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An agency of the European Union

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Overview of comments received on ICH M11 technical specification (EMA/CHMP/ICH/778800/2022)

Please note that comments will be sent to the ICH M11 EWG for consideration in the context of Step 3 of the ICH process.

1. General comments – overview

Name of organisation or individual	Line from	Line to	Section number	Comment and rationale	Proposed changes / recommendation
Content Rules, Inc.	0	0		inspectors/reviewers have requested meta-information about the content history, such as a track changes view. Structured content management systems record the timestamp and username for every change. These systems track the complete history of each component. That information is available and could be transmitted along with the component.	Add attributes to each XML component to ingest content management metadata such as last modified date, component veersion, previous/current content compare,,etc. Technology vendors need to be made aware of this requirement as currently this reporting is available through configuration but not provided by default or a simple "include change history' toggle.
Content Rules, Inc.	0	0		Inspectors requested a way to see amendments per trial, with amendment date and indications of which components changed. Structured content management systems track the change history of the document ("document" is also known as assembly, map, outline, or output). This information is available for reporting and could be transmitted along with the updated components.	Add attributes to each comoponent to capture the amendment number and date of amendment that caused a change. Requires updated guidance for sponsors Sponsors can only capture this information if their structured content management system is configured with the amendment number and amendment date metadata at a component level. Technology vendors also need to be made aware of this requirement.
Content Rules, Inc.	0	0		In general, we find that the structure approaches the protocol from a document perspective. Many of the components are intended to hold quite a bit of information. At this level of granularity, the schema cannot be used to enforce rules related to required or conditional information. Nor can the schema be used to guide sponsors into including all required information for a particular study based on common factors such as study phase, therapeutic area,nnumber of arms, or type of intervention. Sponsors will be able to submit "wall of text" content that is not consistent in terms of what information is provided, in what order, or whether all required information is present.	We recognize that the working group likely spent hours and hours discussing levels of granularity. We also understand that structuring the protocol into components for use by all industry and regulators is a huge undertaking. We also believe that to achieve the full functionality of a digitized protocol, the schemea needs to support a much smaller level of component, with much more specific metadata and purpose defined for the specific data or text to provide in each one. As the M11 model is enhanced in future iterations, Content Rules can make more specific recommendations for supporting this level of specificity to support greater automation of study design, submissions, reviews, approvals, and validations. We have provided some examples to help illustrate the concept. The rest of the rows in this spreadsheet describe some examples of where we see opportunity to further separate the information into much more targeted components.
KKS-Netzwerk e. V. – Netzwerk der Koordinierungszentren für Klinische Studien (KKS Network), Germany	0	0	general comment	A list of abbreviations should be added to the technical specifications to enhance readability.	

Name of organisation or individual	Line from	Line to	Section number	Comment and rationale	Proposed changes / recommendation
TransCelerate BioPharma Inc.	0	0	0	Suggest defining in the Forward what each of the rows in the table mean, to ensure proper understanding of the information in each row.	
TransCelerate BioPharma Inc.	0	0	0	For headers, consider clarifying if cardinality could be considered "1"	
TransCelerate BioPharma Inc.	0	0	0	Suggest to clarify if a separate row for cardinality is needed if a value is provided.	
EFPIA	0	0		Does “D” mean data (ie, value)? If yes, please consider changing "D" to “value?” Since there is plenty of space in the table, there seems no reason to abbreviate the terms. Please spell out for improved clarity.	
EFPIA	0	0		Are the “cardinality’ and “value” fields both needed? Please clarify.	
EFPIA	0	0		For Header (H) elements, shouldn’t 'Value' match exactly the section heading and should cardinality=1? (Example: 6.5.2)	
EFPIA	0	0		Please clarify what is meant by “relationship” and “concept.” The description at the top says “relationship to conceptual model,” and there is a row for this, so it is unclear why they are separate elements under Business Rules. The relationship says things like "not transferred. " Is it correct that this is referring to digital data flow and whether this will come over in downstream systems? Please also clarify how or why "concept" can be n/a.	
EFPIA	0	0	1,1	Generally, Sex/Gender is mandatory for protocol and also for Clinicaltrials.gov, jRCT (Japan Registory of Clinical Trials), and other clinical registration. Therefore, The data as picklist is usuful for data standardization.	Term (Variable) : Sex/Gender Data Type : Picklist Value: Male, Female, All
EFPIA	0	0		An abbreviations list and some guidance for this document would be appreciated.	
Accumulus Synergy, Inc.	0	0		Accumulus Synergy, Inc. would like to express our support of the ICH M11 Technical Specification (EMA/CHMP/ICH/778800/2022).	

2. Specific comments on text

Name of organisation or individual	Line from	Line to	Section number	Comment and rationale	Proposed changes / recommendation
LFB Biotechnologies	12	15	9.3	"For all applicable Secondary objectives sate the null state the null and alternative hypotheses, including the pre-planned type 1 error, or alternative criteria to define Trial success and relevant operating characteristics if appropriate" : secondary objectives do not necessarly focus on trial success (they could focus on other efficacy endpoints)	"[…], or alternative criteria to define the corresponding secondary endpoint"
LFB Biotechnologies	12	12	9.3	Typo on line 12 : "For all applicable Secondary objectives sate the null state the null and alternative hypotheses[…]"	"For all applicable Secondary objectives, state the null and alternative hypotheses[…]"
Gilead Sciences	12	12	Appendix 1	All Level 1 and Level 2 headings in the proposed template are required. Suggest to remove the requirement for some of the Level 2 headings they may not be relevant across studies. For example, Section 5.5 "Lifestyle Considerations" or Section 4.3 "Access after End of Study".	
TransCelerate BioPharma Inc.	17	17		This is the first appearance, but suggest throughout to either use "V" for value entries or change the label for this table entry to be "Topic, Data or Header"	

Name of organisation or individual	Line from	Line to	Section number	Comment and rationale	Proposed changes / recommendation
EFPIA	17	17	p5	For ”Date of Revision”, Data Type should be "Date" instead of "Text", as same as "Approval Date" in p44. Date format (such as dd/mmm/yyyy) should be specified and consistent within all date variables in Protocol.	Term (Variable): Date of Revision Data Type: Date Topic, Value or Header: D Value: dd/mmm/yyyy date format
PTC Therapetics, Inc.	24	24	0,3	According to the technical specification, the heading "Description of Conventions" is missing under (or "in") Section 0.3.	PTC proposes alignment between the guidance.
Gilead Sciences	35	35	Appendix 1	Suggest to clarify that Abbreviations are not a required variable	
EFPIA	39	39	0,3	Unclear what 600 ct.gov means.	
EFPIA	43	43	0,3	Could there be a "null" flavor for the exception when it doesn't exist? - conformance is marked as "required".	
EFPIA	43	43	0,3	Could there be a character limit for protocol number eg. in PV it is limited to 50AN?	
EFPIA	45	45	0,3	The use of "version" seems to be ambiguous. It may cause confusion when there is an optional field with no business rules.	
EFPIA	46	46	0,3	User Guidance: The guidance could be misleading for amendment number, because it specifies entering a version or amendment number. Could this cause confusion with version field?	
Gilead Sciences	47	49	Appendix 1	Amendment Scope is required variable and options are "global" or "country-specific" with country identifier. Suggest to remove country identifier as required, since amendment would be needed to open sites in other countries.	
EFPIA	48	48	0,3	Conformance: Is the conformance "conditional" ie. based on whether amendment number exists?	
EFPIA	49	49	0,3	Conformance: Is Required/Conditional the correct value? would Conditional be sufficient?	
EFPIA	49	49	0,3	Value: Will this allow to include several countries? (this happens sometimes)	
EFPIA	50	50	0,3	Term (variable): Could compound number(s) and name(s) be together in table format in the template?	
EFPIA	52	52	0,3	Definition: It appears that this section "Compound Number" on page 22 has been duplicated with section "Compound Number" on page 21.	
EFPIA	55	55	0,3	Relationship: Recommend a character limit eg. 250 AN?	
EFPIA	58	58	0,3	Value, Phase 4: N/A for https://prsinfo.clinicaltrials.gov/definitions.html	
EFPIA	59	59	0,3	Term (variable): Related Acronym field description table seems to be missing (only heading table present).	
TransCelerate BioPharma Inc.	61	61		Suggest confirming if the value limit of 300AN is based on a specific requirement to ensure this meets reuse use cases and not to limit field if not necessary	
TransCelerate BioPharma Inc.	73	73		Consider if this would be better presented as a pick list for regulatory agency values.	
TransCelerate BioPharma Inc.	85	85		Review value (NTC) which is different than Term (NCT). Likely a typo.	
Gilead Sciences	96	101	Appendix 1	Suggest to clarify that Sponsor Signature is or is not required on title page.	
EFPIA	109	109	0,3	Value: This value does not seem right since it needs to be changed. It should be more flexible.	
EFPIA	121	121	0,3	Value: Should be more flexible since it is suggested text.	
EFPIA	122	122	0,3	Conformance: It is required only for amendments, not the original protocol.	

Name of organisation or individual	Line from	Line to	Section number	Comment and rationale	Proposed changes / recommendation
EFPIA	125	125	0,3	Value: Not clear	
EFPIA	126	126	0,3	Value: Please check, the content does not make sense.	
EFPIA	131	131	0,3	Value: Should be more flexible since it is editable.	
Gilead Sciences	131	131	Appendix 1	"Approximate {(#/%)} enrolled" is a required variable. This may be difficult to keep current. Suggest to provide this as optional.	
EFPIA	132	132	0,3	User Guidance: This is very different from what appears in the template	
EFPIA	135	135	0,3	User Guidance: This does not correspond to what is in the template.	
Gilead Sciences	135	135	Appendix 1	Suggest to simplify pick list for reasons to amend. Currently 13 options plus "Other" and some seem redundant.	
EFPIA	137	137	0,3	Term (variable): Element seems to be missing in the template	
EFPIA	138	138	0,3	Term (variable): Should this be "other reason for amendement"? Furthermore, more user guidance to differentiate between primary and other reasons for amendment so that there is no confusion, would be useful.	
EFPIA	138	138	0,3	User Guidance: Add guidance from table footnote here.	
EFPIA	139	139	0,3	Term (variable): not found	
EFPIA	140	140	0,3	Term (variable): not found	
EFPIA	142	142	0,3	Definition: Add user guidance from template.	
EFPIA	143	143	0,3	Value: Is this value editable? (should be)	
TransCelerate BioPharma Inc.	145	145		Consider if the concept "Protocol Short Title" is the correct concept for this Term. Likely a typo.	
EFPIA	145	145	0,3	User Guidance: Missing: Add lines as needed + other differences with template (eg, section number).	
EFPIA	151	151	0,3	Term (variable): Should be Rationale for Amendment Change.	
EFPIA	156	156	1,1	Duplicate field in other sections: The heading Primary and Secondary Objectives and Endpoints appears to be missing here.	
TransCelerate BioPharma Inc.	158	158		Suggest clarifying the use of "X" in this term. There appears to be inconsistent use of "X" for variable versus multiple variables.	
EFPIA	158	158	1,1	User Guidance: no guidance in the template (Section 1 or 3).	
EFPIA	160	160	1,1	User Guidance: No guidance in the template (Section 1 or 3).	
EFPIA	161	161	1,1	Value: Usually there are several secondary objectives so this should be more flexible. The same comment applies for other objectives and endpoints header values.	
EFPIA	162	162	1,1	User Guidance: No guidance in the template (Section 1 or 3)	
EFPIA	164	164	1,1	User Guidance: No guidance in the template (Section 1 or 3)	

Name of organisation or individual	Line from	Line to	Section number	Comment and rationale	Proposed changes / recommendation
EFPIA	165	165	Overall design	A MedDRA PT code should be added to free text as "Population Diagnosis or Condition." It is because MedDRA code can be easier to find simmilar studies in the following situation; - Regulatory reviewes can compare them for consutations and IND/CTA/CTN. -Patient who want to join a clinical study. Additinaly, free text as "Population Diagnosis or Condition." also need to the section because sometimes MedDRA PT code is not	
EFPIA	170	170	1,1	Relationship: This may need to be more specific? is this list exhaustive?	
TransCelerate BioPharma Inc.	174	174		Consider if the user guidance for population diagnosis or condition is correct. Appears to have been inadvertently copied from prior field.	
Gilead Sciences	178	178	1,1	Suggest to clarify Population Age range requirement in Synopsis. This may not be applicable to all studies.	
EFPIA	183	183	1,1	Term (variable): Not mentioned in the template	
EFPIA	189	189	1,1	User guidance: Not aligned with guidance - should start with "Site distribution"	
EFPIA	189	189	1,1	Value: There should be "other" and describe.	
EFPIA	192	192	1,1	User guidance: Does guidance need to be provided when the number of arms is unknown?	
EFPIA	195	195	1,1	User Guidance: If there is a possibility that the number of arms is unknown then the integer format will not work	
EFPIA	195	195	1,1	Term (variable): Blinding/not blinding	
EFPIA	195	195	1,1	User Guidance: The first half of the instructions is missing, and there are differences in the rest.	
EFPIA	195	195	1,1	Value: Clarify that multiple roles can be selected.	
EFPIA	195	195	1,1	Value: This optional text seems to be missing: ""Not Applicable (No blinding)" indicates an open-label trial."	
EFPIA	207	207	1,1	Data type: Can there be other explanations than the 2 options mentioned as values? there is the need for more flexibility than a 2-item picklist, see guidance: When duration cannot be approximated, provide a short explanation (for example, "event-driven" or "adaptive design").	
EFPIA	208	209	1,1	User guidance: There is no guidance text in the template. Some guidance has been included below but the following is missing: If sufficiently detailed, a cross-reference to the trial schema is appropriate in lieu of text description.	
EFPIA	212	212	1,1	Committees (plural)	
EFPIA	213	213	1,1	Data type: Pick list should allow addition of committee.	
EFPIA	214	214	1,1	Term (variable): Not mentioned in the template.	
EFPIA	222	222	1,2	User Guidance: Not mentioned in the template. Should it be added?	
TransCelerate BioPharma Inc.	223	223		Suggest reviewing what is appropriate in the Value for this field	
EFPIA	223	223	1,2	Term (variable): Not found in the template	
EFPIA	227	227	2	User Guidance: Add guidance	
EFPIA	230	230	2	Definition: Not found in the template.	

Name of organisation or individual	Line from	Line to	Section number	Comment and rationale	Proposed changes / recommendation
EFPIA	230	230	2	User Guidance: Different in the template.	
EFPIA	232	232	2,2	User Guidance: We have guidance in template (include an assessment of known benefits and potential risks, including the basis of the risk [for example, preclinical studies or prior clinical trials]).	
EFPIA	238	238	2,2	Conformance: If this is required, it would be helpful to add to the guidance something like "If not applicable, do not delete but write "Not applicable"."	
EFPIA	240	240	2,2	User Guidance: Guidance is different in the template.	
EFPIA	256	256	4,1	Term (variable): Did not find this under the "Description of Trial Design".	
EFPIA	257	257	4,1	Term (variable): Not found in template	
EFPIA	258	258	4,1	Conformance: Required field here but in the template it appears only as an instruction, not field. Also, the instructions specify "if applicable" so if the field is really required, we should also have the option "Not applicable".	
EFPIA	259	259	4,1	Conformance: Not found in the template. Also note that according to instructions it is not just Yes/No but "provide a summary of these design aspects"	
EFPIA	260	260	4,1	Same comment as for Line 59 "Adaptive Trial" above	
EFPIA	261	261	4,1	Same comment as for Line 59 "Adaptive Trial" above	
EFPIA	264	264	4,1	Conformance: In the template we only have 1 field (Method of assignment to trial intervention) while here we have 4: this and the 3 items below- Please align.	
EFPIA	268	268	4,1	Term (variable): This field in the template contains the 4 elements above	
EFPIA	268	268	4,1	User Guidance: This guidance goes with the field "Additional Description of Design" rather than "Method of Assignment to Trial Intervention"	
EFPIA	269	269	4,1	Term (variable): 5 fields while in the template has only 1 (additional description of design).	
EFPIA	269	269	4,1	User Guidance: Need to be aligned, only the part on geographic scope is applicable.	
EFPIA	270	270	4,1	Term (variable): 'Decentralised'	
EFPIA	271	271	4,1	Data Type: Text may be better.	
EFPIA	272	272	4,1	Data type: Text would be better according to instructions: "if so, refer to details in Section 9.7, Interim analysis"	
TransCelerate BioPharma Inc.	273	273		Check Term here. Should be Number of interim analyses. Consider if this should have an alphanumeric value.	
EFPIA	273	273	4,1	Data Type: Not sure this is useful. If we do need the number then the field should be adapted and instructions given.	
EFPIA	274	274	4,1	Data Type: Text may be better.	
TransCelerate BioPharma Inc.	278	278		Consider if Rationale for Trial Design should also have D for Topic/value/header.	
EFPIA	281	281	4,2	Term (variable): It should be rationale "for Endpoints".	
TransCelerate BioPharma Inc.	282	282		The Term here may be unclear; consider if this should be "Rationale for interim analysis"	

Name of organisation or individual	Line from	Line to	Section number	Comment and rationale	Proposed changes / recommendation
EFPIA	294	294	4,4	User Guidance: Different from template.	
EFPIA	299	299	5,1	User Guidance: Slightly different from template.	
EFPIA	304	304	5,3	User guidance: Suggest adding guidance also here.	
EFPIA	306	306	5,3	Duplicate field in other sections: If deleted during an amendment, the number should remain (not sure we can define this here).	
EFPIA	307	307	5,3	Term (variable): Is this a field containing individual inclusion criteria nested?	
EFPIA	308	308	5,4	Section: same comments apply to this section as for inclusion criteria	
EFPIA	314	314	5.5.1	Conformance: please clarify if separate fields for each item - is this needed?	
EFPIA	316	316	5.5.2	Conformance: please clarify if separate fields for each item - is this needed?	
EFPIA	318	318	5.5.3	Conformance: please clarify if separate fields for each item - is this needed?	
EFPIA	321	321	5.5.4	Conformance: please clarify if separate fields for each item - is this needed?	
Content Rules, Inc.	325	326	6	The author instruction for section 6 says "If multiple trial interventions are to be evaluated, Section 6.1, Description of Trial Intervention, Section 6.3, Dosing and Administration, and Section 6.5, Preparation, Handling, Storage, and Accountability should differentiate between each product."	Ensure components for 6.1, 6.3, and 6.5 are repeatable. Sponsors should not cover all interventions in a single component.
Content Rules, Inc.	326	350	6,1	The author instructions list about 18 pieces of information to include in this section. The schema includes 11 data entries intended to be formatted in a table. The data entries do not correspond exactly to the list of inforamtion described in the author guidance. It is not clear whether the other information should be provided as text (paragraphs) as part of the Additional Information element. The data entries do not include duration of intervention, packaging information, labeling references, or information about devices for combination drug/device studies.	Add optional text/data components to hold the information that is not included in the main table. Add a component to structure the device-related content, for use when applicable.
Content Rules, Inc.	326	350	6,1	The names of the data entries differ from the terminology used in the author instructions. For example, there are data entries for Use, Formulation, and Dose Level. The author instructions refer to "route and mode of administration, dose, dosage regimen, duration of intervention, packaging, labelling, and storage condition."	Harmonize the terminology so users do not have to guess where to provide information. Ensure that the same XML elements are used throughout anywhere that same information is provided. The sponsor should be able to store dosage, mode of administration, and other metadata in their structured content in a single source of truth. They should be able to submit that metadata in one place and have it fill in everywhere it needs to be shown to end users (inspectors, reviewers, general public on websites, etc.).
Content Rules, Inc.	326	350	6,1	It is not clear whether the additional internventions should be included in the trial intervention summary table or if separate components should be created.	Add instructions to the template to clarify that each intervention should be included in the single component OR whether a separate component should be provided. Ensure that the XML elements allow repeatability. Each data entry must relate to the intervention it belongs to.
EFPIA	328	328	6,1	Term (variable): This item and the following ones apparently are parts of a table that does not appear in the template.	Please add corresponding table to the template.
EFPIA	349	349	6,1	Term (variable): There is no corresponding table(s) in the template.	
Content Rules, Inc.	352	352	6,2	Author instructions include five types of information: rationale for selection, relevant results of previous trials, age/sex PK/PD info, optional justification for differences, and rationale for prospective dose modifications.	This component is an example of including different types of information in a single blob. This information could be made more consistent across protocols by separating into more granular components, each one driven by the purpose described in the author instructions.
TransCelerate BioPharma Inc.	355	355		Consider if the dosing and administration should be broken out into minimum required fields, as also suggested in the template. This may be too much content built into a single variable.	

Name of organisation or individual	Line from	Line to	Section number	Comment and rationale	Proposed changes / recommendation
EFPIA	358	358	6.3.1	Definition: This is not in the template.	
EFPIA	361	361	6,4	Definition: This should go into the guidance.	
Content Rules, Inc.	364	366	6.5.1	For this component and any other than allows a reference to a label, investigator's brochure, or other document, include a component specific to the cross-reference.	Include an XML component type for holding the cross-reference rather than submitting the cross-reference as text in a paragraph. The component type of cross-reference could optionally slot in to any section where sponsors are allowed to refer to another document. Users don't need to read the text only to find it's a reference; they can go directly to the other document (if submitted along with the protocol and assigned and ID).
EFPIA	365	365	6.5.1	Definition: This should go into guidance	
EFPIA	368	368	6.5.2	User Guidance: Move the row above here and update content.	
Content Rules, Inc.	371	371		Accountability author instuctions list the types of information to include and implies an order in which to include the information.	This information could be made more consistent across protocols by separating into more granular components, each one driven by the purpose described in the author instructions.
EFPIA	378	378	6.6.2	Definition: Globally it seems that the definition should go into guidance, please check. Globally, please check for alignment between instructional text in this document and the template. It is not clear what is the utility of the "Definition" row in general.	
TransCelerate BioPharma Inc.	381	381		"Unblinding" appears to be missing from the term here. Template uses "Blinding and Unblinding" as the field.	
EFPIA	405	405	7.1.1	Value: Should be "permanent" discontinuation.	
EFPIA	423	423	8	Term (variable): In the template it is not stated that no text is expected here. If text is possible here, then add an item for the text in addition to this item for the header. Alternatively, state in the template that no text is expected here (as done for other sections).	
TransCelerate BioPharma Inc.	426	426		Suggest clarifying why there is a duplicate field in other sections. This should be more of a repeat of the same field, but not the same value, within the same section for each procedure	
EFPIA	444	444	8,35	Conformance: Is this required? According to instructions it is "if the trial meets... criteria" If required, add instructions to the template so the section is not deleted.	
EFPIA	487	487	8,6	Data Type: If no text is expected below the header, add instruction to the template to specify.	
EFPIA	487	487	8,6	Conformance: Guidance says it is an optional section; please align.	
EFPIA	518	518	8,11	Conformance: Please align with template instructions: "Include this section only for any value evidence and outcomes assessments not included in either the efficacy or safety sections".	
EFPIA	522	522	9	Definition: Please check content	
EFPIA	530	530	9.2.1	There are 4 items in this section versus usually only header and text. Please check and correct if needed.	

Name of organisation or individual	Line from	Line to	Section number	Comment and rationale	Proposed changes / recommendation
EFPIA	545	545	9,3	It is not clear as to why there are 7 items in this section versus only header and 1 field in the text. Please clarify in the template or align here.	
EFPIA	572	572	10,1	The following text field(s) seems to be missing: This trial will be conducted in accordance with the protocol and with the following: • Consensus ethical principles derived from international guidelines including the Declaration of Helsinki and Council for International Organisations of Medical Sciences (CIOMS) International Ethical Guidelines • ICH Good Clinical Practice (GCP) Guidelines • Applicable laws and regulation	
EFPIA	582	582	10,3	The following fields seem to be missing from this doc: Emergency consent process Consent requirements for rescreening Additional ICF text for user of remaining samples in optional exploratory research	
EFPIA	585	585	10,4	Text field for Data protection is missing from this document.	
EFPIA	598	598	11,2	Term (variable): This item should be replaced by 2 fields: Sponsor or designee responsibilities for data quality assurance Investigator responsibilities for data quality assurance	
EFPIA	623	623	13.1.1	Term (variable): The item Heading is missing plus correct to "Definition as related to childbearing potential".	
EFPIA	634	634	13,3	Term (variable): This is unclear, same for the 2 following items - not sure how this should look. Propose to clarify in the template.	
EFPIA	641	641	13,4	Several fields from the template Section 13.4 are missing from here. Also, please add 4 other items: Section 14 and 15 headers and text.	
LFB Biotechnologies			13.2	"equations and references for locally calculated labs" : sentence to be corrected	equations and references for locally calculated lab results
LFB Biotechnologies			13.2	Section 13.2 only provides information on clinical laboratory tests. Shouldn't information on specialized Bioanalytical labs performing PK/Biomarkers/Immunogenicity assays be included for completeness ?	Name section 13.2 "Laboratory tests" and include information related to both clinical and bioanalytical lab activities