ERA4HEALTH, WP 16 : Clinical site agreement

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ERA4HEALTH, WP 16:

What do we want to achieve?

- Develop an EU model template for clinical site agreements related to clinical trials on medicines

- **EU model** : accepted and endorsed by a large number of partners across the EU

- **Context of use :**

• EU funded clinical trials (Horizon Europe, IMI, etc) but not only;

• any multinational project could use it as a model

❑Steps and methods:

1. Identify the legal aspects and constraints that must be considered prior to developing an EU template for clinical site agreements

    ° through a Survey and Legal task force

2. Preparation of the 1st draft of the template : content, structure

3. Review and validation steps

- Cross countries review of the first template (completed)
- National/Eu level Validation (in progress)
- Implementation across the EU

❑ Countries : 15

1. France
2. Germany
3. The Netherlands
4. Czech Republic
5. Poland
6. Norway
7. Italy
8. Spain
9. Danmark
10. Ireland
11. Hungary
12. Slovakia
13. Belgium
14. Greece
15. Switzerland

ERA4Health - Task 16.4

Task 16.4 . Harmonization of the site agreement contract

SURVEY (completed in December 2024)

- Overview of the existing documents at national and European levels
- Issues encountered by sponsors and other relevant actors
- Non-negotiable specificities

LEGAL TASK FORCE

- Consensus template
- Implementation
- Endorsement

Survey
Main questions and findings

❑ Survey questions :

- **Check if such models exist and who developed them**
  - What models of Clinical trial agreement templates exist in your country?
  - Who developed it? (Sponsor, Clinical sites, central administration, law firm, etc)
- **Check how these models work in practice and if they are fit for multinational projects**
- **Check if there are national requirements that cannot be avoided**
  - Please specify in more detail the legal issues you have encountered.
  - Which aspects/sections of the clinical site agreement used in your country cannot be subject to negotiation
- **Who can support us with our task**
  - Are you aware of any networks or associations of academic Sponsors in your country that could support our task?

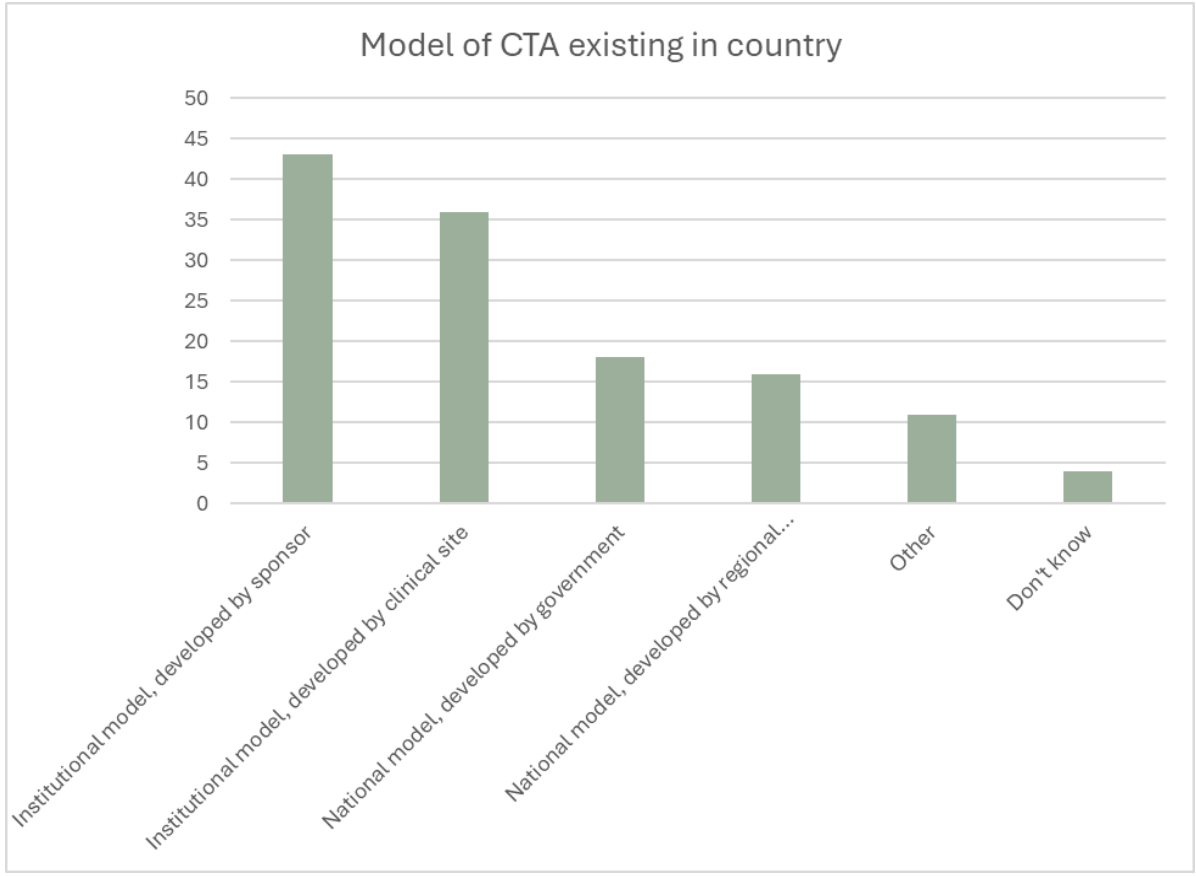
Survey findings

COUNTRY FACTS

- Existing models of CTA in your country (national templates, institutional templates, etc) question 9 and options… (N=83)
- National template:

  France, Czech Republic, Switzerland, Greece
- Regional Template:

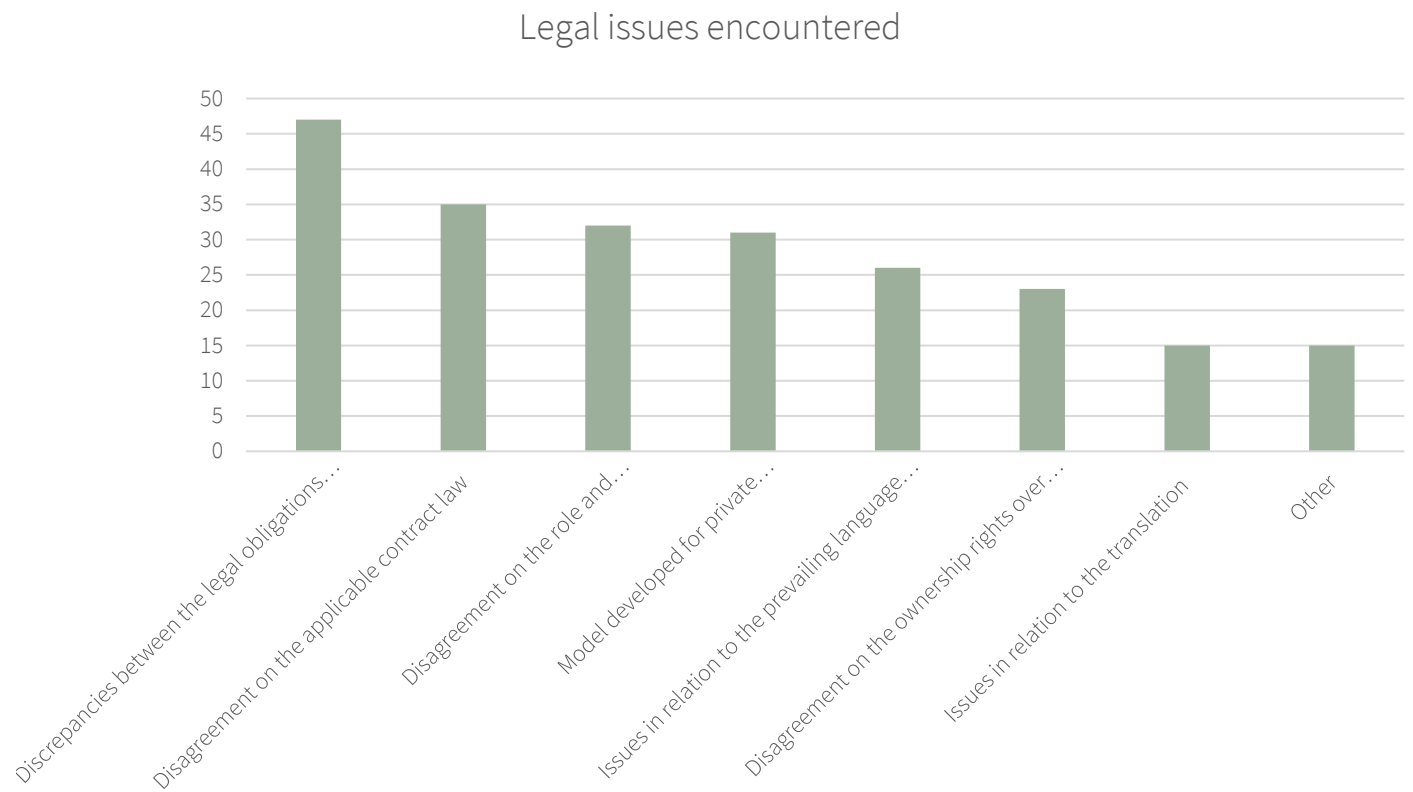
  Spain, Italy, Denmark, Norway, Netherlands, Switzerland



LEGAL BOTTLENECKS

❑ **Main bottlenecks when using these templates in the context of EU/Multinational projects (Q 13 and 14)**

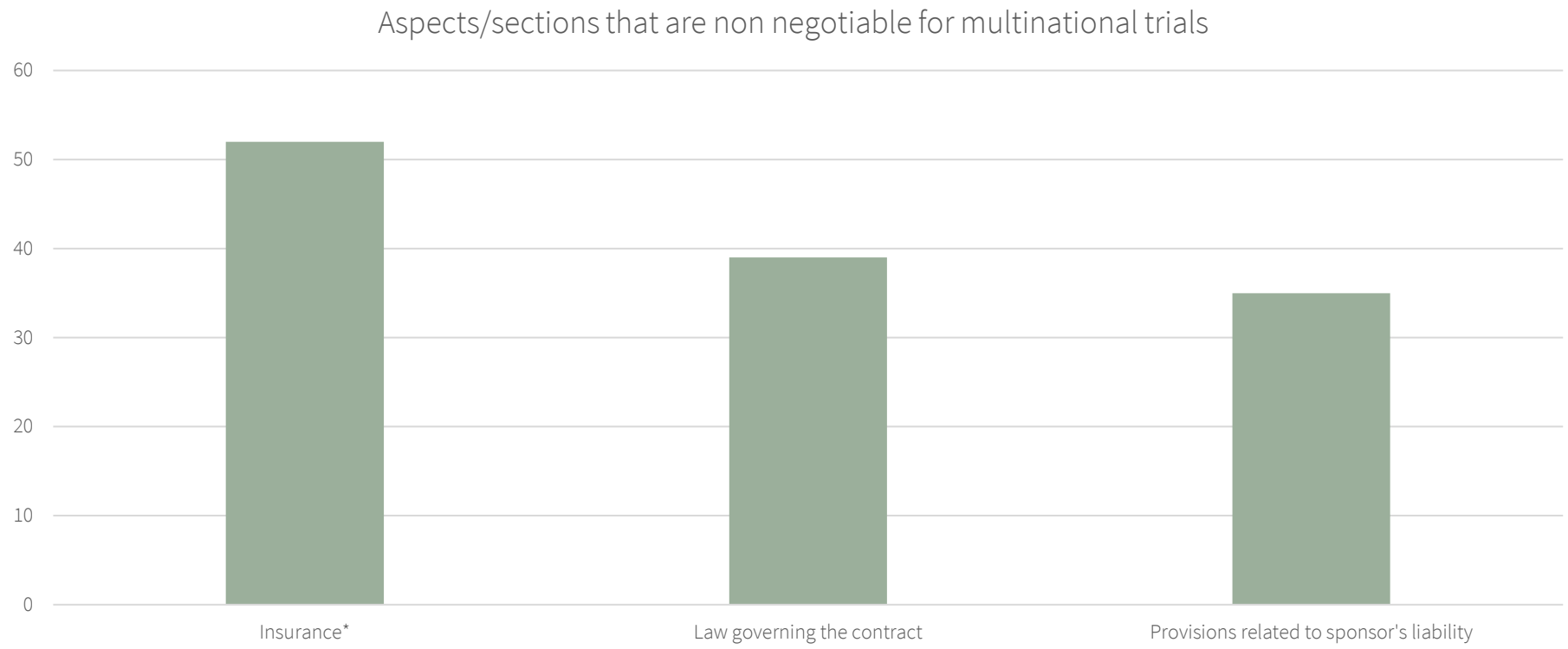
Please specify in more detail the legal issues you have encountered. If you cannot answer this question, please refer it to the relevant person within your organization (N=73)



❑ Legal task force : questions further explored through the legal task force

1. Can we generate a “generic” template escaping the national specificities (references to national laws, codes, etc) similarly to the CA DESCA?
2. Are there any national specificities that cannot be avoided and are not subject to negotiation?
3. Possible structure and content of an EU template
4. How can we ensure cross country reviews and validation of the templates?
5. How can we achieve implementation? Through a specific EU funded project? Are Sponsors willing to participate in a pilot study?

Which aspects/Sections of the CTA used in your country cannot be subject to negotiation in the context of multinational trials? (N=70)



❑Structure and content of the CSA

- **CSA template**

I. The core terms of the agreement : standard clauses/ not controversial in contract law

- Description of Responsabilities (e.g. Description of action)
- Status of the Parties (e.g. Under EU GA)
- Financial rules (EU funded projects, other funding sources)
- Non-disclosure of information, etc

II. Appendix/ Specific clauses : National legal specificities

- Include references to national laws into the agreement as attachements
- The appendices should be validated at national level beforehand to avoid negociation
- Any references to national pieces of legislation translated into clear duties
- Any additional agreements required by law should be attached to the main agreement (data processing agreement; financial agreement)
- Only some aspects can be subject to negociation (e.g. financial agreement)

❑ Updates and Next steps

❑**COMPLETED :**

- DELIVRABLE Annotated version (instructions)
- submitted and approved by the EU Commission DG RTD (a few comments)
- presented at the Clinical trials Coordination Group (EMA) (few comments)
- updated annotated version on-line (Zenodo)

❑**NEXT STEPS**

- **Pilot studies : Platform trial** : adaptations in progress
- **Other pilot studies? :** internal discussions
- Transform the annotated version into a simplified form : in progress
- Publication : in progress

Supporting clinical trials across borders

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