

Article 53

Electronic system on clinical investigations

1. The Commission shall, in collaboration with the Member States, set up, and manage **and maintain** an electronic system:
 - ~~(aa) to create the single identification numbers for clinical investigations; referred to in Article 51(1) and to collate and process the following information:~~
 - ~~(a) the registration of clinical investigations in accordance with Article 51;~~
 - (ab) to be used as an entry point for the submission of all applications for clinical investigations referred to in Articles 51(2), 54,, 55 and 58 and for all other submission of data, or processing of data in this context;**
 - ~~(b) for the exchange of information relating to clinical investigations in accordance with this Regulation between the Member States and between them and the Commission in accordance with including those according to Article 51a and 56;~~
 - (ba) for information by the sponsor in accordance with Article 57;**
 - ~~(c) the information related to clinical investigations conducted in more than one Member State in case of a single application in accordance with Article 58;~~
 - ~~(d) for reporting reports on serious adverse events and device deficiencies and related updates referred to in Article 59(2) in case of a single application in accordance with Article 58.;~~
 - (e) for collecting the clinical investigation reports and the summaries thereof.**

2. When setting up the electronic system referred in paragraph 1, the Commission shall ensure that it is interoperable with the EU database for clinical trials on medicinal products for human use set up in accordance with Article [...] of Regulation (EU) No [536/2014] **as concerns combined clinical investigations of devices with a clinical trial under that regulation.** ~~With the exception of the information referred to in Article 52, the information collated and processed in the electronic system shall be accessible only to the Member States and to the Commission.~~

- 2a. Within one week of any change occurring in relation to the information referred to in paragraph 1 or in Article 51(2), the sponsor shall update the relevant data in the electronic system referred to in this Article. The Member State concerned shall be notified of the update and the changes to the documents shall be clearly identifiable.**
- 2b. The information referred to in paragraph 1 except the information referred to in point b, which shall only be accessible to the Member States and the Commission, shall be accessible to the public, unless, for all or parts of that information, confidentiality of the information is justified on any of the following grounds:**
- (a) protection of personal data in accordance with Regulation (EC) No 45/2001;**
 - (b) protection of commercially confidential information, especially in the investigators brochure, in particular through taking into account the status of the conformity assessment for the device, unless there is an overriding public interest in disclosure,**
 - (c) effective supervision of the conduct of the clinical investigation by the Member State(s) concerned;**
- 2ba. No personal data of subjects participating in clinical investigations shall be publicly available.**
- 2c. The user interface of the electronic system referred to in this Article shall be available in all official languages of the Union.**
- ~~3. The Commission shall be empowered to adopt delegated acts in accordance with Article 89 determining which other information regarding clinical investigations collated and processed in the electronic system shall be publicly accessible to allow interoperability with the EU database for clinical trials on medicinal products for human use set up by Regulation (EU) No [.../]. Article 52(3) and (4) shall apply.~~

Article 54

Clinical investigations with devices authorised to bear the CE marking

1. Where a clinical investigation is to be conducted to further assess a device which is authorised in accordance with Article 42 to bear the CE marking and within its intended purpose referred to in the relevant conformity assessment procedure, hereinafter referred to as ‘post-market clinical follow-up investigation’, the sponsor shall notify the Member States concerned at least 30 days prior to their commencement if the investigation would submit subjects to additionally invasive or burdensome procedures. ***The notification shall be made by means of the electronic system referred to in Article 53. It shall be accompanied by the documentation referred to in Chapter II of Annex XIV. Article 50 paragraph 5 points (b) to (h) and (m), Article 50(1) to (3), Article 52, Article 55, Article 56(1), Article 57(1), the first subparagraph of Article 57(2), Article 59(6) and the relevant provisions of Annex XIV shall apply.***
2. If the aim of the clinical investigation regarding a device which is authorised in accordance with Article 42 to bear the CE marking is to assess such device for a purpose other than that referred to in the information supplied by the manufacturer in accordance with Section 19 of Annex I and in the relevant conformity assessment procedure, Articles 50 to 60 shall apply.

Article 55

Substantial modifications to a clinical investigation

1. If the sponsor ~~introduces~~ ***intends to introduce*** modifications to a clinical investigation that are likely to have a substantial impact on the safety, ***health*** or rights of the subjects or on the robustness or reliability of the clinical data generated by the investigation, he shall notify ***by means of the electronic system referred to in Article 53*** the Member State(s) concerned of the reasons for and the content of those modifications. The notification shall be accompanied by an updated version of the relevant documentation referred to in Chapter II of Annex XIV, ***changes shall be clearly identifiable.***

2. The sponsor may implement the modifications referred to in paragraph 1 at the earliest 380 days after notification, unless the Member State concerned has notified the sponsor of its refusal based on *Article 51a paragraph 4* or considerations of public health, ~~patient subject and user safety or health~~, ~~or~~ of public policy, *or the ethics committee has issued a negative opinion which in accordance with the law of that Member State, is valid for that entire Member State.*
3. *The Member State(s) concerned may extend the period referred to in paragraph 2 by a further 7 days, for the purpose of consulting with experts.*

Article 56

Corrective measures to be taken by Member States and Information exchange between Member States

- 0a. *Where a Member State concerned has grounds for considering that the requirements set out in this Regulation are no longer met, it may at least take the following measures on its territory:*
 - (a) *withdraw or revoke the authorisation of a clinical investigation;*
 - (b) *suspend, temporary halt or terminate a clinical investigation;*
 - (c) *require the sponsor to modify any aspect of the clinical investigation.*
- 0b. *Before the Member State concerned takes any of the measures referred to in paragraph 0a it shall, except where immediate action is required, ask the sponsor and/or the investigator for their opinion. That opinion shall be delivered within seven days.*
1. Where a Member State *has taken a measure referred to in paragraph 0a* or has refused, ~~suspended or terminated a clinical investigation, or has called for a substantial modification or temporary halt of a clinical investigation,~~ or has been notified by the sponsor of the early termination of a clinical investigation on safety grounds, that Member State shall communicate ~~its~~ *this* decision and the grounds therefor to all Member States and the Commission by means of the electronic system referred to in Article 53.

2. Where application is withdrawn by the sponsor prior to a decision by a Member State, that ~~Member State shall inform~~ **information shall be available to** all the other Member States and the Commission of that fact, by means of the electronic system referred to in Article 53.

Article 57

Information by the sponsor in the event of temporary halt or termination of a clinical investigation

1. If the sponsor has temporarily halted a clinical investigation ~~on safety grounds~~ **or has terminated a clinical investigation early**, he shall inform the Member States concerned within 15 days, of the temporary halt **or early termination, providing a justification. In case the sponsor has temporary halted or early terminated the clinical investigation on safety grounds, he shall inform the Member states concerned thereof within 24 hours.**
2. The sponsor shall notify each Member State concerned of the end of a clinical investigation in relation to that Member State, ~~providing a justification in the event of early termination.~~ That notification shall be made within 15 days from the end of the clinical investigation in relation to that Member State.
 - 2a. If the investigation is conducted in more than one Member State the sponsor shall notify all Member States concerned of the overall end of the clinical investigation. That notification shall be made within 15 days from the overall end of the clinical investigation.
3. Within one year from the end of the clinical investigation **or within three months from the early termination**, the sponsor shall submit to the Member States concerned **through the electronic system referred to in Article 53** ~~a summary of the results of the clinical investigation in form of a clinical investigation report referred to in Section 2.7 of Chapter I of Annex XIV.~~ Where, ~~for scientific reasons,~~ it is not possible to submit the clinical investigation report within one year **after the completion of the investigation**, it shall be submitted as soon as it is available. In this case, the clinical investigation plan referred to in Section 3 of Chapter II of Annex XIV shall specify when the results of the clinical investigation are going to be submitted, together with an explanation.

4. *A summary of the clinical investigation report shall be provided by the sponsor at least the latest within 1 year following the provision of the clinical investigation report according to paragraph 3. The summary of the clinical investigation report shall be written in a way that is readily understood by the intended user of the device.*
5. *Submission of information and reports according to paragraphs 1 to 4 shall be accomplished through the electronic system referred to in Article 53. The reports according to paragraphs 3 and 4 shall become publicly accessible through the electronic system, at the latest when the device is CE-marked and before it is placed on the market.*

Article 58

Clinical investigations conducted in more than one Member State

1. By means of the electronic system referred to in Article 53, the sponsor of a clinical investigation to be conducted in more than one Member State may submit, for the purpose of Article 51, a single application that, upon receipt, is transmitted electronically to the Member States concerned, *who have voluntarily agreed to that procedure concerning that clinical investigation.*
2. In the single application, the sponsor shall propose one of the Member States concerned as coordinating Member State. ~~If that Member State does not wish to be the coordinating Member State, it~~ *Concerned Member States shall agree, within six days of submission of the single application, with another Member State concerned that the latter shall be agree on one of them taking the role of the coordinating Member State. If no other Member State accepts to be the* ~~If they do not agree on a~~ *coordinating Member State, the Member State one proposed by the sponsor shall be the coordinating Member State take that role. If another Member State than the one proposed by the sponsor becomes coordinating Member State, the* ~~The~~ *deadlines referred to in Article 51(2) shall start on the day following the notification of the coordinating Member State to the sponsor (notification date) acceptance.*

3. Under the direction of the coordinating Member State referred to in paragraph 2, the Member States concerned shall coordinate their assessment of the application, in particular of the documentation submitted in accordance with Chapter II of Annex XIV, except for Sections **1.13**, 3.1.3, 4.2, 4.3 and 4.4 thereof which shall be assessed separately by each Member State concerned.

The coordinating Member State shall:

- (a) within 6 days of receipt of the single application notify the sponsor ***that it is the coordinating Member State (notification date)***;
- (aa) within 10 days of the single application, notify the sponsor whether the clinical investigation falls within the scope of this Regulation and whether the application is complete, except for the documentation submitted in accordance with Sections 1.13, 3.1.3, 4.2, 4.3 and 4.4 of Chapter II of Annex XIV for which each Member State shall verify the completeness and notify the sponsor accordingly. Article 51(2) to (4) shall apply to the coordinating Member State in relation to the verification that the clinical investigation falls within the scope of this Regulation and that the application is complete, having taken into account considerations expressed by the other Member States concerned, except for the documentation submitted in accordance with Sections 1.13, 3.1.3, 4.2, 4.3 and 4.4 of Chapter II of Annex XIV for which each Member State shall verify the completeness. Concerned Member States may communicate to the coordinating Member State any considerations relevant to the validation of the application within seven days from the notification date. Article 51(2) to (4) shall apply to the coordinating each Member State in relation to the verification that the clinical investigation falls within the scope of this Regulation and that the application is complete, except for the documentation submitted in accordance with Sections 1.13, 3.1.3, 4.2, 4.3 and 4.4 of Chapter II of Annex XIV is complete;***

(b) establish the results of ~~the coordinated~~ its assessment in a *draft assessment* report to be *transmitted within 26 days after the validation date to the concerned Member States. Until day 38 after the validation date the other concerned Member States shall transmit their comments and proposals on the draft assessment report and the underlying application to the coordinating Member State, which shall take due account of it in the finalization of the final assessment report, to be transmitted within 45 days following the validation date to the sponsor and the concerned Member States. The final assessment report shall be taken into account by the other Member States concerned when deciding on the sponsor's application in accordance with Article 51(5), except for Sections 1.13, 3.1.3, 4.2, 4.3 and 4.4 of Chapter II of Annex XIV, which shall be assessed separately by each Member State concerned.*

As concerns the assessment of the documentation related to Sections 1.13, 3.1.3, 4.2, 4.3 and 4.4 of Chapter II of Annex XIV, done separately by each Member State, the Member State may request, on a single occasion, additional information from the sponsor. The expiry of the deadline pursuant paragraph 2 shall be suspended from the date of the request until such time as the additional information has been received.

- 3a. *The coordinating Member State may also extend the periods referred to in paragraph 3 by a further 50 days, for the purpose of consulting with experts. In such case, the periods referred to in paragraphs 3 of this Article shall apply mutatis mutandis.*
- 3b. *The Commission may, by means of implementing acts, set out the procedures and timescales for a coordinated assessment led by the coordinating Member State, that shall be taken into account by concerned Member States when deciding on the sponsor's application. Such implementing acts may also cover the procedures for coordinated assessment in the case of substantial modifications pursuant to paragraph 4 and in the case of reporting of events pursuant to Article 59(4) or in the case of clinical investigations of combination products between medical devices and medicinal products, where the latter are under a concurrent coordinated assessment of a clinical trial under Regulation (EU) No 536/2014. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3).*

3c. Where the conclusion of the coordinating Member State is that the conduct of the clinical investigation is acceptable or acceptable subject to compliance with specific conditions, that conclusion shall be deemed to be the conclusion of the Member State(s) concerned.

Notwithstanding the previous subparagraph, a Member State concerned may disagree with the conclusion of the coordinating Member State concerning the area of joint assessment only on the following grounds:

- (a) when it considers that participation in the clinical investigation would lead to a subject receiving an inferior treatment than in normal clinical practice in the Member State concerned;**
- (b) infringement of national law;**
- (c) considerations as regards subject safety and data reliability and robustness submitted under paragraph 3 point (c).**

Where a Member State concerned disagrees with the conclusion, it shall communicate its disagreement, together with a detailed justification, through the electronic system referred to in Article 53, to the Commission, to all Member States concerned, and to the sponsor.

3d. A Member State concerned shall refuse to authorise a clinical investigation if it disagrees with the conclusion of the coordinating Member State as regards any of the grounds referred to in the second subparagraph of paragraph 3c, or if it finds, on duly justified grounds, that the aspects addressed in Sections 1.13., 3.1.3, 4.2, 4.3 and 4.4 of Chapter II of Annex XIV are not complied with, or where an ethics committee has issued a negative opinion which in accordance with the law of the Member State concerned is valid for that entire Member State. That Member State shall provide for an appeal procedure in respect of such refusal.

3da. Each Member State concerned shall notify the sponsor through the electronic system referred to in Article 53 as to whether the clinical investigation is authorised, whether it is authorised subject to conditions, or whether authorisation is refused. Notification shall be done by way of one single decision within five days from the reporting date. An authorisation of a clinical investigation subject to conditions is restricted to conditions which by their nature cannot be fulfilled at the time of that authorisation.

- 3e. *Where the conclusion of the coordinating Member State report is that the clinical investigation is not acceptable, that conclusion shall be deemed to be the conclusion of all Member States concerned.*
4. The substantial modifications *as* referred to in Article 55 shall be notified to the Member States concerned by means of the electronic system referred to in Article 53. Any assessment as to whether there are grounds for refusal as referred to in ~~Article 55~~ *paragraph 3c* shall be carried out under the direction of the coordinating Member State, *except for substantial modifications concerning sections 1.13, 3.1.3, 4.2, 4.3 and 4.4 of Chapter II of Annex XIV, which shall be assessed by each concerned Member State on its own.*
5. For the purpose of Article 57(3), the sponsor shall submit the clinical investigation report to the Member States concerned by means of the electronic system referred to in Article 53.
6. The Commission shall provide ~~secretarial~~ *administrative* support to the coordinating Member State in the accomplishment of its tasks provided for in this Chapter.

Article 58a

Review of clinical investigations rules

Five years after the date referred to in the first paragraph of Article 97, the Commission shall make a report on the application of Article 58 of the present Regulation and propose a review of the provision of Article 58 in order to ensure a coordinated assessment procedure of clinical investigations conducted in more than one Member State.

Article 59

Recording and reporting of events occurring during clinical investigations

1. The sponsor shall fully record any of the following:
 - (a) an adverse event identified in the clinical investigation plan as critical to the evaluation of the results of the clinical investigation in view of the purposes referred to in Article 50(1);
 - (b) a serious adverse event;
 - (c) a device deficiency that might have led to a serious adverse event if suitable action had not been taken, intervention had not occurred, or circumstances had been less fortunate;
 - (d) new findings in relation to any event referred to in points (a) to (c).

2. The sponsor shall report to all Member States where a clinical investigation is conducted without delay any of the following *by means of the electronic system referred to in Article 53*:
 - (a) a serious adverse event that has a causal relationship with the investigational device, the comparator or the investigation procedure or where such causal relationship is reasonably possible;
 - (b) a device deficiency that might have led to a serious adverse event if suitable action had not been taken, intervention had not occurred, or circumstances had been less fortunate;
 - (c) new findings in relation to any event referred to in points (a) to (b).

The time period for reporting shall take account of the severity of the event. Where necessary to ensure timely reporting, the sponsor may submit an initial incomplete report followed up by a complete report.

3. The sponsor shall also report to the Member States concerned any event referred to in paragraph 2 occurring in third countries in which a clinical investigation is performed under the same clinical investigation plan as the one applying to a clinical investigation covered by this Regulation *by means of the electronic system referred to in Article 53*.

4. In the case of a clinical investigation for which the sponsor has used the single application referred to in Article 58, the sponsor shall report any event as referred to in paragraph 2 by means of the electronic system referred to in Article 53. Upon receipt, this report shall be transmitted electronically to all Member States concerned.

Under the direction of the coordinating Member State referred to in Article 58(2), the Member States shall coordinate their assessment of serious adverse events and device deficiencies to determine whether a clinical investigation needs to be terminated, suspended, temporarily halted or modified.

This paragraph shall not affect the rights of the other Member States to perform their own evaluation and to adopt measures in accordance with this Regulation in order to ensure the protection of public health and patient safety. The coordinating Member State and the Commission shall be kept informed of the outcome of any such evaluation and the adoption of any such measures.

5. In the case of post-market clinical follow-up investigations referred to in Article 54(1), the provisions on vigilance contained in Articles 61 to 66 shall apply instead of this Article.
6. ***Notwithstanding paragraph 5, this Article shall however apply where a causal relationship between the serious adverse event and the preceding investigational procedure has been established.***

Article 60

Implementing acts

The Commission may, by means of implementing acts, adopt the modalities and procedural aspects necessary for the implementation of this Chapter as regards the following:

- (a) harmonised ***electronic*** forms for the application for clinical investigations and their assessment as referred to in Articles 51 and 58, taking into account specific categories or groups of devices;
- (b) the functioning of the electronic system referred to in Article 53;
- (c) harmonised ***electronic*** forms for the notification of post-market clinical follow-up investigations as referred to in Article 54(1), and of substantial modifications as referred to in Article 55;
- (d) the exchange of information between Member States as referred to in Article 56;
- (e) harmonised ***electronic*** forms for the reporting of serious adverse events and device deficiencies as referred to in Article 59;
- (f) the timelines for the reporting of serious adverse events and device deficiencies, taking into account the severity of the event to be reported as referred to in Article 59.
- (g) ***uniform application of the requirements regarding the clinical evidence/data needed to demonstrate compliance with the general safety and performance requirements specified in Annex I.***

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3).

Chapter VII

Post-market surveillance, vigilance ~~Vigilance~~ and market surveillance

SECTION 0 – POST-MARKET SURVEILLANCE

Article 60a

Post-market surveillance system of the manufacturer

- ~~1. The manufacturer shall ensure compliance with the provisions of this Regulation throughout the entire lifetime of the devices he has made available on the market or put into service.~~
2. For any device, proportionate to the risk class and appropriate for the type of device, manufacturers of devices shall plan, establish, document, implement, maintain and update a post-market surveillance system which shall be an integral part of the manufacturer's quality management system according to Article 8, paragraph(6).
3. The post-market surveillance system shall be suitable to actively and systematically gather, record and analyse relevant data on the quality, performance and safety of a device throughout its entire lifetime, to draw the necessary conclusions and to determine, implement and monitor any preventive and corrective actions.
4. Data gathered by the manufacturer's post-market surveillance system shall in particular be used:
 - (a) to update the risk/benefit risk determination ~~analysis~~ and risk management, the design and manufacturing information, the instructions for use and the labelling;
 - (b) to update the clinical evaluation;
 - (c) to update the summary of safety and clinical performance as referred to in Article 26;

- (d) for the identification of needs for preventive, corrective or field safety corrective action;**
- (e) for the identification of possibilities to improve the usability, performance and safety of the device;**
- (f) when relevant, to contribute to the post-market surveillance of other devices.**
- (g) to detect and report trends (in accordance with article 61a).**

The technical documentation shall be updated accordingly.

5. ~~Updates according to paragraph 4 shall be reflected in the technical documentation.~~

6. If in the course of the post-market surveillance a need for preventive and corrective action is identified, the manufacturer shall implement the appropriate measures and, where applicable, inform the notified body and the competent authorities concerned. ~~The identification of~~ When a serious ~~an~~ incident is identified or a field safety corrective action is implemented, this shall be reported in accordance with ~~shall induce actions according to~~ Article 61.

Article 60b

Post-market surveillance plan

The post-market surveillance system as referred to in Article 60a shall be based on a post-market surveillance plan, the requirements of which are set out in Section 1.1 of Annex IIa. For devices other than custom made-devices ~~The the~~ post-market surveillance plan ~~which~~ shall be part of the technical documentation as specified in Annex II.

Article 60c

Periodic safety update report

- 1. Per device and where relevant per category or group of devices, the manufacturer shall prepare a periodic safety update report summarising the results and conclusions of the analyses of the gathered post-market surveillance data according to Annex IIa together with a rationale and description of any preventive and corrective actions taken.**

Throughout the lifetime of the device concerned this report shall set out:

- (a) the conclusion of ~~conclude on~~ the benefit risk determination;**
- (b) ~~include~~ the main findings of the Post Market Clinical Follow-up Report and**
- (c) the volume of sales of devices and an estimate of the population that use the device involved and, where ~~appropriate-practicable, for reusable medical devices~~ the usage frequency of the device.**

The report shall ~~(b)~~ be updated at least annually; and ~~(e)~~ be part of the technical documentation as specified in Annex II.

- 2. Manufacturers of devices in class III or implantable devices shall submit reports by means of the electronic system referred to in Article 66a to the notified body involved in the conformity assessment in accordance with Article 42. The notified body shall ~~will~~ review the report and add its evaluation to the database with details of any action taken. Such reports and the notified body evaluation shall be available to competent authorities through the electronic system.**
- 3. Manufacturers of devices other than those referred to in paragraph 2, ~~I, IIa and IIb~~ shall make reports available to the notified body involved in the assessment and to competent authorities on request.**

SECTION 1 – VIGILANCE

Article 61

Reporting of serious incidents and field safety corrective actions

1. Manufacturers of devices, ***made available on the Union market***, other than ~~custom-made or~~ investigational devices, shall report, through the electronic system referred to in Article 62 ~~66a~~, the following:
 - (a) any serious incident ~~in respect of~~ ***involving*** devices made available on the Union market, ***except expected serious side-effects which are clearly documented in the product information and quantified in the technical documentation and are subject to trend reporting pursuant to Article 61a;***
 - (b) any field safety corrective action in respect of devices made available on the Union market, including any field safety corrective action undertaken in a third country in relation to a device which is also legally made available on the Union market, if the reason for the field safety corrective action is not limited to the device made available in the third country.
- 1a. As a general rule, the time period for reporting shall take account of the severity of the serious incident.*
- 1b. Manufacturers shall ~~make provide~~ the report ***any serious incident as*** referred to in *point (a)* ~~the first subparagraph without delay, and no later than 15 days after they have become aware of the event and~~ ***immediately after the manufacturer has established*** the causal relationship with their device or that such causal relationship is reasonably possible, ***and in not case later than 15 30 days after they have become aware of the event.****

~~The time period for reporting shall take account of the severity of the *serious* incident.~~

- 1c. Notwithstanding paragraph 1b, in case of a serious public health threat the report shall be provided immediately, and ~~in not~~ later than 2 ~~calendar~~ days after awareness by the manufacturer of this threat.**
- 1d. Notwithstanding paragraph 1b, in case of death or unanticipated serious deterioration in state of health the report shall be provided immediately after the manufacturer established or suspected a causal relationship ~~link~~ between the device and the event but not later than 10 elapsed ~~calendar~~ days following the date of awareness of the event.**
- 1e. Where necessary to ensure timely reporting, the manufacturer may submit an initial incomplete report followed up by a complete report.**
- 1f. If after becoming aware of a potentially reportable incident there is still uncertainty about whether the event is reportable, the manufacturer shall submit a report within the timeframe required for that type of incident.**
- 1g. Except in cases of urgency where the manufacturer need to undertake the field safety corrective action immediately, without undue delay, the manufacturer shall ~~provide the report the field safety corrective action referred to in paragraph 1, point (b) the second subparagraph~~ in advance of the field safety corrective action being undertaken.**

2. For similar serious incidents occurring with the same device or device type and for which the root cause has been identified or the field safety corrective action implemented *or where the incidents are common expected and well documented, the* manufacturers may provide periodic summary reports instead of individual *serious* incident reports, on condition that the *coordinating competent authority referred to in Article 63(6), in consultation with the* competent authorities referred to in points (a), *and (b) and (e)* of Article *66a, paragraph 5-7 62(5), has* have agreed with the manufacturer on the format, content and frequency of the periodic summary reporting. *Where a single competent authority is referred to in points (a), (b) and (e) of Article 66a, paragraph 5 7, the manufacturer may provide periodic summary reports on agreement with that competent authority.*

3. The Member States shall take all appropriate measures to encourage healthcare professionals, users and patients to report to their competent authorities, *to the manufacturer and, where appropriate, to the authorised representative* suspected serious incidents referred to in point (a) of paragraph 1. They shall record such reports *that they receive* centrally at national level. Where a competent authority of a Member State obtains such reports, it shall take the necessary steps to ensure that the manufacturer of the device concerned is informed of the *suspected serious* incident.

The manufacturer *of the device concerned* shall *provide to the responsible competent authority of the Member State where the event occurred an initial report on the serious incident in accordance with paragraph 1, or on the change in trend according to Article 61a, and* ensure the appropriate follow-up; *if the manufacturer considers that the event is does not fulfil the definition of a serious incident or an expected undesirable side effect which will be covered by trend reporting according to Article 61a, it shall provide or an explanatory statement why the incident is not a serious incident and ensure the appropriate follow-up.*

The Member States shall coordinate between them the development of standard web-based structured forms for reporting of serious incidents by healthcare professionals, users and patients.

- ~~3a. If the competent authority does not agree with the conclusion of the explanatory statement, it may require the manufacturer to provide a report in accordance with this article paragraph 1 and to take or require the manufacturer to take the that the manufacturer takes appropriate follow-up corrective action.~~
- ~~3e. The Commission shall ensure that the electronic system referred to in Article 66a allows direct reporting from Member States' databases of any reports received pursuant to paragraph 1.~~
4. ~~Manufacturers of custom-made devices shall report any serious incidents and field safety corrective actions referred to in paragraph 1 to the competent authority of the Member State in which the device in question has been made available.~~

Article 64 61a

Trend reporting – ~~and periodic safety update reports by manufacturers~~

1. ~~Manufacturers of devices classified in class IIb and III shall report to~~ *by means of* the electronic system referred to in Article ~~62 66a~~ any statistically significant increase in the frequency or severity of incidents that are not serious incidents or of expected undesirable side-effects that *could* have a significant impact on the risk-benefit analysis referred to in Sections *I.1* and *I.5* of Annex I and which have led or may lead to unacceptable risks to the health or safety of patients, users or other persons when weighted against the intended benefits. The significant increase shall be established in comparison to the foreseeable frequency or severity of such incidents or expected undesirable side-effects in respect of the device, or category or group of devices, in question during a specific time period *as specified in the technical documentation and product information* ~~as established in accordance with the manufacturer's post-market surveillance obligations pursuant to Article 60a(1)~~ conformity assessment. *The manufacturer shall define how to manage these this events and the methodology used for determining any statistically significant increase in the frequency or severity of this these events, as well as the observation period, in the post-market surveillance plan pursuant to article 60b.* ~~Article 63 shall apply.~~