medídee®

Nano-Tera.ch

05 February 2015 – part 12

Special Issues – Q&A Session

Michael Maier
michael.maier@medidee.com
www.medidee.com

Questions you asked 1/17

In WHICH cases to seek approval
1 - Please provide us with a clear decision tree or procedure to evaluate the regulatory needs for each project?

-> Case by case assessment – for research with materials of human origin verify 810.30 Humanforschungsgesetz, HFG (Human Research Act, HRA)
http://www.admin.ch/opc/de/classified-compilation/20061313/index.html

-> Is what you want to do a “clincal investigation” in the sense of HFG article 3 sect. L ?
810.305 Verordnung über klinische Versuche; KlinV (Clinical Trials Ordinance)
http://www.admin.ch/opc/de/classified-compilation/20061313/index.html

Questions you asked 2/17

In WHICH cases to seek approval

2- This procedure would clarify the situation in which some Nano-Tera.ch projects are (i.e. the necessity or not to have an Ethics Committee approval, the necessity or nor to have a Swiss Medic approval, the necessity or not to respect ISO-60601-1 standard, the necessity / or not to show biocompatible certificates, etc.)

-> EC if research falls under HFG

-> Swissmedic if research is “clinical trial” and KlinV applies

> If KlinV applies then “state of the art” principle as explained earlier for safety applies -> IEC 60601, ISO 10993 etc. applies

Questions you asked 3/17

In WHICH cases to seek approval

- Can you clarify and summarize the changes due to the new January 2014 Human Research Act?

The idea behind this request is to clarify the modifications in the list and contents of regulatory documents for those who have been involved in the past in Ethics Committee and/or Swiss Medic accreditation.

-> read the HFG in detail, do not look for what changed but look for what applies NOW

-> check out:
https://www.swissmedic.ch/rueckrufe_medizinprodukte/00833/00834/01643/index.html?lang=de&download=NHzLpZeg7t,lnp6I0NTU042l2Z6ln1acy4Zn4Z2qZpnO2Yuq2Z6gpJCDdnt8f2ym162epYbg2c_JjKbNoKSn6A--

Questions you asked 4/17

In WHICH cases to seek approval

- How to describe experiments to reduce the possibility to unnecessarily go through SwissMedic? It seems any study using “uncertified device” on human need to go through SwissMedic. More generally, in which cases an approval by Swiss Medic is needed or not?

-> Very clear after reading HFG; the objective of the experiment is key
-> you want to do a clinical investigation you go through KlinV

Questions you asked 5/17

In WHICH cases to seek approval

- How much actual patient testing is needed before approval?(are there cases in which approvals can be obtained without patient trials?). Clinical trials – preparation, extend (how many centres, patients etc.)

-> case by case assessment -> ask a biostatician or epidemiologist
-> need for clinical data does not depend on the device class but on clinical data / performance data (IVD) available

Questions you asked 6/17

In WHICH cases to seek approval

- How much validation is needed on cloud or server side?

-> Validation is binary, not quantifiable. If validation is needed then validate, check for GHTF validation guidance, check for GAMP V if computer system, check for harmonized standards if software etc…

Questions you asked 7/17

In WHICH cases to seek approval

- What kinds of medical samples can be used in a scientific study by non-medical people (engineers, physicists, biologists)?

-> There is no restriction on the “scientific speciality” to work with “medical samples”, safety concerns have priority
-> the scientific background needed is dictated by the objective of the research work

Questions you asked 8/17

In WHICH cases to seek approval

- For the development of analytical detection devices that focus on medical applications, does this mean that the device has to be considered as a medical device? (therefore, how reliable is the diagnostic made from biological samples measurements performed with this device ?) If yes, the protocol should be submitted to Swiss Medic and the procedure becomes very complicated and time-consuming (several months to years). Alternatively, a general case could be considered that would be applicable for any project whose objective is to develop/validate an analytical detection device for medical applications in which there is no contact between the volunteer and the device, that would make the corresponding protocol fit automatically in the categories A (procédure facilitée). From our discussions with Prof. Francioli, it seems that the Cantonal Ethic commitee is keen in initiating a general reflexion in this direction, that might be of interest to further NanoTera partners.

-> What is the question ? -> case by case – check with EC

Questions you asked 9/17

Swiss Medic paperwork:
- In which cases an approval by Swiss Medic is needed or not?
- Overview of the Swiss regulation system and different categories (A, B, C, and D)
- How to classify a device as Class I or IIA? Could a sensing device, such as one that senses ECG or breathing, be classified as a simpler Class I device?
- Guidelines about the structure of the documents to be submitted to Swiss Medic: go through a typical application document and give an explanation for each item. For example, what is the study registration? Is it enough to put the grant number 20NA21 143070?

-> read HFG, KlinV
-> classification refer to annex IX and Meddev 2.4.1 -> ask Medidee Services SA
-> study registration ??

Questions you asked 10/17

Advice on how to submit:

- What is the correct procedure for obtaining a permission for experiments with patient samples?
- Will there be / Should there be assistance from NanoTera to facilitate submission to the ethical commission?
- Are there certain types of samples that do not require a lot of paperwork to obtain a permission (e.g. pathology samples)?

-> check with your local EC for procedure to obtain patient samples – check HFG – is your research a “clinical trial” ?
-> can not answer question related to Nano Tera organsation
-> completely anonymized samples that are available from sample banks, check with EC

Questions you asked 11/17

Decision process:
- How does the ethic commission decide, whether an application should be accepted or rejected?
- Does the commission vote on it?
- Who decides about the members of the commission, is this depended on the type of application?
- Can the commission be influenced politically (e.g. certain types of animal experiments should be discouraged) or by pharmaceutical companies?“

-> EC is independent, no political influence
-> if EC rejects your project is either badly explained, ethically unacceptable or a fail
-> EC votes, most cases internationally unanimity is the objective
-> the nature of the project defines competencies required, Canton is responsible for EC

Questions you asked 12/17

Foreign issues:

- In EU or bi-national projects, have we to follow the rules of EMA (FDA) and Swiss medics?
- What are the similarities and differences between Switzerland/EU/US?

-> refer to the entire program of today

-> applicable rules must be followed – if you do not follow the rules your data may not be accepted – bad for market access, bad for science and publication

-> no difference CH to EU (only details), big differences between EU and US

Questions you asked 13/17

Insurance/legal aspects
- How to deal with the insurance required to conduct the experiments?
- What about the legal implications on tests conducted on patients? (what if something goes wrong?)

-> find an insurance company that covers the “clinical investigation”
-> if sth goes wrong, you have the insurance for that…

-> if you did not do “state of the art” first you will not find an insurance and in case sth goes wrong you have a big problem

Questions you asked 14/17

Insurance/legal aspects

- In the case of a software for helping medical doctors to take a drug posology decision, what can be the legal issues in case it contains a bug (the predicted concentration being badly calculated, for instance)?

-> you are liable and responsible as the one “putting a device onto the market”

- Is it possible to sell such a product without risking legal troubles?

-> NO no no!

- Who would be in trouble, the developers, the project manager, the potential startup selling it?

-> The one putting it on the market – means making it available for use (legal entity / physical person)

- Does such a software would require some certification, or not? What would make a software certification mandatory? Will a computer software intended for medical assistance actually be assimilated to a medical device?

-> Refer to guidance on stand alone software, software (Meddevs)

-> If device then CE mark

Questions you asked 15/17

Other issues and topical questions

- Is it acceptable to modify the experiment procedure after it has been approved?

-> Yes, amendment, submit to EC, submit to Swissmedic

- The sponsor (NanoTera) will need to sign several documents and deliver to the cantonal ethical commission. Who is the contact people?

-> check local EC

- What are the materials allowed? How can new materials be certified?

-> no material is per se “allowed” – there is no “biomaterial” – case to case, full evidence required

Questions you asked 16/17

Other issues and topical questions

- What is the regulation for stimulating implants?

-> AIMDD – 90/385 EEC

- How do treatments involving light need to be regulated?

-> can not answer, question not precise

- Nanoparticles for medical applications (Diagnosis and Therapy): Are nanoparticles still handled as medicaments even they are used for diagnostic?

-> what is the intended use ?

- Is GMP fabrication of nanoparticles mandatory if we like to go in clinical tests?

-> Yes

Questions you asked 17/17

Other issues and topical questions

- Which type of preclinical toxicity tests have to be carried out? Its known that several toxicity test established for chemicals are not valid for nanoparticles. Exists projects for the development of new or modified tests acceptable for nanoparticles?

-> FDA has some guidance (under development) for toxicological evaluation of Nano Materials

- Some practical example from the past with in vitro diagnostic medical device. Specific information about in vitro diagnostic medical device regulations

-> IVDD – 98/79 EC, MEDDEVS

End of part
12. Special Issues