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**PRACTICAL INFORMATION GUIDE
FOR APPLICANTS**

**MEDICAL DEVICE CLINICAL
INVESTIGATIONS SUBMITTED TO THE
ANSM AND ETHICS COMMITTEE
WITHIN THE PILOT PHASE**

22 July 2019

Information concerning the assessment of medical device clinical investigations submitted within the pilot phase simulating the application of regulation (UE) n° 2017/ 745 of the European Parliament and of the council of 5 April 2017 on medical devices, amending Directive 2001/83/CE, Regulation (EC) n°178/2002 and Regulation (EC) n°1223/2009 et REPEALING Council Directives 90/385/CEE and 93/42/CEE.

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I. PREAMBLE

This document describes the pilot phase procedure proposed by the ANSM and Ethics Committees (ECs) relating initially to clinical trials conducted on medical devices ('Clinical Investigations') and subsequently to clinical trials carried out on in vitro diagnostic medical devices ('Performance Studies').

European (EU) Regulation No. 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (European Commission) No. 178/2002, and Regulation (European Commission) No. 1223/2009 and repealing Council Directives 90/385/CEE and 93/42/CEC (this regulation is referred to as the 'Medical Device Regulation' in the remainder of this document) was published in the Official Journal of the European Union (OJEU) on 5 May 2017 (document available at: <https://eur-lex.europa.eu/eli/reg/2017/745/oj>) and was the subject of an amendment on 3 May 2019 published in the OJEU on 5 May 2019 available at: [https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32017R0745R\(01\)](https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32017R0745R(01)).

The purpose of this regulation was to strengthen and harmonise all regulations on medical devices (MDs) within the European Union (EU); chapter VI is dedicated specifically to the clinical evaluation and clinical investigations (CIs).

The Medical Device Regulation is due to enter into force in the different EU Member States on 26 May 2020, in particular chapter VI concerning MD CIs, understood to mean any systematic investigation involving one or more subjects aimed at evaluating the safety or performance of a MD.

For MD CIs, the Medical Device Regulation requires:

- An authorisation system for CIs on Class III MDs, implantable MDs and invasive Class IIa and IIb MDs, involving a scientific evaluation and ethical review of the CI by each Member State concerned, using ethical review procedures compatible with those used for the assessment of CI authorisation applications by the competent authority.
- The sponsor's single submission of the CI application on the European portal (EUDAMED), containing all information and data relating to this investigation, some of which will be accessible to the public.
- For CIs conducted in several EU Member States, the implementation of a coordinated assessment procedure for CI applications and requests for their amendments, with the exception of the ethical review which will remain national, and the principle of a single decision from each Member State concerned by the CI, awarded within a defined deadline. This procedure will be mandatory from 26 May 2027. Prior to this date, once the EUDAMED portal is operational, it can be applied in any willing Member State, and by the sponsor on a voluntary basis.
- Greater transparency owing to public access to a large part of the information contained on the EUDAMED database, including the results of the CIs conducted within the EU.

Application of the Medical Device Regulation requires new working arrangements for the competent authorities and Member States' Ethics Committees. In preparation for this, specifically the application assessment timelines and organisation of the coordination with the 39 existing Ethics Committees (ECs) named in France "*Comités de protection des personnes (CPP)*", in collaboration with the ECs, the ANSM is giving willing sponsors the opportunity to take part in a 'pilot phase'.

This 'pilot phase' will therefore simulate the new organisation imposed by the Medical Device Regulation while continuing to comply with current regulations in France.

The primary aim of this 'pilot phase' for CIs conducted on MDs is to ensure France is ready once the Medical Device Regulation shall apply on 26 May 2020.

This experimental procedure will be launched on 16 September 2019 with the collaboration of the 39 existing ECs.

I.1. Scope of the pilot phase

The pilot phase concerns:

- CIs on medical devices that meet the following criteria:
 - Types of MD concerned:
 - ✓ Class III
 - Or
 - ✓ Implantable
 - Or
 - ✓ Invasive Class IIa or IIb

And

- Status of the MD concerned:
 - ✓ Without CE marked
 - ✓ Or with CE marked and whose use in the CI differs from its intended purpose
- Research category involving human subjects: Section 1 of Article L.1121-1 of the *Code de la santé publique* [French Public Health Code].
- All therapeutic areas.
- **Initial study authorisation.**
- All sponsors (academic or private).

The pilot phase does not concern:

- CIs on:
 - Class III MDs, implantable MDs or invasive Class IIa or IIb MDs CE marked and used in the trial in accordance with their intended purpose.
 - Class I or non-invasive Class IIa or IIb MDs.
- Clinical trials (CTs) and performance studies on in vitro diagnostic MDs.
- CTs on a health product (other than a MD), in particular cosmetics and medicinal products, including advanced therapy medicinal products, cell therapy preparations, organs, tissues and labile blood products.
- CTs on non-health products.
- CTs governed by two sets of regulations, i.e. trials on products with different legal statuses (for example, a trial testing both a MD and a medicinal product).
- CTs on 'combined' products: the subject of the trial is a health product that also incorporates a product with a different legal status (for example, a MD incorporating a medicinal product, or a MD incorporating products of human or animal origin, or a combined advanced therapy medicinal product).
- Non-interventional studies and CTs with minimal risks and constraints (Category 2 and 3 research

involving human subjects according to the amended “Jardé Law”¹).

- Obligations relating to the conduct and monitoring of CIs on MDs, including those submitted within the pilot phase (i.e. significant amendments, serious adverse event reports, annual safety reports, new information) and end-of-trial procedures.

I.2. The ANSM and the EC: who does what?

The respective responsibilities of the ANSM and the EC in clinical investigations are defined as follows:

	ANSM	EC
Currently (Articles L.1123-7 and L. 1123-12 of the French Public Health Code)	<p>Safety of people</p> <p>Scientific evaluation (in particular, the quality and safety of the products used in the research, conditions of use)</p> <p>The scientific evaluation includes the methodological aspects [1]</p>	<p>Protection of people</p> <p>Information and consent Recruitment methods / Periods of exclusion / Indemnification Data protection</p> <p>Protocol</p> <p>Ethical aspects (including the population concerned by the research)</p> <p>Resources used</p> <p>Competence of the investigators / Research sites</p>
With the Medical Device Regulation	Maintenance of the scope of evaluation	Maintenance of the scope of evaluation

[1] Within the ‘pilot phase’ procedure, the ANSM is responsible for assessing the methodology, in compliance with current regulations.

¹ Law No. 2012-300 of 5 March 2012 on research involving the human person (known as the Jardé Law), as amended by Ordinance No. 2016-800 of 16 June 2016 and Its implementing decree n° 2016-1537 of 16/11/2016 concerning research involving the human person (JO 17/11/2016)

II. TRANSITIONAL ARRANGEMENTS

This pilot phase is **optional** for sponsors.

The sponsor is therefore free to choose between two options:

1. The sponsor can apply the provisions currently in force, as set out in the amended “Jardé Law”² (Title II, Book II, Part I of the French Public Health Code), the practical details of which are specified in the ‘*Avis aux promoteurs d’essais cliniques de dispositifs médicaux*’ [Notice to sponsors of clinical trials on medical devices] available on the ANSM’s website: <https://www.ansm.sante.fr/Activites/Dispositifs-medicaux-et-dispositifs-medicaux-de-diagnostic-in-vitro/Essais-cliniques-portant-sur-les-dispositifs-medicaux-et-dispositifs-medicaux-de-diagnostic-in-vitro>.
2. The sponsor can choose to simulate application of the provisions set out in the Medical Device Regulation by taking part in the pilot phase proposed by the ANSM, details of which are described in this document.

This procedure is applicable at the sponsors’ request, study by study.

The decisions made by the ANSM and the relevant EC within this pilot phase will be valid pursuant to current regulations and awarded within the current regulatory deadlines defined by the French Public Health Code.

² see footnote [1] page 6/31

III. PROCEDURE FOR THE IMPLEMENTATION OF A MEDICAL DEVICE TRIAL WITHIN THE PILOT PHASE PROPOSED BY THE ANSM

The Medical Device Regulation defines the procedures for assessing CIs and their various processing stages.

III.1. Application submission arrangements

Within this pilot phase:

- D0 = date on which the application is received by the two bodies.
- The same format will be used in the applications sent to both the EC and the ANSM, each body will then assess the section of the application falling under their scope.

III.1.1. Submission to the EC

To obtain the random appointment of an EC, the sponsor must submit their completed application on the IS portal of the *Commission Nationale de la Recherche impliquant la personne humaine* [National Commission for Research Involving Human Subjects] (CNRIPH): <https://cnriph.sante.gouv.fr/> and initiate the random selection process that will determine the EC concerned. The sponsor will communicate the identity of the appointed EC to the ANSM by e-mail to: phasepilote.reglementDM@ansm.sante.fr at the time the application is submitted, formatting the e-mail subject line according to the recommendations set out in Section III.1.2 of this document).

On the same day, the sponsor must then submit their application to the ANSM (see Section III.1.2). The date on which this is sent will represent D0 – start of the application's processing.

The application files must be identified by the sponsors as being applications submitted within the MD pilot phase; the file identification number to be entered in the IT system of assignment to the ethics committee "SI RIPH" is: the **IDRCB number followed by the suffix “_PP”** (ie 2014-A01450-56_PP).

III.1.2. Submission to the ANSM

The applications must be e-mailed to the ANSM's dedicated address: phasepilote.reglementDM@ansm.sante.fr.

Use of the phasepilote.reglementDM@ansm.sante.fr inbox is strictly limited to authorisation applications for clinical investigations on **medical devices** submitted within the pilot phase in preparation for the application of the **Medical Device Regulation**.

The applications can be sent:

- By 'standard' e-mail
- Or using the Eudralink messaging system offered by the European Medicines Agency (EMA) for sending clinical trial applications to the ANSM.

This system allows large files to be sent securely.

Eudralink e-mail system (for communications with the ANSM)

To access Eudralink, the user must first ask for a Eudralink account to be opened in their name by contacting the relevant department of the EMA: <https://servicedesk.ema.europa.eu> (For urgent technical questions: Tel.: +31 (0) 88 781 7523)

If using the Eudralink secure e-mail service, it is recommended to:

- Set a message expiry date of 90 days and do not select send with password.
- Attach the application documents in a compressed file (zip file or 7z file) without a password.

It is very important that you fill in the e-mail's subject field as follows:

	E-mail subject
Initial assessment application	Ph pilote-AIC DM / IDRCB^(a) / CPP concerned E.g.: Ph pilote-AIC DM / 2014-A01450-56 / EC EST I
Responses to validation^(c)	Ph pilote-Réponses AR / ANSM ref^(b) / IDRCB^(a) E.g.: Ph pilote-Réponses AR / DAPTEC/SV / 2014-A01450-56
Answers to questions^(c)	Ph pilote-Réponses CI / ANSM ref^(b) / IDRCB^(a) E.g.: Ph pilote-Réponses CI / DAPTEC/SV / 2014-A01450-56

- (a) Specify the trial IDRCB number
- (b) Specify the reference allocated by ANSM for the application
- (c) Potentially formulated by the ANSM following the validation assessment / the assessment of the initial application (question)

The e-mail received at: phasepilote.reglementDM@ansm.sante.fr will be sent to the relevant unit of the *Direction des dispositifs médicaux, des cosmétiques et des dispositifs de diagnostic in vitro* [Division for Medical Devices, Cosmetics and In Vitro Diagnostic Medical Devices] (DMCDIV).

III.1.3. Table of contacts according to the type of information sought

Type of request	E-mail address	E-mail subject
Request concerning the ANSM		
General questions about the pilot phase concerning the ANSM	phasepilote.reglementDM@ansm.sante.fr	Pilot phase MD Questions
Questions about an MD CI pilot phase application concerning the ANSM	phasepilote.reglementDM@ansm.sante.fr	
Submission of CI authorisation applications within the pilot phase according to the arrangements described by this procedure (as well as the responses provided to the validation letter / questions letter (substantiated objections) potentially formulated by the ANSM on the submitted applications)	phasepilote.reglementDM@ansm.sante.fr	See III.1.2.
Requests for authorisation of a significant amendment to a CI which was authorised within this pilot phase	EC.DM-COS@ansm.sante.fr	In the subject field, state that the initial application was assessed within the pilot phase MD
Other information concerning CIs which were authorised within this pilot phase (for example, declaration of the start and end of the trial in France, transmission of the annual safety report, trial results)	EC.DM-COS@ansm.sante.fr	
Request concerning the EC		
General questions about the pilot phase MD concerning the aspects falling under the EC's scope	l.lacoste@chu-poitiers.fr eofrija@gmail.com dgs-cnriph@sante.gouv.fr	Pilot phase MD Questions
Questions about an MD CI pilot phase application concerning the EC	E-mail of the EC concerned	
Requests for authorisation of a significant amendment to a CI which was authorised within this pilot phase	E-mail of the EC concerned	In the subject field, state that the initial application was assessed within the pilot phase MD

Other information concerning CIs which were authorised within this pilot phase (for example, declaration of the start and end of the trial in France, transmission of the annual safety report, trial results)	E-mail of the EC concerned	
Questions about the instructions for submission on the IS portal	DGS-RBM@sante.gouv.fr	

III.2. Application file content / language / format

III.2.1. Application file content

The content of the IC application file is defined in Annex XV of the Medical Device Regulation (see *Appendix 1* to this guide).

Content of the authorisation application file submitted to the EC within the pilot phase

Since the Medical Device Regulation is not yet applicable, the provisions of the amended “Jardé Law”³ must be complied with during this pilot phase. This is why certain information not required by the Medical Device Regulation must be provided within the pilot phase in compliance with current French regulations in force.

In contrast, certain information required by the Medical Device Regulation and not required by current French regulations does not need to be submitted within this pilot phase (see documents specified in *Appendix 1* to this guide).

It should be noted, however, that certain information required by the current regulations will need to be provided in another format following application of the Medical Device Regulation.

The same application file will be sent to both the EC and the ANSM, each body will check for their respective part of this application.

Since the application file will include most of the documents required by current French regulations, for more detailed information, the sponsor should consult:

- The ‘*Avis aux promoteurs d’essais cliniques de dispositifs médicaux et dispositifs de diagnostic in vitro*’ [Notice to sponsors of clinical trials on medical devices and in vitro medical devices] available on the ANSM's website at: <http://ansm.sante.fr> (*Essais cliniques* [Clinical Trials] section) or: <https://www.ansm.sante.fr/Activites/Dispositifs-medicaux-et-dispositifs-medicaux-de-diagnostic-in-vitro/Avis-aux-promoteurs-Formulaire>.
- Order of 2 December 2016 establishing the content, format, and procedures for presenting the opinion request to the Ethics Committee as stipulated in Section 1 of Article L.1121-1 of the French Public Health Code regarding medical devices and in vitro diagnostic medical devices (referred to in this guide as the ‘EC Opinion Order’) available on the ANSM's website at: <https://www.legifrance.gouv.fr/affichTexte.do?cidTexte=LEGITEXT000033547014&dateTexte=20180908>

³ see footnote [1] page 6/31

(a) **Documents required in compliance with the Medical Device Regulation (see Appendix 1 to this guide)**

▪ **APPLICATION FORM**

Since the European form required by the Medical Device Regulation is not yet available, the form used within the pilot phase will be the one currently in force in France (it is the document entitled '*Formulaire de demande d'autorisation auprès de l'ANSM et d'avis du comité de protection des personnes (CPP) pour une recherche mentionnée au 1° ou au 2° de l'article L.1121-1 du code de la santé publique portant sur un dispositif médical (DM) ou un dispositif médical de diagnostic in vitro (DMDIV)*' [Form requesting the authorisation of the ANSM and the opinion of the Ethics Committee (EC) for research referred to in Article L.1121-1 of the French Public Health Code relating to a medical device (MD) or an in vitro diagnostic medical device (IVDMD)] available on the ANSM's website at: <http://ansm.sante.fr> (*Essais cliniques* [Clinical Trials] section) or: <https://www.ansm.sante.fr/Activites/Dispositifs-medicaux-et-dispositifs-medicaux-de-diagnostic-in-vitro/Avis-aux-promoteurs-Formulaires>.

▪ **INVESTIGATOR'S BROCHURE AND FULL DETAILS OF THE AVAILABLE TECHNICAL DOCUMENTATION**

For the pilot phase, these documents correspond to the information contained in the Investigator's Brochure submitted to the EC and the ANSM and in the MD's technical file sent to the ANSM, as required by current French regulations and described in the '*Avis aux promoteurs d'essais cliniques de dispositifs médicaux et dispositifs de diagnostic in vitro*' [Notice to sponsors of clinical trials on medical devices and in vitro diagnostic medical devices] available on the ANSM's website at: <http://ansm.sante.fr> (*Essais cliniques* [Clinical Trials] section) or: <https://www.ansm.sante.fr/Activites/Dispositifs-medicaux-et-dispositifs-medicaux-de-diagnostic-in-vitro/Avis-aux-promoteurs-Formulaires>.

Within the pilot phase:

- The following documentation must be supplied:
 - Either the statement of compliance with the general safety and performance requirements referred to in Annex I of the Medical Device Regulation, with the sole exception of the aspects covered by the CI, for which the manufacturer certifies that every precaution has been taken to protect the health and safety of the subjects taking part in the CI.
 - Or the statement of compliance with the essential requirements mentioned in amended Directives 93/42/EEC and 90/385/EEC (until the date on which the Medical Device Regulation comes into force).
- The documents listed below (see [Appendix 1](#)) required by the Medical Device Regulation do not need to be submitted:
 - Information on the MD's classification according to the classification rule set out in Annex VIII to the Medical Device Regulation.
 - Data that must be included on the label and instructions for use.

▪ **CLINICAL INVESTIGATION PLAN / PLAN SUMMARY**

The clinical investigation (CI) plan must be accompanied by a plan summary.

Within the pilot phase:

- This summary is the same as the one written in French and required when submitting the opinion request to the relevant EC (see [Appendix 2](#)).
- The plan does not contain the unique single CI identification number referred to in Article 70 of the Medical Device Regulation (see [Appendix 1](#)), since this number is obtained from the European portal which is not yet operational.

The CI plan must be signed by:

- The sponsor
- And either the coordinating investigator (for a multicentre trial, including a multinational trial), or the principal investigator (for a single-centre trial).

There are two possible options:

- Either the plan contains the electronic signatures of the sponsor and the investigator in PDF format.
- Or the sponsor sends, in addition to the unsigned plan, a scanned version (PDF format) of the page of the plan containing the handwritten signatures of the sponsor and coordinating investigator.

▪ **RECRUITMENT METHODS**

Upon application of the Medical Device Regulation, information on the methods used to recruit the subjects taking part in the CI will be included in the CI plan.

For the pilot phase, this information must be included in the supplementary document submitted to the EC as required by the EC Opinion Order. This information also includes advertisements, printed documents, audio and video materials and the procedures for dealing with responses to these advertising activities.

▪ **INFORMATION OF THE SUBJECTS, INFORMED CONSENT FORM AND INFORMED CONSENT PROCESS**

For the pilot phase, this information is the same as that required by the EC Opinion Order.

▪ **INFORMATION ON THE INVESTIGATOR(S)**

Upon application of the Medical Device Regulation, this information will be included in the CI plan.

For the pilot phase, this information is the same as that required by the EC Opinion Order. It concerns the dated and signed CVs of the investigators (with CNOM/RPPS number).

▪ **EVIDENCE OF THE SUITABILITY OF THE CI SITES**

The Medical Device Regulation requires the application form to contain evidence provided by the sponsor to demonstrate that the investigator and the investigational site are capable of conducting the CI in accordance with the CI plan.

For the pilot phase, this information is the same as that required by the EC Opinion Order. Specifically, it is evidence that the human, equipment and technical resources are adequate for the research project, or the copy of the site authorisation referred to in Article L.1121- 13 of the French Public Health Code.

▪ **PROOF OF INSURANCE COVER OR INDEMNIFICATION OF SUBJECTS TAKING PART IN THE CI**

For the pilot phase, this information is the same as that required by the EC Opinion Order.

▪ **DESCRIPTION OF THE ARRANGEMENTS TO COMPLY WITH APPLICABLE RULES ON THE PROTECTION AND CONFIDENTIALITY OF PERSONAL DATA**

This concerns the measures described in point 4.5 of Annex XV to the Medical Device Regulation (see [Appendix 1](#) to this guide).

Within the pilot phase, these measures must comply with Regulation No. 2016/679, called the General Data Protection Regulation (GDPR) and amended French Data Protection Law No. 78-17 of 6 January 1978.

(b) Documents required in compliance with current regulations in force in France (these will no longer be required upon application of the Medical Device Regulation)

▪ **LETTER OF REQUEST**

Applicants are asked to use the template '*courrier de demande d'AIC*' [CIA letter of request] available on the ANSM's website at: <http://ansm.sante.fr> (*Essais cliniques* [Clinical Trials] section) or: <https://www.ansm.sante.fr/Activites/Dispositifs-medicaux-et-dispositifs-medicaux-de-diagnostic-in-vitro/Avis-aux-promoteurs-Formulaires>.

It is a document used by the ANSM which will also be sent to the EC as part of the pilot phase procedure.

The CIA letter of request must be signed. There are two possible options:

- The applicant inserts an electronic signature into the CIA letter of request in PDF format.
- If the applicant is unable to insert an electronic signature into the PDF version of this letter then, in addition to the unsigned PDF version, they send a scanned version (PDF format) of the page of the form containing the handwritten signature.

▪ **ADDITIONAL DOCUMENT**

This is a document that is supplementary to the EC opinion request and is required by the EC Opinion Order; it is to be written in French. The Medical Device Regulation does not require this document, but the information contained in this document should be submitted in another format (for example, the recruitment methods will be included in the plan).

Note: Within the pilot phase, since the sponsor's application is sent to the ANSM and the EC at the same time, the following documents cannot be submitted in the application file, as the submission procedures are carried out in parallel:

- Decision of the ANSM, if available.
- Final opinion of the EC, if available.

▪ **OTHER DOCUMENTS**

If the CI plan requires the use of auxiliary medicinal products that must be imported into France, once the CI has been authorised, the application file submitted within the pilot phase must include the documentation specified in the notice to sponsors of clinical trials on medical devices, including the form available online on the ANSM's website called '*Demande d'attestation en vue de l'importation de médicament nécessaire à la réalisation d'une recherche impliquant la personne humaine*' [Request for certification for the purpose of importing a medicinal product required to conduct research involving human subjects].

Although not specified in the Medical Device Regulation, where necessary, the CI plan will be accompanied by the Data Safety Monitoring Board (DSMB) charter.

III.2.2. Format: Presentation of the documents / Language

It is essential that the sponsor organises and names the documents correctly, following the recommendations drawn up by the ANSM and the EC and presented in Table I below in this guide. It is essential that each document included in the application appears in separate files and sub-files. The sponsor must identify and harmonise the documents.

The documents can be submitted in English or French, except for those mentioned in Table I which must be sent in French.

Table I: File to be submitted to the ANSM / EC

Documents	A	B	C	Comments	Responsibility of the ANSM	Identification (naming of the documents) For ANSM	Responsibility of the EC	Classification of the documents in the IS portal For EC
Letter of request	■		■	Template ANSM letter currently in force	+	COURRIER	+	COU
Application form [◇]	■			ANSM form currently in force	+	FAEC	+	DEM
Clinical Investigation plan And: - Plan summary ^[FR] [◇] - Data Safety Monitoring Board charter	■ ■		■	See Appendix 2 to this guide for the summary's content	+	PROTOCOLE	+	PRO
Investigator's Brochure Information on the investigational MD	■				+	BI	+	BRO
Recruitment methods ^[FR] [◇]	■					RECRUTEMENT	+	PUB
Information letter ^[FR] Consent form ^[FR] Consent procedure ^[FR] [◇]	■					INFO-CO	+	INF
Competence of the investigators ^[FR] [◇]	■					CV	+	CVI
Evidence of the suitability of the CI sites ^[FR] [◇]	■					EQUIP	+	JUS
Insurance certificate ^[FR]	■					ASSURANCE	+	ASS
Evidence of compliance with GDPR data processing rules ^[FR]	■					DONNEES	+	DON
Document supplementary to the EC opinion request for the research project ^[FR]	■		■			DOC ADD	+	ADD

A: Document required in all cases

B: Document required if applicable

C: Requested in compliance with current regulations in force

[◇] Document whose format is likely to change upon application of the Medical Device Regulation

^[FR] All of these documents must be sent in French

III.3. Processing times

The processing times established for CIA application files managed within the pilot phase are similar to those contained in the Medical Device Regulation for assessing MDs submitted for authorisation, for both a non-coordinated assessment procedure, described in Article 70, and a coordinated assessment procedure, described in Article 78 of this regulation. The processing times prescribed in Articles 70 and 78 of the Medical Device Regulation are detailed in [Appendix 3](#).

However, in order to comply with the French regulations in force that impose a processing deadline of 60 days, appropriate arrangements have been made in agreement with the stakeholders (see Appendix 3).

It should be noted that the milestones are counted in calendar days.

Within this pilot phase:

If a milestone falls on a weekend day or bank holiday, the bodies are expected to respond to the sponsor on the last working day before the theoretical milestone date. This also applies to sponsors and the sending of responses to any questions raised by the two bodies.

The aim is to carry out validation within a maximum of 7 days, followed by an initial assessment no later than D33 (sending questions to the sponsor) in order to obtain a response from the sponsor, if additional information is required, by D45 at the latest with a final response from ANSM on D60.

In the event of an initial favourable response by both bodies (ANSM and EC):

Stage	Milestone dates proposed within the pilot phase
Validation	On D7
End of assessment	+ 26 days = on D33
Notification	+ 3 days = on D36

Therefore, if the assessment has not highlighted any obstacles, the final response can be given before D60.

In the case of questions by at least one of the 2 bodies (ANSM and/or EC):

Stage	Milestone dates proposed within the pilot phase
Validation	On D7
Assessment with requests for substantiated objections by ANSM and/or requests for additional information by the EC	+ 26 days = on D33
Sponsor's response	+ 12 days = on D45
Assessment of answers	+ 12 days = on D57
Final notification	+ 3 days = on D60

Within this pilot phase:

The milestone dates have been established on an optional basis to simulate the future tight application processing timelines and sequences required by the Medical Device Regulation.

Deviations from the theoretical milestones proposed during the pilot phase could be therefore be observed. In this case, they will be monitored, but this will not lead to:

- a withdrawal of the file of the pilot phase;
- a rejection file by the EC.

Since the pilot phase is an experimental procedure based on voluntary participation, the milestone dates stated are not legally enforceable.

However, all stakeholders (ANSM, EC, CNRIPH, sponsors) shall make every effort to comply rigorously with the afore-mentioned deadlines and the **notification of the final decision shall comply with the current regulation (i.e. within 60 days at most).**

III.3.1. ANSM

The total processing time for CI applications is the same as that required by the current regulations.

III.3.2. EC

The sponsors taking part in the pilot phase agree to respond to any questions raised by the ECs within a maximum period of 12 days from receipt of the questions letter (in compliance with the Medical Device Regulation).

III.4. Validation of application / acknowledgement of receipt

Purpose of the application admissibility assessment

The validation of the application will focus on the completeness of the dossier (administrative validation, i.e. checking the list of components to be submitted in support of the application, appropriate electronic version, documents drafted in the appropriate language).

In addition to the review of the CI application's validation, the Regulation will include a stage to confirm that the application falls within the scope of the Medical Device Regulation.

Within the scope of the dossier validation assessment, the completeness of the dossier submitted will be checked by each body: ANSM and the EC for their respective scope.

The validation of an application is examined by each body (ANSM and relevant EC) within 7 days of receipt of the application by mail. A letter will be sent to the sponsor by each of the two bodies.

Within this pilot phase:

D0 = date on which the application is received by the two bodies (ANSM and EC)

If the dossier, submitted the same day, is considered not validated by one of the two bodies (ANSM and/or EC):

- The sponsor should be contacted by telephone (or e-mail) within 3 days of receiving the dossier in order to request information.
- Validation correspondence is sent to the sponsor on D7. If the dossier is considered not validated by one of the two bodies, and if the sponsor wishes to continue participating in the pilot phase, it is proposed to 'suspend' the application from the two bodies (i.e. the sponsor asks for the processing schedule for their application to be stopped so they can make a new submission to the ANSM and the initially appointed EC for the same research project - under the conditions established by the pilot phase, i.e. the same day - in order to restart the application's processing with the same D0.

If the application is not acceptable, the sponsor's responses must be sent as prescribed in Section III.1 of this document.

III.4.1. Correspondence regarding the validation of the application submitted to ANSM

If the application is validated, the validation correspondence will be accompanied by a document listing the theoretical key dates to the assessment of this application.

This correspondence will be sent by e-mail by the DMCDIV Division:

- To the sponsor
- With a copy to the EC concerned
- With a copy to: phasepilote.reglementDM@ansm.sante.fr

III.4.2. Correspondence regarding the validation of the application submitted to the EC

Validation correspondence templates will be available on the CNCP website for all ECs participating in this pilot phase <http://www.cncpp.fr/> (this document will specify the date of the session during which the file will be examined).

This correspondence will be sent by e-mail by the EC

- To the sponsor
- With a copy to: phasepilote.reglementDM@ansm.sante.fr

III.5. Dossier assessment

III.5.1. Assessment scope by the ANSM

The assessment will be carried out to check the safety of persons taking part in the trial, paying particular attention to the safety and quality of the products used in the trial, in accordance with current standards, conditions regarding their use and the safety of subjects in view of the procedures implemented and the methods used as well as subject follow-up.

III.5.2. Assessment scope by the EC

The assessment will be carried out to ensure the validity of the trial, with particular reference to:

- protection of persons, especially the protection of subjects participating in the trial;
- the relevance of the research, the appropriate assessment of anticipated benefits and risks and duly justified conclusions.

The data will essentially document protection of persons (information and consent, recruitment procedures) and the qualifications of the investigators/suitability of research centres.

III.6. Correspondence from ANSM and/or CE in the event of any substantiated objections or any questions

III.6.1. In the case of questions from the ANSM

This correspondence will be sent by e-mail by the DMCDIV Division:

- To the sponsor
- With a copy to the EC concerned
- With a copy to: phasepilote.reglementDM@ansm.sante.fr

As under current procedure, the sponsor will be asked to acknowledge to the e-mail sent.

III.6.2. In the case of questions from the EC

This correspondence will be sent by e-mail by the EC concerned:

- To the sponsor (via the IS)
- With a copy of the document to the DMCDIV Division [*]
- With a copy to: phasepilote.reglementDM@ansm.sante.fr

[*] The person responsible for following the application within the ANSM's DMCDIV Division, whose contact details (telephone and e-mail) are given in the correspondence already issued by this division (e.g. the acknowledgement of receipt)

III.7. Sponsor's responses to questions that may be asked by the ANSM and/or EC

The sponsor's responses to ANSM and EC requests must be sent respectively to ANSM and the EC in accordance with the milestone at D45 at the latest.

Presentation of documents

The documents should be gathered according to the subject's matter and questions raised, for example:

- non-clinical data;
- clinical data

III.7.1. Responses sent to the ANSM

The sponsor's responses to ANSM must be sent to ANSM in accordance with the milestone at D45 at the latest.

E-mail responses should be sent to the following address: phasepilote.reglementDM@ansm.sante.fr.

It is very important to complete the "subject" field in the e-mail providing information as indicated in paragraph III.1.2 of this document, in order to facilitate the administrative management of this correspondence.

III.7.2. Responses sent to the EC

The sponsor's responses to EC must be sent to the IS portal within 12 days of receipt of the question mail (in accordance with the European regulation).

III.8. Final notification

It is proposed that:

The final opinion of the CE will be sent **1 to 2 days before the notification milestone date at the latest**

- to the DMCDIV Division [*]
- With a copy to: phasepilote.reglementDM@ansm.sante.fr

and to the sponsor (via the IS portal).

[*] The person responsible for following the application within the ANSM's DMCDIV Division, whose contact details (telephone and e-mail) are given in the correspondence already issued by this division (e.g. the acknowledgement of receipt).

The ANSM's notification of its decision is accompanied by the opinion of EC concerned.

The DMCDIV Division will send this notification by e-mail:

- To the sponsor
- With a copy to the EC concerned
- With a copy to: phasepilote.reglementDM@ansm.sante.fr

III.9. Summary table of communications between the Sponsor / EC / ANSM

	Sponsor	EC	ANSM
Same day submission	On the IS portal: To the ANSM specifying the EC concerned: phasepilote.reglementDM@ansm.sante.fr		
Validation		The relevant EC will send this letter by e-mail: <ul style="list-style-type: none"> To the sponsor With a copy to: phasepilote.reglementDM@ansm.sante.fr 	The DMCDIV Division will send this letter by e-mail: <ul style="list-style-type: none"> To the sponsor With a copy to the EC concerned With a copy to: phasepilote.reglementDM@ansm.sante.fr
Response to Validation	On the IS portal: To the ANSM: phasepilote.reglementDM@ansm.sante.fr		
Transmission of questions		The EC concerned will send this letter by e-mail: <ul style="list-style-type: none"> To the sponsor via the IS With a copy to the DMCDIV Division⁴ With a copy to: phasepilote.reglementDM@ansm.sante.fr 	The DMCDIV Division will send this letter by e-mail: <ul style="list-style-type: none"> To the sponsor With a copy to the relevant EC With a copy to: phasepilote.reglementDM@ansm.sante.fr
Response to the questions letter	On the IS portal: To the ANSM: phasepilote.reglementDM@ansm.sante.fr		
Final notification		The EC concerned sends their opinion on the CI application 1 to 2 days before the notification milestone date by <u>e-mail</u> : <ul style="list-style-type: none"> To the DMCDIV Division⁵ With a copy to: phasepilote.reglementDM@ansm.sante.fr 	The ANSM's notification of its decision is accompanied by the opinion of the EC concerned The DMCDIV Division will send this notification by <u>e-mail</u> : <ul style="list-style-type: none"> To the sponsor With a copy to the relevant EC With a copy to: phasepilote.reglementDM@ansm.sante.fr

Any communication between the ANSM and the EC must be formalised by filling in the e-mail's subject field as follows: **Ph pilote-AIC MD / ANSM reference / IDRCB no.** and specifying, depending on the processing stage: **validation, transmission of questions, final opinion.**

⁴ The person responsible for following the application within the ANSM's Division, whose contact details (telephone or e-mail) are given in the correspondence already issued by this division (e.g. the acknowledgement of receipt)

IV. APPENDICES

Appendix 1: List of documents making up the CI application file set out in Annex XV of the Medical Device Regulation

Appendix 2: Summary of a clinical investigational plan

Appendix 3: Comparison of the CI application processing times (Medical Device Regulation / pilot phase)

Appendix 1: List of documents making up the CI application file set out in Annex XV of the Medical Device Regulation

Extract from the Medical Device Regulation

ANNEX XV CLINICAL INVESTIGATIONS

CHAPTER II DOCUMENTATION REGARDING THE APPLICATION FOR CLINICAL INVESTIGATION

For investigational devices covered by Article 62, the sponsor shall draw up and submit the application in accordance with Article 70 accompanied by the following documents:

1. Application form [1]

The application form shall be duly filled in, containing information regarding:

- 1.1. name, address and contact details of the sponsor and, if applicable, name, address and contact details of its contact person or legal representative in accordance with Article 62(2) established in the Union;
- 1.2. if different from those in Section 1.1, name, address and contact details of the manufacturer of the device intended for clinical investigation and, if applicable, of its authorized representative;
- 1.3. title of the clinical investigation;
- 1.4. status of the clinical investigation application (i.e. first submission, resubmission, significant amendment);
- 1.5. details and/or reference to the clinical evaluation plan;
- 1.6. If the application is a resubmission with regard to a device for which an application has been already submitted, the date or dates and reference number or numbers of the earlier application or in the case of significant amendment, reference to the original application. The sponsor shall identify all of the changes from the previous application together with a rationale for those changes, in particular, whether any changes have been made to address conclusions of previous competent authority or ethics committee reviews;
- 1.7. if the application is submitted in parallel with an application for a clinical trial in accordance with Regulation (EU) No 536/2014, reference to the official registration number of the clinical trial;
- 1.8. identification of the Member States and third countries in which the clinical investigation is to be conducted as part of a multicenter or multinational study at the time of application;
- 1.9. a brief description of the investigational device, its classification and other information necessary for the identification of the device and device type;
- 1.10. information as to whether the device incorporates a medicinal substance, including a human blood or plasma derivative or whether it is manufactured utilizing non-viable tissues or cells of human or animal origin, or their derivatives;
- 1.11. summary of the clinical investigation plan including the objective or objectives of the clinical investigation, the number and gender of subjects, criteria for subject selection, whether there are subjects under 18 years of age, design of the investigation such as controlled and/or randomized studies, planned dates of commencement and of completion of the clinical investigation;
- 1.12. if applicable, information regarding a comparator device, its classification and other information necessary for the identification of the comparator device;
- 1.13. evidence from the sponsor that the clinical investigator and the investigational site are capable of conducting the clinical investigation in accordance with the clinical investigation plan;
- 1.14. details of the anticipated start date and duration of the investigation;
- 1.15. details to identify the notified body, if already involved at the stage of application for a clinical investigation;
- 1.16. confirmation that the sponsor is aware that the competent authority may contact the ethics committee that is assessing or has assessed the application; and
- 1.17. the statement referred to in Section 4.1.

2. Investigator's Brochure

The investigator's brochure (IB) shall contain the clinical and non-clinical information on the investigational device that is relevant for the investigation and available at the time of application. Any updates to the IB or other relevant information that is newly available shall be brought to the attention of the investigators in a timely manner. The IB shall be clearly identified and contain in particular the following information:

- 2.1. Identification and description of the device, including information on the intended purpose, the risk classification and applicable classification rule pursuant to Annex VIII [1], design and manufacturing of the device and reference to previous and similar generations of the device.
- 2.2. Manufacturer's instructions for installation, maintenance, maintaining hygiene standards and for use, including storage and handling requirements, as well as, to the extent that such information is available, information to be placed on the label, and instructions for use [1] to be provided with the device when placed on the market. In addition, information relating to any relevant training required.
- 2.3. Pre-clinical evaluation based on relevant pre-clinical testing and experimental data, in particular regarding in-design calculations, *in vitro* tests, *ex vivo* tests, animal tests, mechanical or electrical tests, reliability tests, sterilization validation, software verification and validation, performance tests, evaluation of biocompatibility and biological safety, as applicable.
- 2.4. Existing clinical data, in particular:
 - from relevant scientific literature available relating to the safety, performance, clinical benefits to patients, design characteristics and intended purpose of the device and/or of equivalent or similar devices;
 - other relevant clinical data available relating to the safety, performance, clinical benefits to patients, design characteristics and intended purpose of equivalent or similar devices of the same manufacturer, including length of time on the market and a review of performance, clinical benefit and safety-related issues and any corrective actions taken.
- 2.5. Summary of the benefit-risk analysis and the risk management, including information regarding known or foreseeable risks, any undesirable effects, contraindications and warnings.
- 2.6. In the case of devices that incorporate a medicinal substance, including a human blood or plasma derivative or devices manufactured utilizing non-viable tissues or cells of human or animal origin, or their derivatives, detailed information on the medicinal substance or on the tissues, cells or their derivatives, and on the compliance with the relevant general safety and performance requirements and the specific risk management in relation to the substance or tissues, cells or their derivatives, as well as evidence for the added value of incorporation of such constituents in relation to the clinical benefit and/or safety of the device.
- 2.7. A list detailing the fulfilment of the relevant general safety and performance requirements set out in Annex I, including the standards and CS applied, in full or in part, as well as a description of the solutions for fulfilling the relevant general safety and performance requirements, in so far as those standards and CS have not or have only been partly fulfilled or are lacking.
- 2.8. A detailed description of the clinical procedures and diagnostic tests used in the course of the clinical investigation and in particular information on any deviation from normal clinical practice.

3. Clinical Investigation Plan

The clinical investigation plan (CIP) shall set out the rationale, objectives, design methodology, monitoring, conduct, record-keeping and the method of analysis for the clinical investigation. It shall contain in particular the information as laid down in this Annex. If part of this information is submitted in a separate document, it shall be referenced in the CIP.

3.1. General

- 3.1.1. Single identification number of the clinical investigation, as referred to in Article 70(1). [1]
- 3.1.2. Identification of the sponsor — name, address and contact details of the sponsor and, where applicable, the name, address and contact details of the sponsor's contact person or legal representative in accordance with Article 62 established in the Union.
- 3.1.3. Information on the principal investigator at each investigational site, the coordinating investigator for the investigation, the address details for each investigational site and the emergency contact details for the principal investigator at each site. The roles, responsibilities and qualifications of the various kinds of investigators shall be specified in the CIP.
- 3.1.4. A brief description of how the clinical investigation is financed and a brief description of the agreement between

the sponsor and the site. [1]

3.1.5. Overall synopsis of the clinical investigation, in an official Union language determined by the Member State concerned.

3.2. Identification and description of the device, including its intended purpose, its manufacturer, its traceability, the target population, materials coming into contact with the human body, the medical or surgical procedures involved in its use and the necessary training and experience for its use, background literature review, the current state of the art in clinical care in the relevant field of application and the proposed benefits of the new device.

3.3. Risks and clinical benefits of the device to be examined, with justification of the corresponding expected clinical outcomes in the clinical investigation plan.

3.4. Description of the relevance of the clinical investigation in the context of the state of the art of clinical practice.

3.5. Objectives and hypotheses of the clinical investigation.

3.6. Design of the clinical investigation with evidence of its scientific robustness and validity.

3.6.1. General information such as type of investigation with rationale for choosing it, for its endpoints and for its variables as set out in the clinical evaluation plan.

3.6.2. Information on the investigational device, on any comparator and on any other device or medication to be used in the clinical investigation.

3.6.3. Information on subjects, selection criteria, size of investigation population, representativeness of investigation population in relation to target population and, if applicable, information on vulnerable subjects involved such as children, pregnant women, immuno-compromised or, elderly subjects.

3.6.4. Details of measures to be taken to minimise bias, such as randomisation, and management of potential confounding factors.

3.6.5. Description of the clinical procedures and diagnostic methods relating to the clinical investigation and in particular highlighting any deviation from normal clinical practice.

3.6.6. Monitoring plan.

3.7. Statistical considerations, with justification, including a power calculation for the sample size, if applicable.

3.8. Data management.

3.9. Information about any amendments to the CIP.

3.10. Policy regarding follow-up and management of any deviations from the CIP at the investigational site and clear prohibition of use of waivers from the CIP.

3.11. Accountability regarding the device, in particular control of access to the device, follow-up in relation to the device used in the clinical investigation and the return of unused, expired or malfunctioning devices.

3.12. Statement of compliance with the recognised ethical principles for medical research involving humans, and the principles of good clinical practice in the field of clinical investigations of devices, as well as with the applicable regulatory requirements.

3.13. Description of the Informed consent process.

3.14. Safety reporting, including definitions of adverse events and serious adverse events, device deficiencies, procedures and timelines for reporting.

3.15. Criteria and procedures for follow-up of subjects following the end, temporary halt or early termination of an investigation, for follow-up of subjects who have withdrawn their consent and procedures for subjects lost to follow-up. Such procedures shall for implantable devices, cover as a minimum traceability.

3.16. A description of the arrangements for taking care of the subjects after their participation in the clinical investigation has ended, where such additional care is necessary because of the subjects' participation in the clinical investigation and where it differs from that normally expected for the medical condition in question.

3.17. Policy as regards the establishment of the clinical investigation report and publication of results in accordance with the legal requirements and the ethical principles referred to in Section 1 of Chapter I. [1]

3.18. List of the technical and functional features of the device, with specific mention of those covered by the investigation.

3.19. Bibliography.

4. Other information

4.1. A signed statement by the natural or legal person responsible for the manufacture of the investigational device that the device in question conforms to the general safety and performance requirements [1] apart from the aspects covered by the clinical investigation and that, with regard to those aspects, every precaution has been taken to protect the health and safety of the subject.

4.2. Where applicable according to national law, copy of the opinion or opinions of the ethics committee or committees concerned. Where according to national law the opinion or opinions of the ethics committee or committees is not required at the time of the submission of the application, a copy of the opinion or opinions shall be submitted as soon as available. [1]

4.3. Proof of insurance cover or indemnification of subjects in case of injury, pursuant to Article 69 and the corresponding national law.

4.4. Documents to be used to obtain informed consent, including the patient information sheet and the informed consent document.

4.5. Description of the arrangements to comply with the applicable rules on the protection and confidentiality of personal data, in particular:

- organizational and technical arrangements that will be implemented to avoid unauthorized access, disclosure, dissemination, alteration or loss of information and personal data processed;
- a description of measures that will be implemented to ensure confidentiality of records and personal data of subjects; and
- a description of measures that will be implemented in case of a data security breach in order to mitigate the possible adverse effects.

4.6. Full details of the available technical documentation, for example detailed risk analysis/management documentation or specific test reports, shall, upon request, be submitted to the competent authority reviewing an application.

[1] not applicable during the pilot phase

Appendix 2: Summary of a clinical investigational plan

The summary is a **mandatory supporting document** for any clinical trial application.

Objective

The summary must provide each member of the Committee with an **easily understandable summary of the research project** in order that they can participate in the deliberation process.

Content

It must contain at least the following information:

- Identification of the plan (title, reference), the sponsor and the investigator (coordinator).
- Justification of the research's relevance.
- The primary objective and any secondary objectives.
- A presentation of the expected benefits to the subjects and society.
- A presentation of the risks incurred by the participants and the constraints they will be subjected to.
- The number and characteristics of the subjects, together with the number of subjects in France.
- The selected methodology: assessment criteria, study plan (potential diagram), type of analysis (descriptive, comparative), number of subjects needed, interim analyses, termination rules.
- The setting up of an independent security committee or justification for not having one.
- Justification of the determined time period in which subjects are prohibited from taking part in other research.
- The provisional research schedule.
- Presentation of the research sites and characteristics of the investigators.
- The arrangements for monitoring and taking care of subjects after their participation in an MD CI has ended, particularly with an implantable device, where these arrangements differ from those normally expected.

Format

- The summary **must be written in French**.
- The document must be paginated and include a date and version number.
- This document binds the sponsor.

Appendix 3: Comparison of the CI application processing times (Medical Device Regulation / pilot phase)

Processing times for clinical investigation authorisation applications

	Medical Device Regulation Non-coordinated assessment procedure (Article 70)	Medical Device Regulation Coordinated assessment procedure (Article 78)	Pilot phase
Date received	D0	D0	D0
Confirmation of validation	+10 days = D10	+10 days = D10	+7 days = D7
<i>Receipt of the sponsor's answers if not validated</i>	*+10 days = D20	+10 days = D20	
<i>Confirmation of validation</i>	*+5 days = D25	+5 days = D25	+26 days = D33 if application admissible straight away
Assessment of dossier	Stage not specified in the Medical Device Regulation	+26 days [2] = D36 if application admissible straight	
Coordination between Member States		+12 days = D48	
Consolidation of questions by rapporteur Member State		+7 days = D55	
Finalising initial report and/or sending questions	Stage not specified in the Medical Device Regulation	D55	
Clock stop	No	Yes	No
Receipt of the sponsor's answers	Stage not specified in the Medical Device Regulation	+12 days = D67	+12 days = D45
Final assessment report / coordination of assessment	Stage not specified in the Medical Device Regulation	Deadline not specified in the Medical Device	+12 days = D57
Transmission of the notification	+45 days [1] = D55 if application admissible straight	+5 days	+3 days = D60
Total maximum instruction time for an validated application <u>without questions</u>	55 days	Deadline not specified in the Medical Device Regulation	36 days
Total maximum instruction time for an validated application <u>with questions</u>	Not specified in the Medical Device Regulation	Not specified in the Medical Device Regulation	60 days

[1]: + 20 days if consultation with experts (for any MD)

[2]: + 50 days if consultation with experts for Class IIb or III MDs only

V. GLOSSARY

ANSM	<i>Agence Nationale de Sécurité du Médicament et des produits de santé</i> [French National Agency for Medicines and Health Products Safety]
AR	Acknowledgement of receipt
CI	Clinical investigation
CIA	Clinical investigation authorisation
CNCP	<i>Conférence nationale des comités de protection des personnes</i> [National Conference of Ethics Committees]
CNRIPH	<i>Commission Nationale de la Recherche impliquant la personne humaine</i> [National Commission for Research Involving Human Subjects]
CT	Clinical trial
DMCDIV	<i>Direction des dispositifs médicaux, des cosmétiques et des dispositifs de diagnostic in vitro</i> [Division for Medical Devices, Cosmetics and In Vitro Diagnostic Medical Devices]
EC	Ethics Committee
EU	European Union
GDPR	Regulation No. 2016/679 called the General Data Protection Regulation
IB	Investigator's Brochure
IC	[Interim correspondence / questions letter] <i>Courrier intermédiaire (questions)</i>
IDRCB number	Unique national identification number for clinical trials (excluding medicinal products)
IS portal	Informatics system portal

Division for Medical Devices, Cosmetics and In Vitro Diagnostic Medical Devices

DAPTEC:	Team in charge of dermatology, patient assistance, transfusion and transplantation, endocrinology, aesthetics and cosmetics products
DIALOG:	Team in charge of diagnosis, x-ray systems and information systems products
ETIMOS:	Team in charge of visceral surgery, gynaecology, urology and orthopaedics products
FLOW:	Team in charge of cardiology, vascular and surgical products/equipments
NOPAD:	Team in charge of neurology, ophthalmology/ENT, chest medicine, anaesthesia, dental and disinfection products