caïber
SPANISH CLINICAL
RESEARCH NETWORK

Outcomes from the

# Multidisciplinary Workshop

To review the

# Concept Paper

**Submitted by the European Commission for public consultation towards the revision of the Clinical Trials Directive 2001/20/EC**

**April 27th, Madrid (Spain)**

Dear Sir:

The European Commission (EC) is planning to put forward, in 2012, a legislative proposal to revise the Clinical Trials Directive 2001/20/EC and has submitted a concept paper for public consultation.

CAIBER Spanish Clinical Research Network is a public consortium essentially comprised by forty of the main Academic Hospitals in Spain with high expertise in clinical trials research, five regional governments and the Carlos III Institute of Health (ISCIII), dependent on the Ministry of Science & Innovation. CAIBER's mission is to promote, facilitate and coordinate the realization of highly valuable multicenter clinical trials in Spain and in Europe, conducted under the highest standards of quality and excellence, with the appropriate resources and in a timely manner.

CAIBER acknowledges and welcomes this opportunity that the EC brings to all the key agents engaged in clinical trials with investigative medicines in Europe to provide with proposals on the preliminary appraisals reflected on such concept paper.

We strongly believe that complementary to the expected individual institutions report-submission in response to the EC call across Europe, a report containing comments and concrete proposals resulting from the simultaneous interaction among the key players on the clinical trials' arena, would be of great added value to the European Commission and to each stakeholder separately.

**Therefore, a multidisciplinary Workshop for the discussion of the concept paper was organized and chaired by CAIBER on April 27th in Madrid, with the active and highly valuable participation of 86 experts from 14 different institutions/collectives in Spain, including Academic clinical investigators, Pharma Industry, Regulators, Ethics, insurance companies, among many others as will be further detailed in this document.**

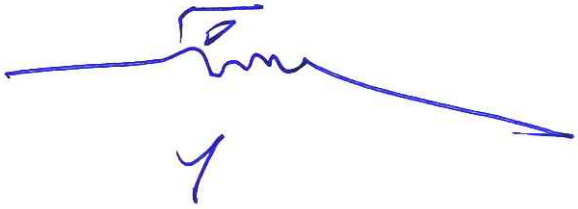
This worthwhile document we are submitting to the EC reflects the high motivation, expertise and engagement of all attending participants, who made a big effort to devote a full day from their busy agendas to join and share their talent at the Workshop. To them, our deepest recognition and personal & professional respect and appreciation.

This report contains the key outcomes from the Workshop and includes all proposals that were generated and discussed among participants. European Commission officers will notice that there existed a high degree of agreement existed on many of the topics and its proposed solutions, whilst some drops of heterogeneity were also observed and collected here, to enrich the EC with a broader world of proposals.

On behalf of CAIBER and all the Workshop participants, I'd like to thank you once more for this opportunity.

I'm sure this report will be of value to the European Commission on its task.

Best regards from Spain,



Joaquin Casariego, M.D.
Director General
CAIBER- Spanish Clinical Research Network
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# INTRODUCTION

In order to provide a complete and realistic perspective of the Spanish vision of the "concept paper for public consultation" for the Revision of the ´Clinical Trials Directive` 2001/20/EC , CAIBER, as chairman, organized an Interactive Workshop with the main stakeholders in clinical trial business/arena 86 experts representing 14 different professional profiles participated the 27th of April 2011 in this forum to discuss the actual situation of the Clinical Trials Directive and the new appraisals originated by concept paper. The participating collectives are listed below:

| | |
|---|---|
| Chair: | CAIBER |
| Participating collectives: | Academia |
| | Pharmaceutical Industry |
| | National Competent Authority (AEMPS) |
| | ERBs/IRBs |
| | CIBERs (Biomedical Research Networking Centers) |
| | RETICs (Thematic Networks) |
| | Clinical Research Organizations |
| | FARMAINDUSTRIA |
| | Hospitals and Primary Care Centers |
| | Insurance companies |
| | Research Health institutes |
| | Scientific societies |
| | Universities |

The detailed list of the Workshop participants and respective institutions (who consented to be included in this document) is detailed in Annex 1.

# Methodology

During the Workshop, a brief introduction of the revision of the Clinical Trials Directive 2001/20/EC and its public consultation was given. After that, 10 working groups discussed the different consultation topics. The conclusions of each working group were shared to all the experts in order to collect the different opinion of the workshop participants.

Two different rolls have been established at each working group:

- **Leader:** responsible for leading the group during the meeting, spokesperson for the presentation of the conclusions, and responsible of the approval of this document.

- **Secretary:** responsible of the transcription of the meeting minutes, support of the leaders and directly involved in the redaction of this document.

The minutes of the meeting are included in this document as comments to each of the consultation items, trying to reflect the assessment performed in this workshop.

## Conclusions

The information outlined in this document reflects the conclusions of the meeting and in some occasions could not represent the opinion of the participants and should not be considered as the position of the institutions in which they are embodied.

# Consultation Topics

## 1. Cooperation in assessing and following up applications for Clinical Trials

**Background and identified Challenges:**

- There is a lack of harmonization within EU regarding the submission and review process of Clinical Trial Application (CTA).
- There are significant differences between Member States in the requirements for the CTA dossier.
- These existing differences have a negative impact, especially on the conduct of multinational clinical trials.
- The administrative burden for the application and authorization of multinational clinical trials should be reduced.

## 1.1 Single submission with separate assessment:

**Consultation Item no. 1***: A single submission would greatly reduce the administrative work of sponsors for submission of documentation to the Member States concerned. Do you agree with this appraisal? Please comment.*

The Working Group agrees with this appraisal: It is supported that for both, national and multinational clinical trials, all necessary applications and notifications of clinical trials to the *Member States concerned* (MSC) should be submitted through a central 'EU portal'. The proposed ´EU portal, should either directly distribute or provide access to the MSC for further distribution of the information to the concerned competent authority and/or Ethics Committee. However, a transitional phase should be allowed were only applications of multinational clinical trials are submitted.

There should be an agreement on a single CTA dossier for all EU Member States. It reflects the need to uniform requirements for national competent authorities and ethics committees at the European level and avoid as much as possible local requirements.

The Working group strongly supports the introduction of a single point of application through an 'EU portal'. The benefits having one streamlined CTA process is the reduction of the administrative work of sponsors for the submission of the

documentation to the Member States concerned. The following principles should apply for the EU portal´:

- It should be simple enough to use for any type of Sponsor.
- A single EU CTA dossier (including all documents required by national Competent Authorities and Ethics Committees with minimal local changes) should be submitted in electronic format.
- All CT applications/notifications, not only initial and substantial amendments, should be introduced in the ´EU portal´. The only exception should be SUSAR reporting.
- The submission through the ´EU Portal´ should be mandatory for all CT. At the beginning, only for all multinational clinical trials subject to a CAP procedure.
- In case of multinational CTs, the applications to all CMS should be simultaneous.

Assuming the good functioning of the 'EU portal', it would be preferable to have only one EU route for the submission of any clinical trial application (except for expeditive SUSAR reports), multinational and national clinical trials to the CMS. This would allow real-time information of all trials submitted for review and approval.

**Challenges**

- The "EU Portal" must allow distribution of the corresponding documentation to both national Competent Authorities and Ethics Committees.
- Implementation of the new central submission system needs to be adapted to the new process covering the submission service for all clinical trials within the EU.

**Consultation Item no. 2:** *A separate assessment would insufficiently address the issue set out above: The difficulties created by independent assessments would remain. Do you agree with this appraisal? Please comment.*

The group agreed with this appraisal, According to the general opinion and despite the fact that the single submission would simplify the process, the separate assessment would not substantially change the current system. Besides that, the difficulties created by independent assessments would remain.

## 1.2 Single submission with subsequent central assessment

**Consultation item no. 3: A c***entral assessment is not appropriate for clinical trials approval and would, as regards clinical trials, not be workable in practice. Do you agree with this appraisal? Please comment.*

The discussion group agreed with this appraisal, and considered that central assessment will not be workable in practice, since it seems not to be feasible, nor operational.

## 1.3 Single submission with a subsequent 'coordinated assessment procedure'

**Challenges identified:**

The Coordinated Assessment Procedure (CAP) will offer the best option for multinational clinical trials. The working group supported the single submission with a subsequent CAP not only for the initial submission and amendments, but also for any other global aspects of the multinational clinical trials such as safety (annual and "ad hoc" safety reports, SUSAR ...).

Changes into the European directive must allow clinical trial started. Changing the European legal framework must also involve the corresponding changes for all Member States. New authorization procedures should be viable, agile, and competitive with third countries.

Initially the CAP could be optional during an "adaptation period of time" until it is proven that the system is functioning correctly.

However, during the discussion several issues highlighted that difficult having a single CTA dossier, including:

- Specific requirements in some Member States of ethics committees and/or competent authorities.
- Language issues since not all the MS may be willing or are able to asses a CTA dossier in English.
- Standardization of documents such as the subject information sheet an informed consent form.

Moreover, the time needed for the collection of information and the preparation of documents for the application may vary between Member States due to local specifications and requirements. This may lead to a delay in obtaining approval in the

"quicker MSC" if the principle of sending simultaneous applications to all MSC were applied to the CAP. As a consequence, Sponsors could decide to exclude some countries, unless they improve their procedures. European clinical trials have to be competitive and thus, regulations to avoid this situation have to be implemented.

The following conditions are defined for CAP procedure:

- Simultaneous submission of the CTA dossier that reflects the different requirements for national competent authorities and ethics committees review at the European level. This option minimizes local requirements so that they are not an impediment that could lead to a delay in obtaining approval.
- Include initial application and amendments, as well as other global aspects such as safety (annual safety reports and "ad hoc" reports, SUSAR ...)
- It should be optional in a first step, before making it mandatory for all multinational clinical trials.
- Competitive timelines with the existing timelines, so that CAP procedure must become faster to get a clinical trial started.
- Local differences in national traditions, therapeutic standards and healthcare systems make the CAP not suitable to asses:
    - Ethical aspects related to informed consent, recruitment and reward.
    - Local aspects related to suitability of sites, the investigator and national rules.
    - Additional local aspects should be taken into account: since the procedures regarding the following issues are not clear:
        - Insurance certificate.
        - Data protection.

### 1.3.1. Scope of the CAP

| **Consultation item no. 4:** *Is the catalogue proposed complete?* |
|---|

The catalogue to be assessed by the CAP is considered to be complete by the working group.

**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 labeling) and only these aspects, in the scope of the CAP?*

The working group agreed with the risk-benefit assessment. Drug quality and labeling are the only aspects to be included in the scope of the CAP.

Comments and remarks:

Risk-benefit assessment:

Regarding the "Characteristics of the intervention compared to normal clinical practice" the following changes were proposed:

- "Normal" should be replaced the "standard"
- Evaluation of "normal/standard clinical practice" should be under a national or a site evaluation.

Manufacture and importation requirements
In a few cases, manufacturing procedures are carried out at national level (e.g. hospital pharmacies) after the approval of the National Competent Authority. This approach should be maintained in these exceptional cases.

Labeling assessment:

Centralized labeling approval would be acceptable, even convenient, but validated translation would be required by the National Competent Authority.

### 1.3.2. Disagreement with the assessment report

**Consultation item no. 6:** *Which of these approaches is preferable? Please give your reasons.*

- *An individual Member State could be allowed an 'opt out', if justified on the basis of a 'serious risk to public health or safety of the participant'*

The working group had long discussions about this option, since it is the only one that offers a flexible appraisal to solve disagreements. However, this option allow an "opt

out", justified by the Member State on the basis of a "serious risk to public health or safety of the participant". That statement has been considered as an **inadmissible** option by the group, as far as a "serious risk to public health or safety of the participant" should have as consequence the immediate refusal of all the member states.

As conclusion the working group has suggested a new option, allowing an "opt out" of individual Member states, only if it has a clear justification in order to ensure transparency.

- *The Member States concerned could vote on the issue and decide by simple majority.*

Most of the participants of the working group disagreed with this option

- *The matter could be referred to the Commission or the Agency for a decision at EU level.*

Most of the participants of he working group disagreed with the third option.

### 1.3.3. Mandatory/Optional use

**Consultation item no. 7:** *Which of these approaches is preferable? Please give your reasons.*

- *CAP is mandatory for all clinical trials. (This would mean that the provisions on authorization in the Clinical Trials Directive would be replaced)*

The Working group rejected this approach. It seems an illogical situation to evaluate Clinical Trial performed only in a single-country by CAP.

- *CAP is mandatory for all multinational clinical trials. (This would mean that the provisions on authorization in the Clinical Trials Directive would be maintained only for single-country clinical trials)*

This option had higher support in the discussions of the working group.

- *CAP is optional. (This would mean that sponsors could continue to refer to the national procedures laid down in the Clinical Trials Directive)*

A minority of the Working Group supported this option.

However, a new approach was proposed by the working group as the most preferable approach:

An “adaptation period” should be allowed with optional use of CAP , in order to grow in experience and having enough flexibility to avoid technical issues. After this experimental-adaptation period, the mandatory use of CAP would be welcomed for all multinational clinical trials.

### 1.3.4. Tacit approval and timelines

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|---|
| **Consultation item no. 8:** *Do you think such a pre-assessment is workable in practice? Please comment.* |

The comments on this item were split into two opinions. On one hand, insufficient definitions are developed in the concept paper on “Tacit approval” and timelines. A second group supported this kind of evaluation based in the model performed by the Clinical Trials Facilitation Groups (Voluntary Harmonization Procedure: VHP).

The inclusion of timelines as well as an “explicit approval” in writing to the Sponsor for initial authorizations and substantial amendments was one of the appraisals with higher support.
Additionally, a clear definition should be provided for “*Type A”* Studies;

- *Type A trials* should be identified by the Sponsor, according to the aforementioned, so a pre-assessment should not be required.
- If European Authorities dismiss a *Type A* request, an option to redirect the administrative process to the appropriate type of assessment should be provided in order to avoid stopping or delaying the procedure.

## 2. Better adaptation to practical requirements and a more harmonized, risk-adapted approach to the procedural aspects of Clinical Trials

**Challenges identified:**

The risk adapted approach was an issue discussed in almost all the working groups, being welcomed by the different stakeholders. Just some terms of the definition were considered as a problem, due to the different/subjective interpretations of “insignificant low risk”

## 2.1. Limiting the scope of the Clinical Trials Directive

### 2.1.1. Enlarging the definition of "non-interventional" trials

**Consultation item no. 9:** *Rather than limiting the scope of the Clinical Trials Directive through a wider definition of 'non-interventional trial', 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. Do you agree with this appraisal? Please comment.*

The Working group completely agreed with the appraisal. The group considered that the scope of the Clinical Trials Directive should not be modified. Nevertheless, some recommendations were made:

- The modification of the name "non-interventional trials" to "non-interventional studies" is proposed, as "trial" implies interventional procedures.

- Studies with a lower frequency of the monitoring or low risk procedures are considered as low risk clinical trials (Type A). The working group agrees with the appraisal of adapting the corresponding requirements.
- A standardized procedure for the classification clinical trials would be welcomed, as long as the risk evaluation has a main subjective character. An algorism with a possible appraisal is included in a detailed Annex.

### 2.1.2. Excluding clinical trials by 'academic/non-commercial sponsors' from the scope of the Clinical Trials Directive

**Consultation item no. 10:** *Rather than limiting the scope of the Clinical Trials Directive, it would be better to come up with harmonised and proportionate requirements for clinical trials. These proportionate requirements would apply independently of the nature of the sponsor ('commercial' or 'academic/non-commercial'). Do you agree with this appraisal? Please comment.*

All the members of the Working Group, with no exception, completely agreed with this appraisal- There should not be any difference between commercial and non-commercial trials. Patient safety and data quality should be guaranteed by the same legislation regardless of who is the sponsor of the clinical trial.

- Besides form this general agreement in the topic it was considered the fact that the directive makes no distinction between different types of clinical trials (early phase, phase IV…), and this is should be avoided in the future. In opinion of the group, general requirements must be establish for all study types

(independent of the sponsor or the non-commercial character), but the new directive should consider exceptions to this rules based on the risk of the trial.

## 2.2. More precise and risk-adapted rules for the content of the application dossier and for safety reporting

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

The group agreed to adapt the content of the application dossier and security to risk-adapted rules, establishing differences in the process of authorization.

**Consultation item no. 12:** *Are there other key aspects on which more detailed rules are needed?*

The group agreed that in order to define a risk-adapted approach, it would be necessary to consider four critical factors:

1. Investigational Medicinal Product Classification: An individualized assessment (with differences in the criteria used and in the authorization process) should be considered for:
    - Biotechnology products
    - Gene therapy products
    - Cell therapy products
    - Genetically modified organism

2. For medicinal products not included in the previous point, three categories of risk (based on the marketing authorization status and previous experience of use) would be defined:
    - Type A: Authorized medicinal product under the authorized conditions.
    - Type B: Authorized medicinal product under different conditions of use.
    - Type C: Pre-Authorization (different clinical trials phases should have different requirements: first-in-human studies compared with Phase III)

3. Existence of an “standard of care”

4. Study population: individualized assessment should be considered for subgroups: pediatric, elderly, pregnant women...

## 2.3. Clarifying the definition of 'investigational medicinal product' and establishing rules for 'auxiliary medicinal products'

**Consultation item no. 13:** *Clarifying the definition of 'investigational medicinal product' and establishing rules for 'auxiliary medicinal products' clarify, and streamline the rules for medicinal products used in the context of a clinical trial. Do you agree with this appraisal? Please comment.*

- The group agreed to differentiate between IMP and "auxiliary medicinal product".
- The group agreed on the modification of the term IMP provided by the concept paper, but considered that depending on the type and the design of the protocol, safety, relabeling, covering and information to be provided about the IMP should be specified, differences should be implemented depending on whether the IMP is(are) an authorized or a non-authorized drug (s).
- The group agreed on the modification of the term IMP provided by the concept paper, differences should be implemented depending on whether the IMP is(are) an authorized or a non-authorized drug (s), taking into account the type and the design of the protocol, safety, relabeling, covering costs.

- Regarding the "auxiliary medicinal products" the group considered it is recommended to specify which kind of treatments should be included in the definition. The following definition is suggested: *"A medicinal product as referred to in Article 3 (3) of Directive 2001/83 EC which is not an investigational medical product such as challenge agents, rescue medication and background treatment"*
- Rules to be applied to "auxiliary medicinal product" should be the same applying to authorized drugs in terms of documents, costs covering, information and labelling.

## 2.4. Insurance/indemnisation

### 2.4.1. The issue

The "risk-profiles definition for clinical trials" was supported by the working group. In order to define the risk related to a clinical trial, all the members agree in the importance of having a sound knowledge and sufficient prior experience with the IMP, with the intervention, how it differs from normal clinical practice, as well as the subject population involved. Otherwise as long as each trial has specific characteristics, we also agree with the concept paper that the risk of a trial subject varies considerably depending on the actual circumstances of the trial.

### 2.4.2. Policy options

| **Consultation item no. 14:** *Which policy option is favorable in view of legal and practical obstacles? What other options could be considered?* |
|---|

| Option 1: Removing insurance/indemnisation requirements for low-risk trials | Option 2: Optional indemnisation by Member States | New proposal |
|---|---|---|
| According with the 2.4.1 issue, and considering that not only the drug but the simple fact of a trial being performed is a risk for the subject (voluntarily participating in the trial), the group agree that removing insurance is not applicable in any case. | it could be an alternative option, but some questions remain unsolved:<br><br>- Who will be the responsible of contracting the insurance?<br><br>- Is that possible in Spain with 17 different local Governments?<br><br>- Is it only applicable for low risk clinical trials?<br><br>- Would it be possible for the Regulatory Agency to cover the indemnisation as responsible for the total number of trials performed in Spain?<br><br>- How long will it take to transfer the new Directive into Spanish laws? | Representatives from insurance business pointed out that Spanish law in reference to indemnisation (RD 223/2004 art 8), determines as indemnisation the minimum amount to be considered in case of damage related to a clinical trial. They consider that this should be described in the Directive in order to homogenize the equal compensation in any European country implied. |

**Proposal:**

- The first option cannot be considered for clinical trials as every trial involves additional risks for the simple fact of being performed in experimental conditions.
- Taking into account the classification of level of risks in clinical trials (discussed in working group 6), we propose to offer pre-established prices for insurance contracting according to the classification in low/high level of risk.

- The proposal should be sent to the European Committee of Insurance in order to know their position regarding these issues.

## 2.5. Single Sponsor

**Consultation item no. 15:** *Maintaining the concept of a single sponsor is preferable. Do you agree with this appraisal? Please comment.*

Both options have been discussed in the working group. However, as a result, discrepant views emerged and no consensus was agreed on the most adequate option was achieved (single vs. multiple sponsorship). The group identified pros and cons for both options which have been summarized as:

Cons of following Option1: Single Sponsorship

- Even if European requirements for submission are harmonized, still the sponsorship requisites by country will be subject to the legal requirements by country, meaning that assuming single sponsor responsibilities in Europe will be only harmonized for the submission piece but still diverse for the country responsibilities. It will be more difficult for smaller companies and investigators to assume Sponsor awareness and responsibilities beyond their country. There have always been different research groups that could act as sponsors in their own countries, but they do not want to assume some of the responsibilities of other sponsors.

- Impossibility of an investigator to act as sponsor and assume all responsibilities (insurance, IMP,…), although a partner company would be keen to participate. (If there's an investigator willing to initiate and promote a study, it limits the possibility of having an investigator acting as Sponsor together with a partnering Sponsor or company that is keen to officially assume part of the responsibilities that the investigator is not dimensioned to assume (insurance, IMP, etc…).

- In the context of independent research, the single sponsor model for the complete EU territory limits the possibility of implementing contingency plans during the course of the study to complete studies that are not achieving the initial expectations. In the case of independent research it is sometimes necessary to seek for partnerships between centers in order to complete their studies, and these centers in this case could not assume the responsibilities of the other participants and vice versa.

- It is the most excluding model, as it does not allow multiple sponsorship (whereas the other model still allows single or multiple as preferred)

Cons of following Option2: Multiple Sponsorship

- It would create an additional step that can be perceived (EU versus other regions) as additional specificities and bureaucratic burden lack of clear and unique owner of sponsor responsibilities for a given trial. Multiple Sponsorphip makes it difficult to assume all the responsibilities of the sponsor. For example, from the point of view of the pharmacovigilance, adverse event reports from each of the participants; it is apparently safer to have a single sponsor in charge.
- Multiple Sponsorship would still require always one of them to assume a "coordinating" role and all the responsibilities should be clearly determined among them. This adds some room for confusion and additional bureaucracy.
- If there are multiple sponsors, we would not have to give local explanations that delay the studies.

## 2.6. Emergency Clinical Trials

**Consultation item no. 16:** *Clinical Trials Directive could be amended to the effect that the informed consent and the information from the investigator may take place during or after the clinical trial in Emergency Clinical Trials. Do you agree with this appraisal? Please comment.*

- The performance of an Emergency Clinical Trial (ECT) is considered clinically relevant and its specific regulation should be equally regarded.
- The definition of ECT has to be written in the protocol of the study and it has to be clearly justified from the relevant scientific point of view.
- The ERBs/IRBs and Competent Authorities must assess specifically the characteristics of the emergency and endorse this condition.
- The IC (Informed Consent) obtention and the Patient Information carried out by the Investigator could be placed after inclusion of the patient in the study under the following circumstances:

    - The study subject is not capable of giving consent.
    - The physical and mental condition of the subject that prevents from providing the IC is a (necessary) characteristic of the study population.
    - Due to the emergency situation it is impossible to obtain the IC from the parents/legal representative.
    - The study subject has not previously expressed objections known by the Investigator.

- Additionally, it is suggested that the Inform Consent Document of the ECTs must have a format adapted to the emergency condition.
- In case of absence of the Legal Representative figure in Spain, relatives can give consent in the exceptional conditions previously mentioned.
- The Insurance should specifically consider the characteristics of the Emergency Clinical Trials including the uniqueness in the obtaining of the IC.
- Taking into account the special vulnerability of the pediatric population and especially in the neonatal period, Emergency Clinical Trials should only be considered in exceptional situations.
- In general, in this population, parents or Legal representatives are available to give the IC, so their absence only is considered in exceptional situations.

## Annex 1: List of participants

### Working Groups Leaders:

| Name | Family name | Institution |
|---|---|---|
| Rocío | Arce | UCCA CAIBER |
| Rafael | Bañares Cañizares | Hospital Gregorio Marañón |
| Pilar | Hereu Boher | No Aplicable |
| Ángela | Ibáñez Cuadrado | CIBER SAM |
| Santiago | Martín Gil | HDI Seguros |
| Ana | Pérez Domínguez | Glaxo Smithkline |
| Salvador | Pita Fernández | SERGAS (CEIC) |
| Javier | Revuelta | AECIC |
| María Antonia | Serrano Castro | AEMPS |
| Juan | Tamargo | Instituto Farmacología y Toxicología.UCM. |

### Working Groups Secretaries:

| Name | Family name | Institution |
|---|---|---|
| Alba | Álvarez | CAIBER |
| María | Díaz | CAIBER |
| Nerea | Egües | CAIBER (Hospital Donostia) |
| Arantzazu | Miner | CAIBER |
| Raquel | Muñoz | CAIBER (Fundacion Jiménez Diaz) |
| Marta | Pavía | CAIBER |

| | | |
|---|---|---|
| Claudia | Plaza | CAIBER |
| Graciela | Rodrigálvarez | CAIBER |
| Clara | Rosso Fernández | CAIBER (Hospital Universitario Virgen Del Rocio) |
| Ángela | Salsón | CAIBER |
| María | Sanchiz | CAIBER |
| Rosa María | Vega | CAIBER (Hospital Universitario 12 De Octubre) |
| Javier | Villanueva | CAIBER (Hospital de la Santa Creu i Sant Pau) |

## Working Groups Participants:

| Name | Family name | Institution |
|---|---|---|
| Carmen | Ayuso | CIBERER |
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| Ana | Becerro de Bengoa | AEMPS |
| Fernando | Cabañas Gonzalez. | Hospital Universitario la Paz |
| Joaquin | Casariego | CAIBER |
| Claudia | Cases Langhoff | CAIBER (Hospital Universitario Valle De Hebrón) |
| Mar | Castelló | MSD |
| Jesús | Cebrecos Pérez | Esteve |
| Ramón | Colomer | Instituto Catalán de Oncología |
| Hernán | Cortés-Funes | Hospital 12 de Octubre |
| Natividad | Cuende Melero | Iniciativa Andaluza De Terapias Avanzadas |
| Lourdes | Cuervo Ariosa | Marsh S.A. |

| | | |
|---|---|---|
| María | De la Cruz Arguedas | UCICEC Hospital Gregorio Marañón |
| Exuperio | Díez Tejedor | Hospital Universitario La Paz |
| Emili | Esteve | FARMAINDUSTRIA |
| Carmen | Esteve Taboada | Instituto de Investigación Sanitaria La Fe |
| Emma | Fernández de Uzquiano | Hospital Universitario La Paz |
| José Antonio | Fernández Formoso | CIBEROBN |
| Isabel | Fernández García | No Aplicable |
| Carmen | Fernández Sánchez | No Aplicable |
| Mercedes | Francés Foz | Farmaindustria |
| Inma | Fuentes Camps | CAIBER (Hospital Universitario Valle De Hebrón) |
| Mª Ángeles | Gálvez | CAIBER Hospital Universitario Ramón y Cajal |
| Victoria | González Fernández | HDI Seguros |
| María José | González Suso | ISCIII. Unidad de Calidad |
| Carlos | Hernández Fernández | Hospital Universitario Gregorio Marañón. Asociación Española de Urología |
| Manuel | Hidalgo | CNIO. CIOCC - Hospital de Madrid |
| Paz | Iglesias Casarrubios | Hospital Universitario de Fuenlabrada |
| María del Carmen | Lage Varela | CIBEROBN |
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| Francisco Javier | López Román | FFIS Murcia |
| Gloria | Luque Fernández | CAIBER Hospital Carlos Haya |
| Javier | Malpesa | No Aplicable |
| María Jesús | Mamblona | PPD |
| Alicia | Mari | PPD |
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| | | |
|---|---|---|
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| Esther | Martin-Blas Garrido | Sociedad Española Reumatología |
| Rosario | Mata | No Aplicable |
| Raúl | Montalbán | Dynamic Solutions |
| Jaume | Mora | Hospital San Joan de Deu |
| Irene | Morales | No Aplicable |
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