The European Association for Bioindustries

EUROPABIO RESPONSE TO THE EUROPEAN COMMISSION CONSULTATION ON A CONCEPT PAPER ON THE REVISION OF THE 'CLINICAL TRIALS DIRECTIVE' 2001/20/EC

EuropaBio welcomes the opportunity to submit these comments which represent the views of our members in response to the questions posed in the concept paper on the revision of the Clinical Trials Directive 2001/20/EC. We also offer recommendations to ensure a supportive regulatory environment for conducting clinical trials in the European Community.

EuropaBio looks forward to continuing to work with the European Commission and other stakeholders in the development of the legislative proposal for the revision of the Clinical Trials Directive to the ultimate benefit of both patients and the bioscience industry. We believe it is important to improve the competitiveness of the EU as a location for clinical research and the development of new, innovative medicines.

EuropaBio is the European Association for Bioindustries, bringing together bioscience companies from all fields of research and development, testing, manufacturing and distribution of biotechnology products. It has 66 corporate and 7 associate members, 4 Bioregions and 22 National Biotechnology Associations representing some 1800 small and medium sized enterprises in Europe.

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COOPERATION IN ASSESSING AND FOLLOWING UP APPLICATIONS FOR CLINICAL TRIALS

A single submission - Consultation item no. 1: Do you agree with this appraisal? Please comment.

EuropaBio agrees with the Commission's appraisal. This would greatly reduce the administrative burden and costs for sponsors, particularly for multinational clinical trials.

Indeed, a single submission through a single 'EU portal' would be welcomed.

As a first step, a common standardised clinical trial authorisation application dossier is needed for submission (without any additional national requirements) to support clinical trials to be conducted in the EU Member States. This would include one core set of documentation for the risk/benefit assessment of a given trial as well as quality aspects of the investigational medicinal product, one core set for the assessment of ethical aspects and another set for assessment of local facilities – the latter set being specific to each site. We aspire to having such an 'EU portal' that would greatly facilitate this information to be submitted through a 'single point', though it is recognised that 'a single submission through a single point' may not be achievable in the short term.

In order for the European Medicines Agency (EMA) to deliver this 'EU portal' that meets the requirements of all stakeholders it is important that sufficient financial and manpower resources are made available to develop the appropriate IT framework for submission of applications and related documentation and distribution to the Member States concerned.

EuropaBio recommendations:

- The portal would allow submission of one application dossier suitable for review by both National Competent Authorities and Ethics Committees.
- The portal would be used for all submissions irrespective of whether the trial is conducted in one or more than one Member State. This would greatly facilitate expanding the clinical development programme and including additional Member States.
- Validation of applications at central level would ensure that standardised requirements are adopted and published allowing sponsors to achieve a 'first-time-right' submission and reduce costs, which is welcomed by our member companies, especially SMEs.
- The possibility for subsequent applications for clinical trial authorisation to refer to information previously submitted to the EU portal (as stated in the concept paper) would facilitate maintenance of the Investigational

Medicinal Product Dossiers. This would allow the same sponsor or other sponsors (based on a letter of agreement) to cross-refer to information already submitted, as well as the inclusion of additional Member States in the clinical development at a later stage.

- A 'rolling Investigational Medicinal Product Dossier' would offer further significant reduction in the administrative work.
- Use of one single language (i.e. English) for all submissions would significantly reduce administrative costs. Patient documents (such as the Patient Informed Consent form, patient information leaflet, labelling for outpatient trial design and insurance leaflet) and ethics committee specific documents would be translated in the language of the country where the trial is intended to be performed, and submitted through the EU portal as country specific annexes.
- The single submission to the EU portal should trigger the distribution of information and review of clinical trial authorisation applications in all Member States concerned at the same time, with the National Competent Authority and Ethics Committee review processes being carried out in parallel. In addition, the use of this portal should further support the advantage of a fast review and approval of the trial, as currently is the case in Belgium, Germany, and the United Kingdom.

A separate assessment - Consultation item no. 2: Do you agree with this appraisal? Please comment.

EuropaBio agrees with the Commission's appraisal that assessment conducted independently by each Member State would not address the potential for divergent and conflicting views, which have adversely impacted on the ability of our member companies to carry out multinational clinical trials. Indeed, a timely initiation of the trial is hindered because of the need to respond to national requests for additional information and address questions due to variations in assessments of the same clinical trial authorisation dossier.

There remains a serious concern about the inconsistency in interpretation and application of requirements amongst the EU Member States. Examples are local requirements for real-time shelf-life data for medicinal products or substantial amendments for shelf-life extension for particular countries, different interpretation of the definition of substantial amendments, etc, notwithstanding the guidance already promulgated by the Commission. Furthermore, even if Scientific Advice has been obtained from the EMA's Committee for Medicinal Products for Human Use (CHMP) or if an agreed Paediatric Investigational Plan from EMA's Paediatric Committee is available, some Member States could still have comments on a particular trial, requiring an amendment to the study protocol which has already been agreed at an EU level. In certain extreme cases,

the sponsor has to omit a Member State from the original list of trial sites to allow the multinational clinical trial to proceed.

Conducting separate assessments will continue to lead to potentially different outcomes and will not facilitate the gradual harmonisation of regulatory and ethical standards across Europe. Furthermore, they risk delaying access by patients to important medicines being investigated in clinical trials.

Single submission with subsequent central assessment - Consultation item no. 3: Do you agree with this appraisal? Please comment.

Overall, EuropaBio concurs with the Commission's appraisal that a 'central' assessment as presented in the concept paper is an inflexible option and not appropriate for clinical research. This would make the review process very cumbersome and could lead to a lengthy decision-making process, since a full committee structure with a robust supporting infrastructure is required. Moreover, there is concern that the formation of such committee would take resources from countries not concerned by the trial unnecessarily. Consequently the assessment of applications for trials conducted in one or two countries, such as Phase I studies, may be significantly slowed down.

However, we continue to believe that an optional centralised assessment process could offer an attractive alternative in certain circumstances, particularly multinational clinical trials and trials in the field of rare diseases and advanced therapies, and should be further explored by the Commission and EU Member States. A closely coordinated assessment procedure in a virtual environment, supported by a robust IT infrastructure and involving the relevant experts from Member States, may provide a pragmatic, easily implementable and fast solution. This would result in the grant of a Community clinical trial authorisation allowing the trial to be conducted across the entire EU (pending positive opinions from relevant Ethics Committees). A single pan-European outcome is the way forward and this is what the ultimate goal should be. This is the outcome that will best improve the EU's competitiveness as a location for clinical research.

The concept paper states that for "ethical, national and local perspectives … a parallel, national procedure would have to be established in any case". We believe that only well-defined ethical aspects would be addressed by the national Ethics Committee system as currently provided in the Clinical Trials Directive, and well integrated into the procedure for authorisation of a clinical trial in the European Community. A single ethical opinion per Member State is required in accordance with Article 7 of the Clinical Trials Directive to overcome the divergence of opinions at regional/local levels. The introduction of a tacit approval is the favoured option in this respect. Moreover, the roles and responsibilities of National Competent Authorities and Ethics Committees in the

approval process need to be clearly defined. It would not be acceptable to introduce any additional national regulatory requirements.

Single submission with a subsequent 'coordinated assessment procedure'

Scope of the coordinated assessment procedure (CAP) - Consultation item no. 4: Is the above catalogue complete?

In general, the catalogue as set out by the Commission on page 5 of the concept paper is complete. However, we believe that the following aspects should be included in the list under a):

- The principles of Good Clinical Practice (GCP) - key to the conduct of clinical trials - should be followed.
- Greater emphasis on the assurance of safety of subjects participating in the trial.
- Statements that a particular clinical trial follows a CHMP's Scientific Advice or a Paediatric Investigational Plan agreed by EMA's Paediatric Committee should be taken into account because of the pan-European applicability.

Overall, EuropaBio concurs with the Commission's appraisal that the CAP could offer a flexible approach, although we believe some refinements to the proposal are required.

The CAP might be modelled on the Voluntary Harmonisation Procedure (VHP) for the assessment of multinational clinical trial applications trialed by the EU Heads of Medicines Agencies' Clinical Trials Facilitation Group (CTFG) and would build on experience of CTFG and sponsors with the VHP process. In light of our members experience with the operation of the VHP, we produced a report providing some key considerations for companies planning to use the VHP and recommendations to improve and render this procedure more attractive for broader application by the life sciences sector, irrespective of whether the sponsor is a large biopharmaceutical company or an SME.

The concept paper states that "the CAP would lead to a 'single decision' per Member State which would include the aspects assessed in the CAP, as well as the ethical/local aspects of a clinical trial assessment". If the CAP as proposed by the Commission results in a single decision per Member State, we would suggest that the National Competent Authority takes responsibility for coordinating and obtaining the required approval from the respective national Ethics Committee within the given timeline. This would also provide an opportunity for a more harmonised legal framework and governance structure at the local level, giving the health authority a greater mandate.

Although the 'single decision' would encompass only the regulatory and ethical/local aspects, there is a need, however, for joined up regulatory oversight from the National Competent Authority and other national and EU authorities/committees where clinical research involves the use of genetically-modified organisms (GMOs), medical devices, radiation, biobanks, etc, to ensure proper coordination amongst these bodies.

In the context of advanced therapy medicinal products consideration should be given to the involvement of the EMA's Committee for Advanced Therapies (CAT). With reference to the work programme 2010-2015 issued in November 2010, the CAT aims to initiate interaction with the CTFG to achieve harmonisation of evaluation of clinical trial authorisation applications for advanced therapy products in collaboration with the Commission in order to promote access and availability of these products to EU patients.

EuropaBio identified the following key points to be considered for the CAP:

- It is vital that the document requirements for a single submission are harmonised in all Member States and clearly defined.
- The development of a harmonised Ethics Committee procedure using the single electronic submission to the EU portal (see response to consultation item no. 1) is desirable to fully capitalise on the benefits offered by the CAP. This requires harmonisation of the operations and responsibilities of Ethics Committees across Europe.
- Good coordination among Member States and between the National Competent Authority and Ethics Committee will be required to ensure the grant of a clinical trial authorisation from the participating Member States within a defined timeframe.
- The process for appointment of the 'Reporting Member State' should be clearly defined and must not have any implication on timelines and consistency of assessments of clinical trials with similar design features or in the same disease area.
- The process for including additional sites or Member States after submission of the application or authorisation of the trial should be clearly defined.
- There is no need to duplicate the scientific assessment carried out in the CAP when a trial is extended to include additional Member States. Only a review of ethical/local aspects would be required to obtain authorisation of the clinical trial from the Member States concerned.
- Shorter review timelines should be applied in some circumstances to allow rapid access to treatments in certain therapeutic areas and for unmet medical needs. This should also be allowed where the assessment is limited to new data added to the Investigational Medicinal Product Dossier

which has already been reviewed, or when the trial follows a Scientific Advice or an agreed Paediatric Investigational Plan.

Therefore we urge the Commission and Member States to take this opportunity to create a unified approval process. This is important to ensure a supportive regulatory environment for clinical trials in the European Community and improve Europe's competitiveness as a location for the development of new, innovative medicines for patients benefit.

Consultation item no. 5: Do you agree to include the aspects under a), the risk-benefit assessment, as well as aspects related to quality of the medicines and their labelling, and only these aspects, in the scope of the CAP?

In general, we agree that aspects included under a) are appropriate for the CAP. EuropaBio welcomes the Commission's approach and differentiation between aspects suitable or not suitable for the CAP. In addition, we propose that certain aspects should be included in the scope of the CAP (see response to consultation item no. 4).

Furthermore, the definition of 'Investigational Medicinal Product' should be applied consistently across all EU Member States and trials, as there are implications for inconsistent safety reporting or labelling requirements.

A single 'EU portal' would greatly facilitate the workload for all parties, including National Competent Authorities, Ethics Committees and all types of sponsors. It would allow for cross-referencing not only within a clinical development programme from another sponsor but also cross-referencing for co-development of two investigational medicinal products (a concept more and more often followed and encouraged by the EMA in the field of oncology) as well as investigator-driven trials conducted by academic sponsors. See also response to consultation item no. 1.

Disagreement with the assessment report - Consultation item no. 6: Which of these approaches is preferable? Please give your reasons.

If there is a major disagreement with the assessment report under the CAP, we would prefer the 'opt out' option for the following reasons:

- We would favour a system which strives to achieve a common decision throughout the EU whenever possible, avoiding the complexity of a voting/referral system. There is concern about potential delay to authorisation of the trial that could result from referral to the Commission or the EMA.

- Member States should be allowed to opt out on the basis of 'differing medical practice' not on the basis of 'serious risk to public health or safety of the participant'. Otherwise there is a perception that patients are more protected in one country than in another, which would ultimately undermine the validity of the approval process.
- This would allow commencing the trial in those Member States which supported the assessment report; and
- Continue discussions with the Member State which 'opted out' to resolve outstanding questions without holding up the trial in other Member States.
- Adequate appeal mechanisms should be foreseen.

In case a Community clinical trial authorisation is granted, the 'opt out' option may not be the best option for addressing disagreements.

Mandatory/optional use of the CAP - Consultation item no. 7: Which of these three approaches is preferable? Please give your reasons.

The CAP should be optional. The national authorisation process may be more appropriate for early development clinical trials which tend to be conducted in one or a few Member States. It is a good approach to achieve a simple and harmonised system and set similar standards across the EU.

It is difficult to assign a 'one-size-fits-all' approach as there are many factors to be considered when designing and running a clinical trial. Member companies wish to have flexibility in choosing the most appropriate route for clinical trial approval with the possibility of using different procedures throughout product development.

For single site or single country trials, specifically Phase I studies, faster procedures facilitated by the Member State concerned should be adopted. Nevertheless, the same principles and requirements should apply to all clinical trials conducted in the EU. This will help to ensure that the same standards are applied, but also that the competitiveness of the EU as a place to conduct clinical research is enhanced.

Tacit approval and timelines - Consultation item no. 8: Do you think such a pre-assessment is workable in practice? Please comment.

In principle, EuropaBio agrees that there should be a simplified, quicker process for the authorisation of trials conducted with an approved product in accordance with its marketing authorisation.

A pre-assessment by the sponsor to identify such ‘type A’ trials could be helpful. A notification system is currently being piloted in the United Kingdom.

However, we do have concerns that the pre-assessment could in general add to the bureaucracy, the workload and the overall timeline for obtaining clinical trial approval in the EU. Therefore there may be limited benefit in having such a step to identify these trials.

While a categorisation might appear to be attractive at first glance, it will in practice be difficult to rigorously define and apply the criteria for the individual categories, in particular if interpretation will differ between Member States. It should be noted that the criterion set out in sub-paragraph (b) is somewhat vague and open to interpretation in practical situations.

The ‘tacit approval’ system has been helpful, in that it imposes a clear deadline with legal consequences if no action is taken by the Member State concerned. Therefore it is supported to allow a predictable development timeline and planning.

We would suggest applying the following timelines:

- Tacit approval within 30 days for studies conducted in line with a Scientific Advice, as part of an agreed Paediatric Investigational Plan, or in case there are no questions raised by the National Competent Authorities or Ethics Committees
- Approval within 60 days for trials involving advanced therapy medicinal products or where questions are raised
- Approval within 30 days where a Member State is added to a clinical trial authorised in recognition of the earlier assessment conducted by other Member States in the CAP

Furthermore, the advantage of a fast review currently provided by some Member States should not get dismissed, e.g. Belgium, Germany and the United Kingdom have faster review timelines.

BETTER ADAPTATION TO PRACTICAL REQUIREMENTS AND A MORE HARMONISED, RISK-ADAPTED APPROACH TO THE PROCEDURAL ASPECTS OF CLINICAL TRIALS

Limiting the scope of the Clinical Trials Directive

Enlarging the definition of 'non-interventional' trials - Consultation item no. 9: Do you agree with this appraisal? Please comment.

In general, EuropaBio agrees with the preliminary appraisal that it would be better to come up with harmonised and proportionate requirements which would apply to all clinical trials falling within the scope of the present Clinical Trials Directive.

In addition, it would be important to make clear in the new clinical trials legislation that non-interventional trials are not covered.

It is worth noting that Directive 2010/84/EU regarding pharmacovigilance lays down provisions for regulatory supervision of all non-interventional post-authorisation safety studies, which will be reviewed by the Pharmacovigilance and Risk Assessment Committee. Therefore some non-interventional trials would already be conducted under EU regulatory oversight.

As regards certain non-interventional trials which are regulated at national level, EuropaBio strongly recommends that a separate legal framework is developed by the Commission in conjunction with the Members States and relevant stakeholders. It would be useful to harmonise the requirements in the EU to enable better protection of trial participants but also to improve the conduct of these trials and reliability of resulting data. A Regulation would help to achieve this objective.

Excluding clinical trials by 'academic/non-commercial sponsors' from the scope of the Clinical Trials Directive - Consultation item no. 10: Do you agree with this appraisal? Please comment.

EuropaBio concurs with the preliminary appraisal that harmonised and proportionate requirements for clinical trials should apply to all sponsors. It is critical that the same rules are applied to all academic/non-commercial and commercial sponsors in the interests of patient protection.

The nature/stringency of the requirements and obligations should not be driven by the status/identity of the sponsor.

There is an urgent need to eliminate unnecessary regulatory requirements, which do not improve patient safety and data quality. We would like to stress that unduly complex administrative requirements imposed by either Community law or national domestic law coupled with a lack of predictability of the regulatory process could have a damaging effect on innovation and increase costs of clinical development. This would have a direct impact on the life sciences industry, particularly SMEs.

In certain therapeutic areas (e.g. oncology), data from trials conducted by academic sponsors (Investigator-driven trials) are included into marketing authorisation applications as supportive trials. This opportunity should still remain and not be compromised by any potential differentiation of the requirements for studies conducted by an academic or a commercial sponsor.

More precise and risk-adapted rules for the content of the application dossier and for safety reporting - Consultation item no. 11: Do you agree with this appraisal? Please comment.

EuropaBio agrees with the Commission's proposal to provide for one single, EU-wide, risk-adapted set of rules for the content of the clinical trial application dossier and for safety reporting. However, the effectiveness of such approach may be affected by national interpretation of a Directive which can lead to divergence in requirements. Concerns were raised about the differences in translation and interpretation and synchronising the timelines for implementation and application of such rules across EU Member States.

There is a need for greater awareness, discussion and understanding of what constitutes a risk-based approach to the procedural aspects of clinical trials. It should be emphasised that the application of such risk-based approach would need to be consistent and in accordance with defined criteria, and the stage of product development.

We would be in favour of integrating the Commission's detailed guidances (CT-1, CT-2 and CT-3) in the Annexes to the future legal act so that they would be binding on all EU Member States. With regard to Guidance 2010/C82/01 we believe the text should also be adjusted to prevent Member States from requesting additional information or follow national procedures. As such, the Directive should be converted into a Regulation in order to ensure that requirements are fully and sufficiently harmonised across all EU Member States. We need also to ensure that there is an enabling provision in the body of the legislation to allow for revision of the Annexes through the comitology procedure.

The concept paper states that "In drawing up these Annexes, one would have to take into account … international harmonisation work, such as guidelines of the International Conference on Harmonisation ('ICH')". However, there are a

number of ICH guidelines, especially as regards quality, where application to the restricted environment of clinical trials is not appropriate and it is clearly stated in these guidelines that they do not cover applications for clinical trial authorisation; examples are ICHQ1A and its extension ICHQ1E, and ICHQ3A. Problems arise when some National Competent Authorities strictly apply the requirements intended for commercial products in the development phase. Such a request is wholly unreasonable, and fails to appreciate that product development is an incremental process.

Consultation item no. 12: Are there other <u>key aspects</u> on which more detailed rules are needed?

Member States should be encouraged to remove any duplicate or additional national requirements that cannot be objectively justified. Local legislation should be adapted accordingly where it is currently in the way of effective harmonisation. Scrutiny should be applied to all requirements listed and/or envisioned by analysing whether a certain requirement would help to allow the assessment of the benefit/risk of a given trial, and protect the safety, rights and well-being of trial participants. A harmonised list of requirements would contribute to reducing bureaucratic burden and not comprise the largest common denominator of all Member States. Moreover, the possibility to transpose the requirements differently into national law should be minimised. A Regulation would help to achieve this aim.

Any new/revised legal instrument should set out detailed procedures and provide clearer agreed definitions (for example, investigational medicinal product, legal representative, reporting procedures). It should also provide for a simplified procedure for authorisation of a clinical trial or more flexible requirements which could apply to trials conducted with an approved product in accordance with its marketing authorisation.

There are some key aspects on which more detailed rules are needed:

- Substantial amendments: Member States still have different interpretations. A detailed list of changes falling within the scope of substantial amendment should be established in order to give a single interpretation for both National Competent Authorities and sponsors.
- Safety reporting requirements: The information obtained from safety reporting in clinical trials should be useful and meaningful so that, following analysis, a thorough understanding of the safety profile of the product and procedures used in the trial is available. Ensuring such changes to the reporting of suspected unexpected serious adverse reactions (SUSARs) could result in having more meaningful (medically relevant) safety reports that ultimately contribute to the safety of trial participants and patients. It is recommended that the system for safety

reporting in clinical trials is closely aligned to reporting requirements in the post-marketing phase to ensure continuous evolvement of a product's safety profile.

Clarifying the definition of 'investigational medicinal product' and establishing rules for 'auxiliary medicinal products' - Consultation item no. 13: Do you agree with this appraisal? Please comment.

There is a need for EU-wide agreed definitions of terms, including 'investigational medicinal product', 'non-investigational medicinal product', and data requirements for each. Notwithstanding the availability of guidelines, legal uncertainties on the definition of 'investigational medicinal product' remain and call for further clarification.

EuropaBio believes that the introduction of the notion of 'auxiliary medicinal products' as proposed in the concept paper would lead to misinterpretation and create confusion, unless the term 'auxiliary medicinal product' replaces the term 'non-investigational medicinal product'. This would not cover any additional interventions used in clinical trials. Conversely, EuropaBio believes that 'auxiliary medicinal products' could be defined taking account of the purpose of usage as well as the mode of administration. Proportionality and the level of information available should be considered for these products. Sponsors should be able to justify their use if a full dossier cannot be provided.

Auxiliary products would include both non-investigational medicinal products (rescue, background, challenge agents) and ancillary materials (such as infusion/saline solutions, etc).

Clarification is needed for products used as 'base therapy' (often in both treatment arms). Currently, the existing guideline is often not followed by National Competent Authorities. Thus, a National Competent Authority may consider an authorised product as an investigational medicinal product, while another National Competent Authority would consider the same product as a non-investigational medicinal product. EuropaBio believes that a pragmatic, reliable and consistent approach should be followed across EU Member States. Moreover, the rationale why a base therapy agent may be considered an investigational medicinal product should be taken into consideration and differentiated requirements for safety reporting, labelling and documentation should be applied.

Insurance / Indemnisation - Consultation item no. 14: Which policy option is favourable in view of legal and practical obstacles? What other options could be considered?

EuropaBio does not consider the suggested options to be appropriate. Insurance requirements should be maintained for all trials. The cost for insurance is not the key factor that could prevent companies from conducting clinical trials in the EU.

Regardless of the potential level of risks, trial participants should be effectively covered by insurance or indemnity against any damage they may suffer.

Requiring insurance for all trials provides legal certainty and clarity to all stakeholders in case of injury or death. Making Member States responsible for providing insurance will likely lead to uncertainties and a reduced incentive for sponsors/investigators to be involved.

Single sponsor - Consultation item no. 15: Do you agree with this appraisal? Please comment.

EuropaBio agrees with the Commission's appraisal. We believe that the concept of a 'single sponsor' per trial should be maintained to ensure clear assignment of roles and responsibilities.

Emergency clinical trials - Consultation item no. 16: Do you agree with this appraisal? Please comment.

EuropaBio agrees with the Commission's proposal which provides both a perfect analysis and a viable solution in line with existing international agreements. We support a full harmonisation of the rules applicable to emergency clinical trials across EU Member States. Again, a Regulation would help to achieve this objective.

ENSURING COMPLIANCE WITH GOOD CLINICAL PRACTICES IN CLINICAL TRIALS PERFORMED IN THIRD COUNTRIES

Consultation item no. 17: Do you agree with this appraisal? Please comment.

In general, EuropaBio agrees with the Commission's appraisal and the proposed actions. We support further international cooperation in the regulation of clinical trials, encouraging dialogue with all stakeholders on GCP compliance as well as capacity building in relevant third countries.

While we fully support the requirement for public disclosure of interventional trials in a registry accessible to the public, we would urge consistency with existing registration and results posting requirements in other ICH regions. Therefore the use of registries such as Clinicaltrials.gov is recommended. In this regard, the WHO operates an International Clinical Trials Registry Platform to ensure that a complete view of research is accessible to all those involved in healthcare decision making.

Mandatory inclusion of trials conducted in third countries into the EudraCT database would present an additional complexity and administrative burden requiring additional resources without public health benefits necessarily. The EU should rather work collaboratively with other regions to coordinate the transparency of clinical trials without unnecessary duplication of registration or differing requirements.

In addition, we would appreciate if the context between GCP compliance in trials performed in third countries and their registration in a registry could be explained further as registration of a trial would not necessarily indicate compliance/non-compliance with GCP.

It should be clarified whether registration of a trial could be done retrospectively, even if a study has been completed.

FIGURES AND DATA

Consultation item no. 18: Do you have any comments or additional quantifiable information apart from that set out in the annex to this document? If so, you are invited to submit them as part of this consultation exercise.

We do not have any further comments or additional information.