

21 March 2019  
EMA/144064/2019

## European Medicines Agency policy on publication of clinical data for medicinal products for human use

POLICY/0070

Status: Adopted

Effective date: 21 March 2019

Review date: No later than March 2021

Supersedes: Policy/0070, dated 2 October 2014 (EMA/240810/2013)

### 1. Introduction and purpose

The aim of the European Medicines Agency ('the Agency') is to protect and foster public health. Transparency is a key consideration for the Agency in delivering its service to patients and society.

Although the Agency since its creation has launched several initiatives to increase transparency of information on medicinal products, there is growing demand from stakeholders for additional transparency, not only about the Agency's deliberations and actions, but also about the clinical data on which regulatory decisions are based. The Agency is committed to continuously extend its approach to transparency and has, therefore, taken the initiative to develop a policy on publication of clinical data, in accordance with article 80 of Regulation (EC) No 726/2004<sup>1</sup>. Consultations with a broad range of stakeholders and European Union (EU) bodies have taken place in drafting this policy. It should be noted that this policy is without prejudice to Regulation (EC) No 1049/2001<sup>2</sup>, and, therefore, it does not replace the existing 'Policy on access to documents (related to medicinal products for human and veterinary use)' (POLICY/0043) ([EMA/110196/2006](http://www.ema.europa.eu/ema/ViewDocument.aspx?docid=2006)), which came into effect in December 2010. Moreover, the provisions of this policy are not intended in any manner to limit the application or the rights given by Regulation (EC) No. 1049/2001. Any natural or legal person may continue to submit a request for access to documents to the Agency independently of the proactive publication mechanisms established by this policy.

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<sup>1</sup> Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency.

<sup>2</sup> Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents.

This policy is also without prejudice to Regulation (EU) No 536/2014<sup>3</sup>.

## 2. Scope

The scope of the policy relates to clinical data, composed of clinical reports and individual patient data (IPD), submitted under the centralised marketing authorisation procedure after the effective date (see chapter 4.3. for further information), either using the common technical document (CTD) format or another format:

- as part of a marketing authorisation application (MAA);
- or as part of a post-authorisation procedure for an existing centrally authorised medicinal product;
- or as part of a procedure under Article 58 of Regulation (EC) No 726/2004;
- or submitted by a third party in the context of a MAA or a post-authorisation procedure for an existing centrally authorised medicinal product;
- or requested by the Agency/ submitted by the applicant/marketing authorisation holder (MAH) as additional clinical data in the context of the scientific assessment process for the aforementioned situations.

The following clinical data are not covered by the scope of the policy:

- Clinical data held by the Agency for applications submitted under the centralised procedure before 1 January 2015, and for extension of indication applications and line extension applications submitted before 1 July 2015.
- Clinical data (either data provided to the Agency before 1 January 2015 or data not yet held by the Agency) submitted to the Agency for non-centrally authorised products.

These clinical data continue to be made available to external requesters on a reactive basis in accordance with the aforementioned Agency's policy on access to documents.

In addition, the following clinical data are not covered by the scope of the policy:

- Clinical data that are not held by the Agency, even if they concern a medicinal product that has been authorised by the Agency (e.g. clinical trials on an authorised product conducted by independent investigators and not submitted to the Agency).
- Pharmacovigilance data based on individual case safety reports (ICSRs). Access by third parties to ICSR data is addressed in the Agency's 'EudraVigilance access policy for medicines for human use' ([EMA/759287/2009 corr.](#)).

## 3. Definitions

For the purpose of this policy the following definitions apply:

- **Applicant/MAH:**

Applicant/MAH shall mean the natural or legal person(s) or organisation(s) that submitted the clinical reports to the Agency in the context of applications in support of centralised marketing authorisations (MAs)/post-authorisation submissions for existing centrally authorised medicinal products, as well as

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<sup>3</sup> Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC.

any person(s) or organisation(s) who own(s) copyright or other intellectual property rights in the clinical reports.

- **Clinical data:**

Clinical data shall mean the clinical reports and IPD.

- **Clinical reports:**

Clinical reports shall mean the clinical overviews (generally submitted in module 2.5) and clinical summaries (generally submitted in module 2.7) and the clinical study reports (generally submitted in module 5, "CSR"), together with appendices to the CSRs no. 16.1.1 (protocol and protocol amendments), 16.1.2 (sample case report form) and 16.1.9 (documentation of statistical methods).

- **Clinical study:**

Clinical study shall mean any investigation in relation to humans intended to:

- discover or verify the clinical, pharmacological or other pharmacodynamic effects of one or more medicinal products;
- identify any adverse reactions to one or more medicinal products; or
- study the absorption, distribution, metabolism and excretion of one or more medicinal products;

with the objective of ascertaining the safety or efficacy of those medicinal products.

- **Commercially confidential information (CCI):**

CCI shall mean any information contained in the clinical reports submitted to the Agency by the applicant/MAH that is not in the public domain or publicly available and where disclosure may undermine the legitimate economic interest of the applicant/MAH.

- **Individual patient data (IPD):**

IPD shall mean the individual data separately recorded for each participant in a clinical study.

- **Personal data:**

Personal data shall mean any information relating to an identified or identifiable natural person ('data subject'); an identifiable person is one who can be identified, directly or indirectly, in particular by reference to an identification number or to one or more factors specific to their physical, physiological, mental, economic, cultural or social identity (Article 2(a) of Regulation (EC) No 45/2001).

## 4. Policy statement

The following aspects are addressed in this policy:

- Objectives of the policy.
- Characteristics of the policy.
- Date of coming into effect of the policy.

### 4.1. Objectives of the policy

The main objectives of the policy by making clinical data available proactively, are to enable

- public scrutiny,

- and application of new knowledge in future research,

all this in the interest of public health.

A high degree of transparency will take regulatory decision-making one step closer to EU citizens, and promote better-informed use of medicines. In addition, the Agency takes the view that access to clinical data will benefit public health in future. The policy has the potential to make medicine development more efficient by establishing a level playing field that allows all medicine developers to learn from past successes and failures. Furthermore, it will enable the wider scientific community to make use of detailed clinical data to develop new knowledge in the interest of public health. Access to clinical data will allow third parties to verify the original analysis and conclusions, to conduct further analyses, and to examine the regulatory authority's positions and challenge them where appropriate.

The Agency also takes the view that transparency should be mutually respected. Those who perform secondary analysis of clinical data, published in accordance with this policy, must be held to the same standard of transparency as those who generate clinical data in the first place. Hence, all secondary analyses are expected to also be in the public domain and accessible for further scrutiny by the scientific community. In addition, those who perform secondary analysis of clinical data published in accordance with this policy, are encouraged to provide the Agency with a copy of any article resulting from such secondary analysis before publication, in particular in those circumstances where the secondary analysis might result in the need for regulatory action to protect public health. This is a critical consideration in view of the Agency's role and responsibilities for a timely review of all available information which might have an impact on the benefit/risk ratio of centrally authorised products.

The Agency cannot guarantee that all secondary data analyses that are enabled by the policy will be conducted and reported to the highest possible scientific standard; this is not possible with a truly open approach.

Allowing external parties access to clinical data held by the Agency will directly or indirectly affect different stakeholders' rights, interests and values. In developing this policy the Agency had to consider a number of competing principles which needed to be carefully balanced in order to best ensure the overarching, long-term goal of protecting and fostering public health. These principles, as well as the Agency's positions and views, are described below:

- **Protecting personal data:**

The protection of personal data is enshrined in EU legislation; it is a fundamental right of EU citizens. The policy has to ensure adequate personal data protection; it must be fully compliant with applicable regulations in the EU, in particular Regulation (EC) No 45/2001 and Directive 95/46/EC. There are ways and means to anonymise data and protect patients from retroactive identification. Yet, the Agency is primarily concerned that emerging technologies for data mining and database linkage will increase the potential for unlawful retroactive patient identification. The Agency, therefore, takes a guarded approach to the sharing of patient-level data, which is done to enable legitimate learning from sharing patient-level data while preventing rare but potentially damaging instances of patient identification. Furthermore, patients' informed consent should be respected. The secondary analysis of personal data will have to be fully compatible with the individual privacy of clinical trial participants and data protection.

- **Protecting commercially confidential information (CCI):**

The Agency respects and will not divulge CCI. In general, however, clinical data cannot be considered CCI. The Agency acknowledges that there are limited circumstances where information could constitute CCI.

- **Protecting the Agency's and the European Commission's deliberations and decision-making process:**

Regulators have a legal mandate to evaluate medicines. In doing so, they should only focus on the science and the best interests of patients. The decision-making process should be protected against external pressures from whatever direction. Once a decision has been reached, this consideration no longer applies.

- **Ensuring future investment in pharmaceutical research and development (R&D):**

Sustained and extensive pharmaceutical research activity is a precondition for future improvements in public health. The policy has no intention to negatively impact on the incentives to invest in future pharmaceutical R&D. It is designed to guard against unintended consequences, e.g. breaches of intellectual property rights that might disincentivise future investment in R&D.

## **4.2. Characteristics of the policy**

The main characteristics of the policy are:

- Introduction of a publication process for clinical reports.
- Management of CCI in clinical reports.
- Methods for balancing the protection of patients' privacy whilst retaining scientific value of the data.
- Stepwise implementation of the policy.

### **4.2.1. Introduction of a publication process for clinical reports**

The introduction of a publication process for clinical reports is based on 2 pillars:

- Terms of use (ToU) which govern the access to and use of clinical reports.
- A user-friendly technical tool allowing access to such clinical reports.

The ToU provide more information in relation to the access to the information contained in the clinical reports and the intended use of such information. Two sets of ToU are available, depending on the intended use of the information contained in the clinical reports, as described below:

- **Clinical reports available on-screen for any user, with a simple and limited registration process:**

The main characteristics are:

*Registration process:*

- Obtaining a user ID/password.
- Accepting the ToU.

*ToU for general information purposes (see annex 1):*

- Intended use is for general information and non-commercial purposes, including non-commercial research purposes.
- Clinical reports are made available in a "view-on-screen-only" mode.
- Clinical reports will be made available in a searchable format and will be permanently available.

- **Downloadable clinical reports available to identified users:**

The main characteristics are:

*Registration process:*

- Obtaining a user ID/password.
- Accepting the ToU.
- Providing the Agency with elements concerning the identity of the user (i.e. name, date of birth, passport or ID card number, expiry date of the document; for juridical persons, the affiliation and position within the organisation of the user should also be provided).

*ToU for academic and other non-commercial research purposes (see annex 2):*

- Intended use is for academic and non-commercial research purposes.
- Clinical reports can be downloaded, saved and printed.
- Clinical reports will be made available in a searchable format and will be permanently available.

Common to the two sets of ToU are the following elements:

- No attempt shall be made to re-identify the trial subjects or other individuals from the information.
- The clinical reports may not be used to support a MAA/ extensions or variations to a MA nor to make any unfair commercial use of the clinical reports.
- A watermark is applied to the published information to emphasise the prohibition of its use for commercial purposes.
- The Agency accepts no responsibility for the user's compliance with the ToU.

#### **4.2.2. Management of CCI in clinical reports**

Although generally the information contained in clinical reports should not be considered CCI, the Agency acknowledges that in limited circumstances the clinical reports could contain CCI, and could, therefore, be subject to redaction prior to publication. Where redaction of CCI is proposed by the applicant/MAH, a consultation with the applicant/MAH will be undertaken, following scrutiny by the Agency of the proposed redaction, including the justification provided by the applicant/MAH, as to whether the definition of CCI applies (see annexes 3 and 4).

##### **4.2.2.1. Redaction principles**

The clinical reports that will be published in accordance with this policy shall only be subject to redactions when needed to protect those specific elements which qualify as CCI that should not be released. This complements the aforementioned use controls that will need to be accepted by recipients of the documents in order to protect the originator against misuse of the data as a whole. This covers information that is not in the public domain or publicly available and where disclosure may undermine the economic or competitive position of the applicant/MAH. In this regard, the assessment of this information will take into account the justification provided by the applicant/MAH with regard to various factors, including the nature of the product concerned, the competitive situation of the

therapeutic market in question, the approval status in other jurisdictions, the novelty of the clinical development, and new developments by the same company.

In general, as already mentioned, most of the information in clinical reports would not be considered CCI. There are, however, limited circumstances where the clinical reports could contain CCI.

The information referred to in annex 3, which is contained in the sections of the clinical reports, may be considered CCI and, therefore, may have to be redacted as per the aforementioned redaction principles, after assessment by the Agency of the justification provided by the applicant/MAH. The same rules regarding CCI and the redaction principles will apply to the same information presented in other formats or other sections in the documents submitted by the applicant/MAH to the Agency.

If justification for additional redaction going beyond the list in annex 3 has been provided by the applicant/MAH, and agreed upon by the Agency, the Agency will then proceed with the publication of the so redacted clinical reports. The Agency will, once further experience with the implementation of the policy has been obtained, undertake first a consultation with all relevant stakeholders in order to explore if the outcome of the individual case(s) should exceptionally lead to a revision of the redaction principles.

#### **4.2.2.2. Process for publication of clinical reports**

The process for publication of clinical reports is described in annex 4. This process foresees in consultation with the applicant/MAH in case the Agency disagrees with the redaction proposed by the applicant/MAH.

#### **4.2.3. Methods for balancing the protection of patient's privacy whilst retaining scientific value of the data**

Protection of patients' identity is of crucial importance. In order to achieve this objective both identification and re-identification of patients need to be avoided. Particular challenges in this respect are continuous developments in the field of technologies relating to data mining and database linkage, as well as specific scenarios to be considered in the area of medicine regulation, for instance the situation of rare diseases. In deciding on the most optimal approach (anonymisation versus pseudonymisation) the Agency will take due account of recent developments, e.g. the work undertaken by the network of EU Data Protection Authorities on anonymisation techniques<sup>4</sup>, and subsequently discuss with stakeholders (e.g. patients' organisations, academia, pharmaceutical industry) to agree on the best way forward.

#### **4.2.4. Stepwise implementation of the policy**

The implementation of the policy will be undertaken in a stepwise manner:

- In a first phase, the publication of clinical data will relate to clinical reports only.
- In a second phase, the Agency will review various aspects in relation to IPD, including finding the most appropriate way to make IPD available, the latter in compliance with privacy and data protection laws<sup>5</sup>.

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<sup>4</sup> Opinion 05/2014 on anonymisation techniques, adopted on 10 April 2014 by the Article 29 Data Protection Working Party.

<sup>5</sup> The Agency will notify the European Data Protection Supervisor (EDPS) accordingly.

#### **4.2.4.1. First phase: publication of clinical reports**

The publication of clinical reports will be in accordance with the arrangements described in chapters 4.2.1., 4.2.2. and 4.2.3. of the policy.

In addition, the following principles will apply as regards the timing of publication:

The timing of publication takes into account the need to protect the Agency's and the European Commission's deliberations and decision-making process. In order not to undermine such decision-making process the Agency will only publish clinical data once the concerned procedure has been finalised. In practical terms this means:

- following the European Commission Decision granting or refusing the MA/post-authorisation submission outcome; or
- following the scientific committee Opinion if there is no subsequent European Commission Decision; or
- following the scientific committee conclusion if there is no Opinion; or
- following receipt of the applicant's/MAH's letter notifying the withdrawal of the MAA/post-authorisation submission.

The process described in chapter 4.2.2.2. for publication of clinical reports, including where necessary interaction with the applicant/MAH, will start following the adoption of the scientific committee Opinion/conclusion or the receipt of the withdrawal letter, as referred to above.

#### **4.2.4.2. Second phase: reviewing various aspects in relation to IPD**

Before IPD can be made available, there is a need to first clarify:

- the submission of IPD for subsequent scientific review by the Agency, and
- how to best provide access to such IPD, including the conditions to be fulfilled.

It is important to emphasise in this regard that the Agency will not request applicants/MAHs to submit IPD for the sole purpose of publication of IPD.

The Agency will first undertake a targeted public consultation with all concerned stakeholders on the various aspects in relation to IPD to provide clarification. Subsequently, in consultation with the Agency's Management Board, the policy will be amended to reflect the outcome of this targeted public consultation.

### **4.3. Date of coming into effect of the policy**

For the coming into effect of the policy a stepwise approach will be applied.

The effective date will be 1 January 2015 for any new MAAs, and Article 58 applications submitted as from the effective date onwards.

The effective date will be 1 July 2015 for extension of indication applications and line extension applications relating to existing centrally authorised medicinal products submitted as from the effective date onwards. For all other post-authorisation procedures relating to existing centrally authorised medicinal products where supporting clinical reports have been submitted, the effective date will be determined in 2015.



## 5. Related documents

Further information on the development and implementation of the policy is provided in a Q&A document<sup>6</sup>.

## 6. Changes since last revision

The following changes have been made:

Further to the decision by the United Kingdom to leave the European Union in accordance with the provisions of Article 50 TEU, the governing law of the Terms of Use is changed from England and Wales' to the Netherlands' and the Amsterdam District Court replaces London as a non-exclusive jurisdictional venue. Annex I and Annex II hereto have been updated accordingly.

London, 21 March 2019

*Signature on file*

Guido Rasi  
Executive Director

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<sup>6</sup> Q&A on the European Medicines Agency policy on publication of clinical data for medicinal products for human use (EMA/357536/2014).

# Annex 1

## Terms of Use for general information purposes

These Terms of Use ("**Terms**") govern the access and use of clinical data, as defined in chapter 3. of the EMA policy on publication of clinical data, Policy 0070 ("**Policy**"), that are made available to *Users* via such *Policy*. By accepting these *Terms* and upon being granted access to the *Clinical Reports*, you agree to be bound by these *Terms*. Please read them carefully.

### 1. Definitions

In these *Terms* the terms below have the following meaning:

"**EMA**" means the European Medicines Agency.

"**Clinical Reports**" means the clinical overviews (module 2.5), the clinical summaries (module 2.7) and the clinical study reports (module 5, "CSR"), together with appendixes to the CSRs no. 16.1.1, 16.1.2 and 16.1.9 which are accessible via the *EMA* website as a result of the implementation of the *Policy*.

"**Applicant/MAH**" means the natural or legal person(s) or organisation(s) that submitted the *Clinical Reports* to the *EMA* in the context of applications in support of centralised marketing authorisations/post-authorisation submissions under Regulation (EC) No 726/2004, as well as any person(s) or organisation(s) who own(s) copyright or other intellectual property rights in the *Clinical Reports*.

"**User**" means the natural or legal person or organisation who, having registered with the *EMA* website in connection with the implementation of the *Policy*, receives access to the *Clinical Reports*.

### 2. Access to the *Clinical Reports* under the *Policy*

The *User* acknowledges that the *Clinical Reports* are protected by copyright or other intellectual property rights of the *Applicant/MAH* and can be considered commercially valuable when used for commercial and regulatory purposes.

The *User* acknowledges that the *Clinical Reports* will be made available to the *User* on the *EMA* website in a "view-on-screen-only" mode, after completing the registration process. The *User* agrees that the *User* is not permitted to download, save, edit, photograph, print, distribute or transfer the *Clinical Reports*. The *User* agrees not to access the *Clinical Reports* using a method other than the interface provided by the *EMA*, or remove, bypass, circumvent, neutralise or modify any technological protection measures which apply to the *Clinical Reports*.

### 3. Use of the *Clinical Reports*

The *User* agrees to use the *Clinical Reports* according to these *Terms* and, in particular, that:

- a) The *User* may use the *Clinical Reports* for general information and non-commercial purposes, including non-commercial research purposes, subject to these *Terms*.

- b) The *User* is not granted any intellectual property or other commercial rights in relation to the *Clinical Reports* other than as expressly set out in these *Terms*.

When using the *Clinical Reports*, the *User* shall:

- a) acknowledge that its source is the *Applicant/MAH*;
- b) not use it in a way that suggests that the *Applicant/MAH* endorses the *User's* use of the *Clinical Reports* for any other purpose than general information and non-commercial purposes, including non-commercial research purposes;
- c) ensure that the use of the *Clinical Reports* comply at all times with applicable law;
- d) not misrepresent the source of the *Clinical Reports*;
- e) not seek to re-identify the trial subjects or other individuals from the *Clinical Reports* in breach of applicable privacy laws.

The *User* may not:

- use the *Clinical Reports* to support an application to obtain a marketing authorisation and any extensions or variations thereof for a product anywhere in the world;
- share the *User's* username, password or other account details with a third party or otherwise provide a third party with access to the *User's* account;
- make any unfair commercial use of the *Clinical Reports*.

If the *User* fails to accurately complete the registration process, comply with these conditions, or uses the *Clinical Reports* in breach of these *Terms*, the rights to access and use the *Clinical Reports* will be revoked.

## 4. Warranties and liability

Without prejudice to any obligation of the *Applicants/MAHs* in accordance with the Union legislation:

- The *EMA* and the *Applicant/MAH* exclude all representations, warranties, obligations and liabilities in relation to the *Clinical Reports* as accessible via the *EMA* website to the maximum extent permitted by law;
- Neither the *EMA* nor the *Applicant/MAH* are liable for any errors or omissions in the *Clinical Reports* as provided via the *EMA* website and shall not be liable for any loss, injury or damage of any kind caused by its use.
- The Agency accepts no responsibility for the *User's* compliance with the *Terms*.

## 5. Third party rights

The restrictions and conditions and the warranty and liability provisions of these *Terms* are also made for the benefit of any and all *Applicants/MAHs* and, accordingly, each such *Applicant/MAH* may in its own right enforce these *Terms* in accordance with the provisions of the Dutch Civil Code ("Burgerlijk Wetboek").

## **6. Governing law**

These *Terms* and any dispute or claim arising out of or in connection with them or their subject matter or formation (including non-contractual disputes or claims) shall be governed by and construed in accordance with the law of the Netherlands.

## **7. Jurisdiction**

The Amsterdam District Court shall have non-exclusive jurisdiction to settle any dispute or claim arising out of or in connection with these *Terms* or their subject matter or formation (including non-contractual disputes or claims).

## Annex 2

### Terms of Use for academic and other non-commercial research purposes

These Terms of Use ("**Terms**") govern the access and use for academic and non-commercial research purposes of clinical data, as defined in chapter 3. of the EMA policy on publication of clinical data, Policy 0070 ("**Policy**"), that are made available to *Users* via such *Policy*. By accepting these *Terms* and upon being granted access to the *Clinical Reports*, you agree to be bound by these *Terms*. Please read them carefully.

#### 1. Definitions

In these *Terms* the terms below have the following meaning:

**"EMA"** means the European Medicines Agency.

**"Clinical Reports"** means the clinical overviews (module 2.5), the clinical summaries (module 2.7) and the clinical study reports (module 5, "CSR"), together with appendixes to the CSRs no. 16.1.1, 16.1.2 and 16.1.9 which are accessible via the *EMA* website as a result of the implementation of the *Policy*.

**"Applicant/MAH"** means the natural or legal person(s) or organisation(s) that submitted the *Clinical Reports* to the *EMA* in the context of applications in support of centralised marketing authorisations/post-authorisation submissions under Regulation (EC) No 726/2004, as well as any person(s) or organisation(s) who own(s) copyright or other intellectual property rights in the *Clinical Reports*.

**"User"** means the natural or legal person or organisation who, having registered with the *EMA's* website in connection with the implementation of the *Policy*, receives in electronic format a copy of the *Clinical Reports*.

#### 2. Access to the *Clinical Reports* under the *Policy*

The *User* acknowledges that the *Clinical Reports* are protected by copyright or other intellectual property rights of the *Applicant/MAH* and can be considered commercially valuable when used for commercial and regulatory purposes.

The *User* acknowledges that the *Clinical Reports* will be made available to the *User* in electronic format for academic and non-commercial research purposes. Before being granted access to the *Clinical Reports* in electronic format, the *User* shall provide the *EMA* with:

- An e-mail address,
- A place of address in the European Union; in the event that the *User* does not have a place of address in the European Union and wishes to avail itself of the services of a third party resident or domiciled in the European Union, such third party shall be considered *User* for the purposes of these *Terms* and shall comply with all the terms hereof,

- Elements concerning the identity of the user (i.e. name, date of birth, passport or ID card number, expiry date of the document; for juridical persons, the affiliation and position within the organisation of the user should also be provided).

### 3. Use of the *Clinical Reports*

The *User* agrees to use the *Clinical Reports* according to these *Terms* and, in particular, that:

- a) The *User* may use the *Clinical Reports* solely for academic and non-commercial research purposes, subject to these *Terms*.
- b) The *User* is not granted any intellectual property or other commercial rights in relation to the *Clinical Reports* other than as expressly set out in these *Terms*.

The *User* may not:

- use the *Clinical Reports* to support an application to obtain a marketing authorisation and any extensions or variations thereof for a product anywhere in the world;
- share the *User's* username, password or other account details with a third party or otherwise provide a third party with access to the *User's* account;
- make any unfair commercial use of the *Clinical Reports*;
- seek to re-identify the trial subjects or other individuals from the *Clinical Reports* in breach of applicable privacy laws.

For the avoidance of doubt, the *User* is permitted to download, save and print the *Clinical Reports*, subject to these *Terms*.

If the *User* fails to accurately complete the registration process, comply with these conditions, or uses the *Clinical Reports* in breach of these *Terms*, the rights to access and use the *Clinical Reports* will be revoked.

### 4. Warranties and liability

Without prejudice to any obligation of the *Applicants/MAHs* in accordance with the Union legislation:

- The *EMA* and the *Applicant/MAH* exclude all representations, warranties, obligations and liabilities in relation to the *Clinical Reports* as made accessible to the *Users* to the maximum extent permitted by law;
- Neither the *EMA* nor the *Applicant/MAH* are liable for any errors or omissions in the *Clinical Reports* as made accessible to the *Users* and shall not be liable for any loss, injury or damage of any kind caused by its use.
- The Agency accepts no responsibility for the *User's* compliance with the *Terms*.

### 5. Third party rights

The restrictions and conditions and the warranty and liability provisions of these *Terms* are also made for the benefit of any and all *Applicants/MAHs* and, accordingly, each such *Applicant/MAH* may in its own right enforce these *Terms* in accordance with the provisions of the Dutch Civil Code ("Burgerlijk Wetboek").

## **6. Governing law**

These *Terms* and any dispute or claim arising out of or in connection with them or their subject matter or formation (including non-contractual disputes or claims) shall be governed by and construed in accordance with the law of the Netherlands.

## **7. Jurisdiction**

The Amsterdam District Court shall have non-exclusive jurisdiction to settle any dispute or claim arising out of or in connection with these *Terms* or their subject matter or formation (including non-contractual disputes or claims).

## **Annex 3**

### **Information contained in the sections of the clinical reports that may be considered CCI**

The information contained in the clinical reports that may be considered CCI and the reference to the relevant sections is provided in the table below. Guidance described in column 2 advises what should be discussed in case of information that may be considered CCI.



Title	Information that may be considered CCI	Justification for redaction
<b>Elements relating to clinical trials and contained in “The common technical document for the registration of pharmaceuticals for human use” (from ICH harmonised tripartite guideline, Module 2 and 5)</b>		
<p>Product Development Rationale</p> <p><i>Information expected to be found in section 2.5.1 of the clinical overview as per ICH M4(R3) guideline</i></p>	<ul style="list-style-type: none"> <li>• “Describe the clinical development programme of the medicinal product, including ongoing and planned clinical studies and the basis for the decision to submit the application at this point in the programme....”</li> <li>• “Regulatory guidance and advice from outside the EU should be identified, with discussion of how that advice was implemented.”</li> <li>• “Formal advice documents (e.g., official meeting minutes, official guidance, letters from non EU regulatory authorities) should be referenced....”</li> </ul>	<ul style="list-style-type: none"> <li>• Information for planned clinical studies may include “exploratory endpoints” that are not intended to yield data in support of the then-current approval of a use or indication, but could provide clues to potential uses and indications for competitors.</li> <li>• Regulatory advice from outside the EU is typically non-public and includes agreements with regulators on study design, strategies for organisation and presentation of findings, and other aspects of the regulatory process that competitors could copy.</li> <li>• Same justification as above.</li> </ul>
<p>Overview of Biopharmaceutics</p> <p><i>Information expected to be found in section 2.5.2 of the clinical overview as per ICH M4(R3) guideline</i></p>	<ul style="list-style-type: none"> <li>• Detailed assay information/quantitative composition/lot numbers</li> </ul>	<ul style="list-style-type: none"> <li>• As the Biopharmaceutical Summary Documents (2.7.1) are considered CCI, this section may contain some overlapping information.</li> </ul>
<p>Overview of Clinical Pharmacology</p> <p><i>Information expected to be found in section 2.5.3 of the clinical overview as per ICH</i></p>	<ul style="list-style-type: none"> <li>• Stereochemistry issues.</li> </ul>	<ul style="list-style-type: none"> <li>• Competitors could gain a detailed understanding of the stereoisomers and three-dimensionality of the molecule.</li> </ul>

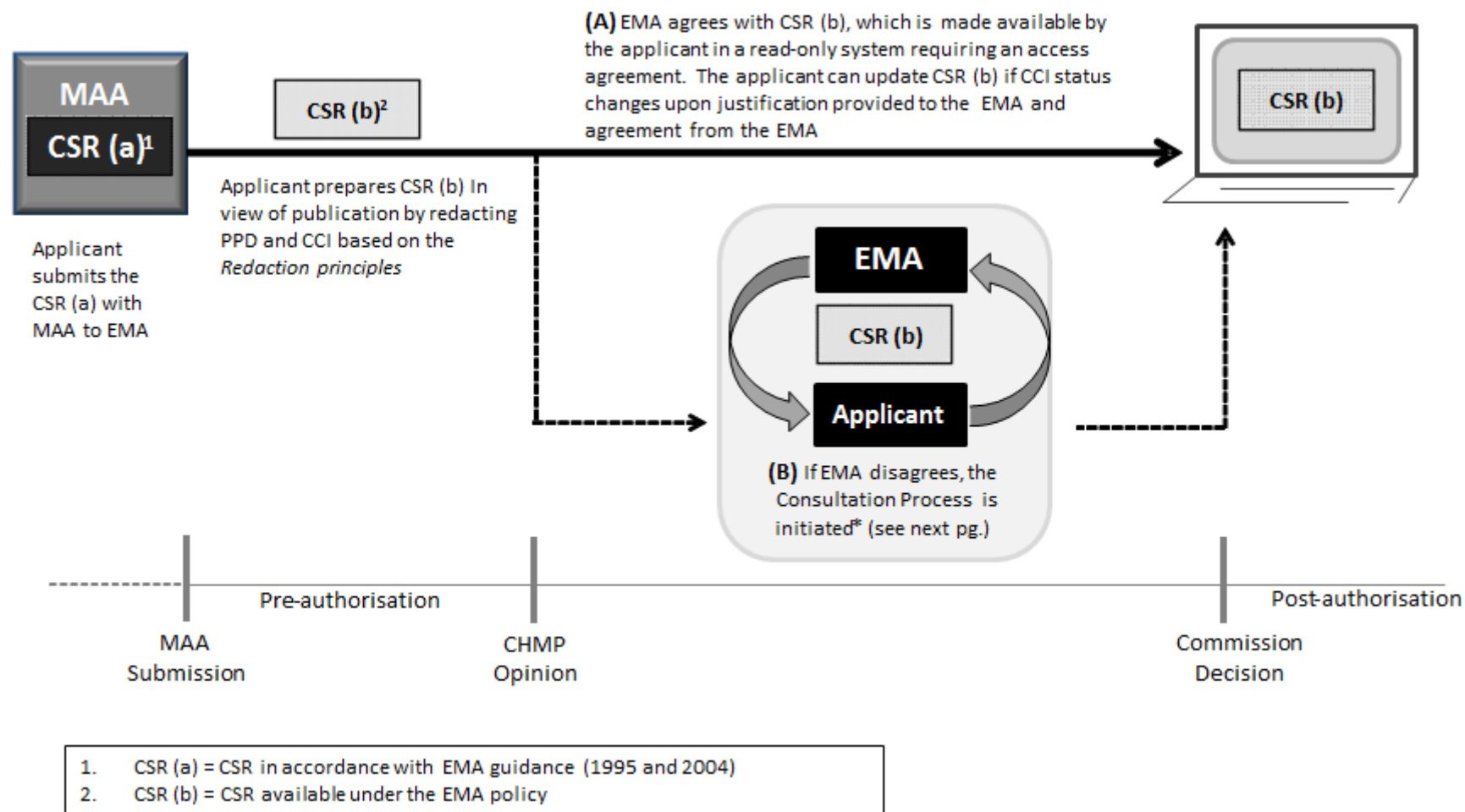
Title	Information that may be considered CCI	Justification for redaction
<i>M4(R3) guideline</i>		
<p>Benefits and Risks Conclusions</p> <p><i>Information expected to be found in section 2.5.6 of the clinical overview as per ICH M4(R3) guideline</i></p>	<ul style="list-style-type: none"> <li>• Implications of any deviations from non EU regulatory advice or guidelines.</li> </ul>	<ul style="list-style-type: none"> <li>• The company may include justifications for any deviation from regulatory advice or guidance outside of the EU jurisdiction, a competitor may have an unwarranted new perception of the regulatory risk associated with a certain regulatory strategy.</li> </ul>
<p>Summary of Biopharmaceutic Studies and Associated Analytical Methods</p> <p><i>Information expected to be found in section 2.7.1 of the clinical summary as per ICH M4(R3) guideline</i></p>	<ul style="list-style-type: none"> <li>• Information about specifications on company assays.</li> </ul>	<ul style="list-style-type: none"> <li>• This section may contain CCI in the form of details and specifications on assays developed by the company. The information may bring significant advantages to competitors if published.</li> </ul>
<p>Summary of Clinical Pharmacology Studies</p> <p><i>Information expected to be found in section 2.7.2 of the clinical summary as per ICH M4(R3) guideline</i></p>	<ul style="list-style-type: none"> <li>• Information about specifications on company assays and immunogenicity assays.</li> </ul>	<ul style="list-style-type: none"> <li>• This section may contain CCI in the form of details and specifications on assays developed by the company. The information may bring significant advantages to competitors if published.</li> </ul>
<p>Reports of Biopharmaceutic Studies</p> <p><i>Information expected to be found in section 5.3 of module 5 "Clinical study reports" as per ICH M4(R3) guideline</i></p>	<ul style="list-style-type: none"> <li>• Information about specifications on company assays by which the results of the studies (e.g. Bioavailability, In Vitro – In Vivo Correlation) are obtained.</li> <li>• Information about company innovative bioassays/analytical methods.</li> </ul>	<ul style="list-style-type: none"> <li>• This section may contain CCI in the form of details and specifications on assays developed by the company. The information may bring significant advantages to competitors if published.</li> </ul>

Title	Information that may be considered CCI	Justification for redaction
<b>Structure and content of clinical study reports (CSRs) (from ICH harmonised tripartite guideline, E3)</b>		
<p>Introduction</p> <p><i>Information expected to be found in section 7 of the clinical study reports as per ICH E3 guideline</i></p>	<ul style="list-style-type: none"> <li>Development of the protocol or any other agreements/meetings between the sponsor/company and non EU regulatory authorities that are relevant to the particular study, should be identified or described.</li> </ul>	<ul style="list-style-type: none"> <li>May contain non-public information that the sponsor agreed in another jurisdiction outside of the EU.</li> </ul>
<p>Study Objectives (including Exploratory Endpoints and Efficacy and Safety Variables)</p> <p><i>Information expected to be found in sections 8 and 9.5 of the clinical study reports as per ICH E3 guideline</i></p>	<ul style="list-style-type: none"> <li>Statements/descriptions relating to objectives that are not supportive of a label claim and they were not taken into consideration in the overall benefit/risk evaluation. This includes the definition of efficacy and safety variables collected and analysed in support of exploratory objectives.</li> </ul>	<ul style="list-style-type: none"> <li>The exploratory study objectives could be used by a competitor to gain insights into additional future study plans and/or indications for the product. For example, in some trials for a new anti-inflammatory medicinal product, an exploratory lipid profile was included, investigating the lipid metabolism in patients treated with the product, to inform future studies rather than to support the MAA. The results of these analyses were included in the CSRs submitted to the EMA in the course of the MAA procedure.</li> <li>Alternatively the exploratory objectives may include biomarkers that could be used as 'hypothesis generating' for future studies. At that stage there would not be enough information to file patent applications on these objectives until some data are available from clinical and non-clinical studies. Disclosing these exploratory objectives may preclude obtaining patents that would cover biomarkers/diagnostics themselves, as well as method of use patents directed to</li> </ul>

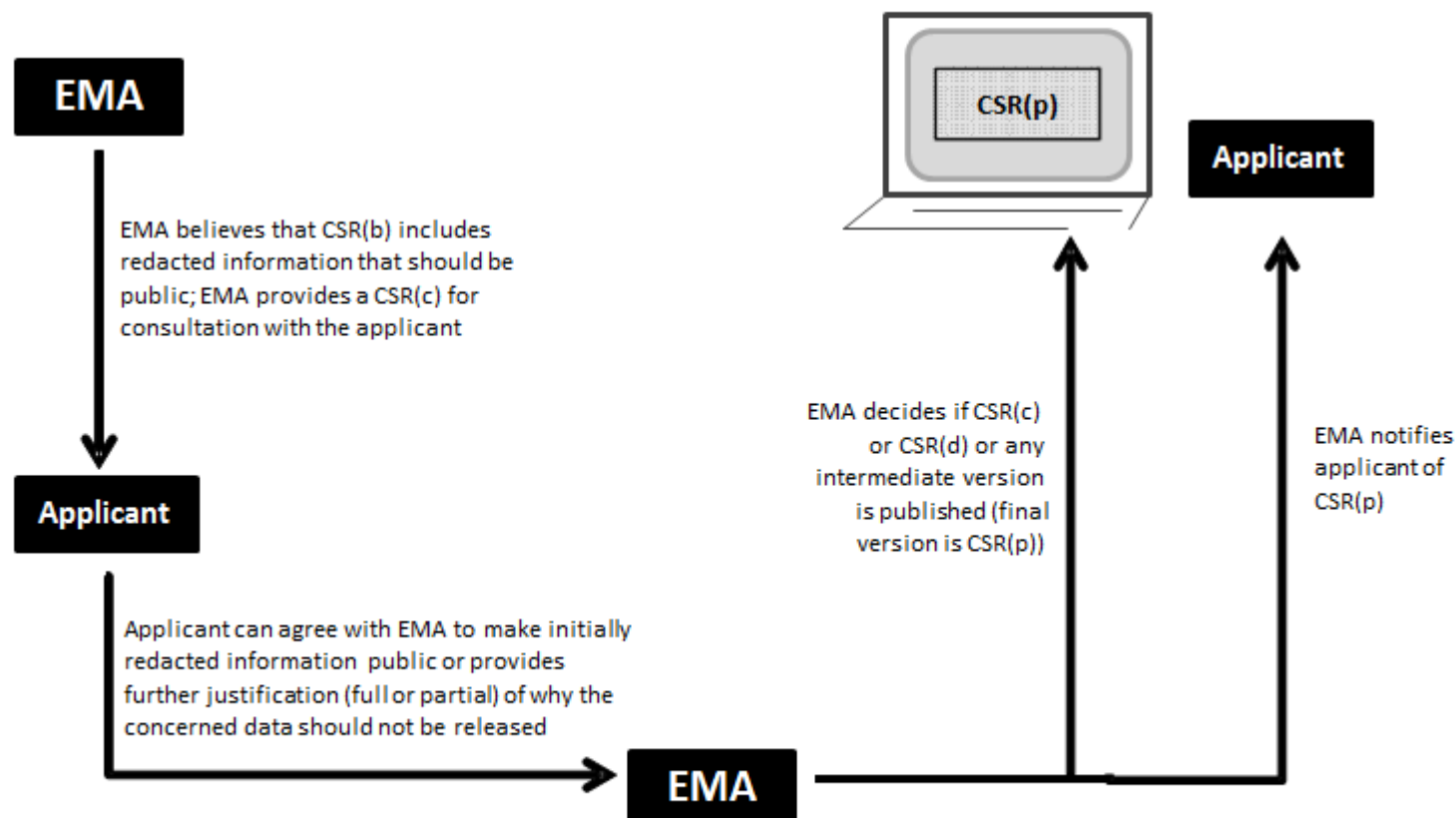
Title	Information that may be considered CCI	Justification for redaction
		patient subpopulations.
<p>Determination of Sample Size</p> <p><i>Information expected to be found in section 9.7.2 of the clinical study reports and appendix 16.1.9 as per ICH E3 guideline</i></p>	<ul style="list-style-type: none"> <li>Analysis of the information that drives the sample size calculation (e.g. estimates of endpoint variability, measurement precision, screening and retention rates).</li> </ul>	<ul style="list-style-type: none"> <li>The sample size per se is not considered CCI. However there may be occasions when the intellectual consideration that goes into the analysis of the information that drives the sample size calculation (e.g. estimates of endpoint variability, measurement precision, screening and retention rates) is considered CCI.</li> </ul>
<p>Method of PK/PD determination</p> <p><i>Information expected to be found in section 9.5.4 of the clinical study reports as per ICH E3 guideline</i></p>	<ul style="list-style-type: none"> <li>CCI on analytical methods.</li> </ul>	<ul style="list-style-type: none"> <li>This section may have proprietary information on how analyses are performed.</li> </ul>

## Annex 4

### Process for publication of clinical reports (scenario: MAA)



## \* Consultation process



\* Consultation process to be concluded within Decision making process timelines – exact timing still to be determined.