obstacles for a uniform application of the CTR. More and more working parties are established.
- The contradictions between the CTR and the GDPR are difficult to overcome.
- The situation re the EU MDR seems to be similar.