9 October 2016

Submission of comments on 'Draft Guideline on the requirements to the chemical and pharmaceutical quality documentation concerning investigational medicinal products in clinical trials ' (EMA/CHMP/QWP/834816/2015)

Comments from:

Name of organisation or individual
ACRO (Association of Clinical Research Organizations)

Please note that these comments and the identity of the sender will be published unless a specific justified objection is received.

When completed, this form should be sent to the European Medicines Agency electronically, in Word format (not PDF).

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1. General comments

Stakeholder number *(To be completed by the Agency)*	General comment (if any)	Outcome (if applicable) *(To be completed by the Agency)*
	The Association of Clinical Research Organizations (ACRO) represents the world's leading, global clinical research organizations (CROs). Our member companies provide a wide range of specialized services across the entire spectrum of development for new drugs, biologics and medical devices – from discovery, pre-clinical, proof of concept and first-in-man studies through post-approval and pharmacovigilance research. With more than 110,000 employees engaged in research activities around the world (including 30,000 in Europe), ACRO advances clinical outsourcing to improve the quality, efficiency and safety of biomedical research. Each year, ACRO member companies conduct more than 9,000 clinical trials involving nearly two million research participants in 142 countries. On average, each of our member companies works with more than 500 research sponsors annually. ACRO welcomes and supports the draft guideline on the requirements to the chemical and pharmaceutical quality documentation concerning investigational medicinal products in clinical trials. In particular, ACRO supports the following underlying principles of the draft guideline: • The risk-based approach to documentation requirements focused on risk aspects of the	

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	investigational medicinal product, taking into account the nature of the product, the state of development/clinical phase, patient population, nature and severity of the indication and the characteristics of the proposed clinical trial. • The recognition that, as a consequence, it is not possible to define detailed requirements applicable to all different sorts of products and therefore that there must be flexibility in the documentation requirements, proportionate to the potential risk. • The emphasis on presentation of data in the form of succinct tabulated summaries, accompanied by an evaluation and justification, where appropriate, rather than a detailed description of studies and results. • The application of the same documentation requirements to both investigational medicinal products and auxiliary medicinal products, given that all medicinal products administered during a clinical trial should meet appropriate quality standards.	

2. Specific comments on text

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Stakeholder number *(To be completed by the Agency)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted using 'track changes')*	Outcome *(To be completed by the Agency)*
199 - 201		Comment: Regulation (EU) No. 536/2014 came into force on 20 June 2014 but, as currently estimated by the EMA, will not take effect until October 2018. The guideline should therefore clarify whether it will be effective only from the effective date of the Regulation or will replace current guidance issued with respect to current legislation (Directive 2001/20/EC), while recognising that some of the terminology used (e.g., auxiliary medicinal product) is specific to the Regulation and not referenced in the Directive. Proposed change (if any): Clarify whether the guideline will be effective only from the effective date of the Regulation or will replace current guidance issued with respect to current legislation (Directive 2001/20/EC).	
206		Comment: There is a typo (additional Space after the word “of-”) in “state-of- the-art” Proposed change: “state-of-the-art”	
297		Comment: There is a typo (additional Space after the word “radio”) in “radio -labelling” Proposed change: “radio-labelling”	
321		Comment: There is a typo (additional Space and “.”) in	

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		between two sentences: "…should be provided. . Any relevant…" Proposed change: "…should be provided. Any relevant…"	
331		Comment: The preferred term should not be "organic-chemical" but "organo-chemical" Proposed change (if any): "organo-chemical"	
348 - 349		Comment: ACRO concurs that information on process validation and/or evaluation is not applicable for a risk assessment of active substances intended for clinical trial use. Proposed change (if any):	
435 - 441		Comment: ACRO recommends adding guidance on the minimum number of batches on which analytical data should be provided to support each phase of clinical research. Proposed change (if any): Add guidance on the minimum number of batches on which analytical data should be provided to support each phase of clinical research.	
438		Comment: There is a typo (additional Space between two words"): "If data are not" Proposed change: "If data are not"	
459		Comment : More guidance should be provided here as some regulatory authorities routinely ask for sponsors to confirm that the components of the drug substance container closure	

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		system comply with applicable Ph.Eur monographs, EC Directives and EC Regulations. As examples, here are some blinded questions, from an assessor who reviewed an IMPD in 2015 to support a CTA for a Phase III study, to illustrate this point: *It should be confirmed that the plastic manufactured by XXXX meets Regulation (EC) 10/2011 and its amendments.* *The Applicant should confirm that the drug substance is packaged in a container closure system that meets the corresponding relevant standards in force (I. e. Directives, Eur. Ph. etc.).* Proposed change (if any): Describe in more detail the information that is required on the drug substance packaging system.	
473		Comment: More guidance should be provided here regarding the pharmaceutical form for the drug product. Sponsors should be encouraged to use one of the standard terms in the EDQM Standard Terms database. For example, some sponsors often use the term 'solution for injection' in the IMPD to describe the IMP, which does not match the route of administration described in the clinical trial protocol where the IMP will be administered by intravenous infusion. Proposed change (if any): Encourage use of standard terminology from the EDQM Standard Terms database.	

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508		Comment: ACRO recommends that the guideline should confirm whether or not the site where QP release is performed in the EEA should be included in this section of the IMPD. Proposed change (if any): Clarify whether or not the site where QP release is performed in the EEA should be included in this section of the IMPD.	
527		Comment: The plural “Controls” is inconsistent with the singular “Control” used for example in the equivalent guideline for biological investigational medicinal products (EMA/CHMP/BWP/534898/2008). Proposed change (if any): Ensure consistency across guidelines.	
536 - 540		Comment: While ACRO concurs that, in general, information on process validation and/or evaluation is not applicable for a risk assessment of finished products intended for clinical trial use, in the case of sterile products manufactured using aseptic processes, ACRO suggests including the recommendations provided in the guideline for biopharmaceuticals (EMA/CHMP/BWP/534898/2008) for information connected directly to the safety of the product (such as bioburden prior to filtration) and information about media fill runs, in order to demonstrate the efficacy of aseptic processing operations. Proposed change (if any): In the case of sterile products manufactured using aseptic processes, include the	

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		recommendations provided in the guideline for biopharmaceuticals (EMA/CHMP/BWP/534898/2008) for information connected directly to the safety of the product (such as bioburden prior to filtration) and information about media fill runs.	
600 - 611		Comment: ACRO recommends adding guidance on the minimum number of batches on which analytical data should be provided to support each phase of clinical research. Proposed change (if any): Add guidance on the minimum number of batches on which analytical data should be provided to support each phase of clinical research.	
630 to 632		Comment: Frequently, for non-compendial packaging materials, sponsors are asked by some EU national regulatory authorities to confirm that the materials comply with applicable EU Directives and Regulations. This should therefore be noted in the guideline. Proposed change (if any): Include a statement that, where non-compendial materials are used, confirmation should be provided that the materials comply with applicable EU Directives and Regulations.	
646 - 648		Comment: ACRO welcomes adoption of the concept that extrapolation of the shelf life for an investigational medicinal product may be based on an appropriately justified algorithm. The text states one example of “X + 12 months”. However, X is not defined.	

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		Additionally, it would be helpful for Sponsors if the table provided on page 2 of the MHRA guidance document 'Points to consider when preparing the IMP dossier' is provided in this guideline. Three months real-time data 12 months shelf life Six months real-time data 18 months shelf life 12 months real-time data 24 months shelf life 24 months real-time data 36 months shelf life Proposed change (if any): Clarify the definition of X in the stated formula, and include the table provided on page 2 of the MHRA guidance document *'Points to consider when preparing the IMP dossier*' in this guideline.	
672 – 678 and 1026 - 1035		Comment: ACRO welcomes the recognition that stability data on the investigational medicinal product may not be available at the start of a phase I clinical trial or a bioequivalence study, and agrees that these trials can be supported by relevant data from development studies, with a stability programme using a relevant batch or batches of the product initiated prior to the start of the clinical trial. However, clinical trial protocols for investigational medicinal products early in clinical development often combine both phase I and phase II aspects, therefore ACRO recommends that the guideline should specify the requirements for this situation.	

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		Proposed change (if any): Specify the stability testing requirements to support clinical trial protocols that combine phase I and II aspects of clinical development.	
691 - 695		Comment: This section includes as 'authorized' products also those from ICH-regions and Mutual Recognition Agreement (MRA)-partner countries. However, the definitions of 'authorized' products in article 2, sections (9) and (10) of regulation 536/2014, do not include ICH-countries or MRA-partner countries. Furthermore, section 52, table 1 of Annex I of Regulation 536/2014 distinguishes between 'authorized' IMP [i.e. those within the scope of definitions given in article 2, sections (9) and (10)] and products that have a 'marketing authorization in an ICH country', while 'MRA-partner countries' are not mentioned. Clarification should be sought, how the inclusion of MRA-partner countries in this section of the guidance is covered by the regulation 536/2014. Proposed change (if any): To adapt the wording to read "For test and comparator products to be used in clinical trials which have already been authorised in the EU/EEA, or have a marketing authorization in one of the ICH-regions it will be sufficient to provide the name of the MA-holder and the MA-number as proof for the existence of a MA, incl. copy of the SmPC/Summary of Product Characteristics or its equivalent e.g. Prescribing information."	
702 - 825		Comment: The guidance should specify what 'modification' entails, and when an IMPD/auxiliary medicinal product dossier	

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		should be prepared in accordance with this guidance following sections 52 and 55 of Annex I of Regulation 536/2014. It should preferably give guidance on which of the following are included as falling under 'modification': • Trial-specific operations that could affect the product quality, such as o Modification of the pharmaceutical form (e.g. over-encapsulation, trial specific colour or coating, dilution, re-tableting for blinding etc.) or o Primary re-packing (e.g. removal from the immediate container and repacking into another immediate packing. • Secondary packaging, i.e. any other placing the medicinal product, which is already sealed within its primary packaging material into a trial-specific different outer packaging material • Trial-specific assembly Trial-specific labelling with no other primary or secondary packaging (Article 2, sections (9) and (10) of regulation 536/2014 exclude 'changes to the labelling'. This is of relevance, where a comparator has a marketing authorization (MA) in multiple EU Member States, and the sponsor chooses to use the IMP registered in Germany for the purposes of the trial, it will be sufficient to provide the name of the German MA-holder and MA-number as proof for the existence of a MA, incl. copy of its Summary of Product Characteristics. However, as the marketing authorisation holder (MAH) of the comparator product is only responsible for the unchanged	

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		product in its designated and authorised (German) packaging, it should be specified if the sole addition of a clinical trial specific labelling will constitute a modification of the comparator or not. Proposed change (if any): Provide more detailed guidance on what comprises modification of an authorised comparator/auxiliary medicinal product.	
704 - 705		Comment: 'Study' (i.e. clinical study) or 'clinical trial' should be consistently used in this guidance in line with the definitions given in article 2 of regulation 536/2014, and the use of modified comparator products is not necessarily limited to blinded studies. Proposed change (if any): Change wording to "In preparing supplies for clinical trials, applicants often modify or process medicinal products which have already been authorised in order to use them as comparator products in clinical trials blinded studies."	
738 – 742		Comment: Wording should match with corresponding other sections in the guidance (lines 512 – 516, 934 – 937, 1055 – 1059) and of article 61, section 5 (a) of regulation 536/2014 and include re-packaging and or re-labelling. Proposed change (if any): To include 'labelling', e.g. "When packaging *and or labelling* is carried out at a hospital, health centre or clinic where the investigational medicinal 738	

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		product is to be used for the trial exclusively at that institution, […]"	
754		Comment: There is a typo (additional Space after "film-"): "film- coating" Proposed change (if any): "film-coating"	
810		Comment: Frequently, for non-compendial packaging materials, sponsors are asked by some EU national regulatory authorities to confirm that the materials comply with applicable EUC Directives and Regulations. This should therefore be noted in the guideline. Proposed change (if any): Include a statement that, where non-compendial materials are used, confirmation should be provided that the materials comply with applicable EU Directives and Regulations.	
829 - 831		Comment: This section of the guideline refers back to previous sections with regard to the required information on the active substance and finished product of a reference comparator/innovator product used during the development of a generic product. However, when a comparison study with the originator product is performed to analyse various parameters as part of the pharmaceutical development of a generic product, ACRO recommends that it would be helpful to include guidance on selecting the age of the samples of reference product to be considered equivalent to the generic (as marketed reference product will be exposed to different	

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		conditions from generic products under development). This is especially important for sensitive products like dry powder inhalers and will help in generating uniform data throughout the Generics industry. Proposed change (if any): Add guidance on selecting the age of the samples of reference comparator/innovator product to be considered equivalent to the generic product when a comparison study with the reference product is performed to analyse various parameters as part of the pharmaceutical development of a generic product.	
920		Comment: More guidance should be provided here as some regulatory authorities routinely ask for sponsors to confirm that the components of the drug substance container closure system comply with applicable Ph.Eur monographs, EC Directives and EC Regulations. Proposed change (if any): Describe in more detail the information that is required on the drug substance packaging system.	
928		Comment: More guidance should be provided here regarding the pharmaceutical form for the drug product. Sponsors should be encouraged to use one of the standard terms in the EDQM Standard Terms database. For example, some sponsors often use the term 'solution for injection' in the IMPD to describe the IMP, which does not match the route of administration described in the clinical trial protocol where the	

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		IMP will be administered by intravenous infusion. Proposed change (if any): Encourage use of standard terminology from the EDQM Standard Terms database.	
951-954		Comment: While ACRO concurs that, in general, information on process validation and/or evaluation is not applicable for a risk assessment of finished products intended for clinical trial use, in the case of sterile products manufactured using aseptic processes, ACRO suggests including the recommendations provided in the guideline for biopharmaceuticals (EMA/CHMP/BWP/534898/2008) for information connected directly to the safety of the product (such as bioburden prior to filtration) and information about media fill runs, in order to demonstrate the efficacy of aseptic processing operations. Proposed change (if any): In the case of sterile products manufactured using aseptic processes, include the recommendations provided in the guideline for biopharmaceuticals (EMA/CHMP/BWP/534898/2008) for information connected directly to the safety of the product (such as bioburden prior to filtration) and information about media fill runs.	
1021-1022		Comment: Frequently, for non-compendial packaging materials, sponsors are asked by some EU national regulatory authorities to confirm that the materials comply with applicable EUC Directives and Regulations. This should therefore be noted in the guideline.	

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		Proposed change (if any): Include a statement that, where non-compendial materials are used, confirmation should be provided that the materials comply with applicable EU Directives and Regulations	
1068		Comment: While ACRO concurs that, in general, information on process validation and/or evaluation is not applicable for a risk assessment of finished products intended for clinical trial use, in the case of sterile products manufactured using aseptic processes, ACRO suggests including the recommendations provided in the guideline for biopharmaceuticals (EMA/CHMP/BWP/534898/2008) for information connected directly to the safety of the product (such as bioburden prior to filtration) and information about media fill runs, in order to demonstrate the efficacy of aseptic processing operations. Proposed change (if any): In the case of sterile products manufactured using aseptic processes, include the recommendations provided in the guideline for biopharmaceuticals (EMA/CHMP/BWP/534898/2008) for information connected directly to the safety of the product (such as bioburden prior to filtration) and information about media fill runs.	
1105-1106		Comment: Frequently, for non-compendial packaging materials, sponsors are asked by some EU national regulatory authorities to confirm that the materials comply with applicable EUC Directives and Regulations. This should	

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		therefore be noted in the guideline. Proposed change (if any): Include a statement that, where non-compendial materials are used, confirmation should be provided that the materials comply with applicable EU Directives and RegulationsComment	
1141 - 1144		Comment: According to the proposed guidance, the marketing authorisation holder (MAH) of the comparator product is only responsible for the unchanged product in its designated and authorised (e.g., German) packaging. Where an auxiliary medicinal product has a marketing authorization (MA) in multiple EU Member States, and the sponsor chooses to use the IMP registered in, for example, Germany for the purposes of the trial, the guidance should specify if the sole addition of a clinical trial specific labelling into national language(s) of other Member States will constitute a modification in accordance with Article 65 of regulation 536/2014 or not. The guidance should further clarify here whether no auxiliary medicinal product dossier (SmPC or simplified dossier as applicable) will be required for such authorized auxiliary medicinal product, in accordance with section 55, table 1 of Annex I of Regulation 536/2014. Proposed change (if any): Describe in more detail whether the sole addition of a clinical trial specific labelling into national language(s) of other Member States will constitute a modification in accordance with Article 65 of regulation	

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		536/2014 or not, and any need for an auxiliary medicinal product dossier under such circumstances.	
1145 - 1152		Comment: This section refers to changes to investigational medicinal product. It should also indicate that such changes shall also be considered for auxiliary medicinal products as applicable. Proposed change (if any): Include auxiliary medicinal products in section header “Changes to the investigational medicinal product or auxiliary medicinal product with a need to request a substantial modification to the IMPD/auxiliary medicinal product dossier”, and add a sentence in the guidance text to include auxiliary medicinal products for changes and request for substantial modification, e.g. “The guidance in this section should also be referred to for auxiliary medicinal products as applicable.”	
1152 – 1178 and Tables 1, 2 and 3		Comment: The list of examples and examples given in tables 1 and 2 should match. “Manufacturer(s) of the medicinal product” is included in table 2 but not listed in the body text of this section. Proposed change (if any): Add “Manufacturer(s) of the medicinal product.” to the body text of this section.	
1155		Comment: In order to provide clarity it would be helpful for sponsors if more information is provided here. For example, for a product which is diluted prior to intravenous administration, does immediate packaging material just refer	

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		to the drug product container closure system (glass vial and stopper) or does it also refer to the material from which the infusion bag is manufactured? Additionally, it should be noted that n-use stability data needs to be provided in the IMPD which covers the practice described in the clinical trial protocol. Proposed change (if any): Expand the guidance to explain more about the requirements for changes to the immediate packaging material that will represent a substantial modification to the IMPD.	
1179 - 1182		Comment: The classification criteria for “substantial” listed in this section are based on wording following current Directive 2001/20/EC and detailed guidance CT-1: – The safety or physical or mental integrity of the patients; – The scientific values of the trial; – The conduct or management of the trial; – The quality or safety of any IMP used in the trial. Criteria should be aligned with the definition following article 2, section (13) of regulation 536/2014, where “The conduct or management of the trial” or “the quality or safety of any IMP used in the trial” are not explicitly stated. Proposed change (if any): Change wording to align with definition of article 2, section (13) regulation 536/2014, stating: “[…] are only to be regarded as “substantial” where they are	

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		likely to have a significant impact on: – The safety or rights of the subjects, or on – The reliability of the robustness of the data generated in the clinical trial" If further details to this definition are needed for changes to medicinal product quality, and if permitted by the definition given in the Regulation 536/2014, the additional points should be added for supportive clarification, e.g. "'Substantial' shall also entail a change with significant impact on the quality or safety, or management of any IMP or auxiliary medicinal product used in the trial".	
Table 2 and Table 3		Comment: For clarity, ACRO recommends adding "addition of tests (no safety reason)" and "tightening of acceptance criteria (no safety reason)" to the "not required" column for both active substance and investigational medicinal product. Additionally, ACRO recommends that the final guideline should include a more comprehensive and detailed list of examples of changes that will warrant a substantial modification. Current guidance on changes that will require a substantial amendment is incomplete and therefore remains open to differences of interpretation by both applicants and assessors. Proposed change (if any): Add "addition of tests (no safety reason)" and "tightening of acceptance criteria (no safety reason)" to the "not required" column for both active substance and investigational medicinal product, and include a	

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		more comprehensive and detailed list of examples of changes that will warrant a substantial modification.	
Table 3 Shelf-life		Comment: The guidance should include the possibility to file a shelf-life extension plan not only with the initial filing but also later as a substantial modification. Proposed change (if any): Include in both columns the possibility of a later substantial modification approval e.g. "[…] with the initial *or a previous substantial modification* filing of the IMPD […]"	
		ACRO thanks the Agency for the opportunity to comment on this 'Draft Guideline on the requirements to the chemical and pharmaceutical quality documentation concerning investigational medicinal products in clinical trials ' (EMA/CHMP/QWP/834816/2015). Please do not hesitate to contact ACRO (knoonan@acrohealth.org) if we can provide additional details or answer any questions at all.	

Please add more rows if needed.