NL	FR
Doel van deze QC-tool? *De opdrachten van de Ethische comités en het College betreffende kwaliteitscontrole staan beschreven in de wetgeving. Zie tablad Wetgeving.* *Het College vraagt aan de ECs om aan de hand van de kwaliteitscontrole-tool (QC-tool)* *- jaarlijks een zelfevaluatie te doen, en* *- om de 3 jaar een interne audit te laten uitvoeren (door een instantie die onafhankelijk is van het EC)*	***Le but de cet outil de QC?*** *Les tâches des comités d'éthique et du Collège concernant le contrôle de la qualité sont décrites dans la législation. Voir onglet Législation.* *Le Collège demande au CE d'utiliser l'outil de contrôle de qualité pour la réalisation* *- d'une autoévaluation annuelle; et* *- d'un audit interne tous les 3 ans (par une autorité indépendante de la CE)*
1e rapport wordt verwacht tegen 31/01/2024 voor studies van 2023, geëvalueerd volgens de CTR, MDR en/of IVDR.	1er rapport est demandé pour le 31/01/2024 pour les études de 2023, évaluées selon le CTR, MDR ou/et IVDR.

FINAL VERSION dd: 30/01/2023

NL

De opdrachten van de ECs en het College betreffende kwaliteitscontrole staan in de wetgeving als volgt beschreven.

Wet van 7 mei 2017

Afdeling 2. - Ethisch comités

Art. 8. De Ethische comités verzekeren een hoge kwaliteit. Zij zetten hiertoe een systeem op van kwaliteitscontrole.

De kwaliteitscontrole berust op een onafhankelijke, objectieve, systematische en methodologische aanpak onder toezicht van het College.

De Ethische comités waken door middel van dit systeem van kwaliteitscontrole in het bijzonder over de onafhankelijkheid en de vermijding van belangenconflicten, conform artikel 6, § 3, tweede lid, 2°, van deze wet.

De Koning kan de nadere regels bepalen van de kwaliteitscontrole.

Afdeling 3. - Het College

Art. 9.

§ 3. Het College heeft als opdracht:

5° het coördineren, harmoniseren, ondersteunen, evalueren en opvolgen van de kwaliteitscontrole verricht door de Ethische comités. Het College kan hiertoe aanbevelingen uitvaardigen;

Koninklijk Besluit van 9 oktober 2017

Onderafdeling 2. - Kwaliteitssysteem

Art. 8. Het Ethisch comité beschikt over een kwaliteitssysteem voor de toepassing van de beginselen en richtsnoeren inzake goede klinische praktijken, zoals voor het publiek beschikbaar gesteld door de Europese Commissie op grond van artikel 47, derde lid, van de verordening.

Daartoe werkt het Ethisch comité schriftelijke procedures en hun documentatie uit, die ten minste betrekking hebben op:

1° de samenstelling van het Ethisch comité met vermelding van de kwalificaties van de leden en de wijze waarop het is samengesteld en waarop de leden worden benoemd;

2 ° de verplichtingen en verantwoordelijkheden van de leden op basis van hun hoedanigheid, met name het volgen van opleidingen voor de evaluatie van klinische proeven, alsook de taken en verantwoordelijkheden van het administratief personeel;

3° de planning, aankondiging aan de leden en de organisatie van vergaderingen;

4° de beoordeling van aanvragen tot toelating van klinische proeven, substantiële wijziging en latere toevoeging;

5° het formuleren van adviezen, hun gedocumenteerde, uitdrukkelijke motivering, zowel juridisch als feitelijk, en hun vorm(en);

6° het beroep doen op externe deskundigen, externe patiëntvertegenwoordigers en eender welke andere externe persoon en hun aanduiding;

7° de besluitvormingsprocedure om adviezen uit te brengen alsook de schriftelijke procedure bedoeld in artikel 6, § 4;

9° het beheer van de documenten ingediend bij en opgesteld door het Ethisch comité alsook de archivering ervan;

10° de communicatie tussen het Ethisch comité en de andere belanghebbenden bij de toelating van klinische proeven;

11° de regels inzake vertrouwelijkheid;

12° het opstellen en bijwerken van de procedures.

Onderafdeling 1. - Erkenningsprocedure

Art. 17. Het FAGG vergewist zich ervan dat alle verstrekte inlichtingen correct zijn overeenkomstig artikel 16 en dat het Ethisch comité voldoet aan de voorwaarden opgelegd door de artikelen 6, §§ 2 en 3, van de wet en afdeling 2 van dit hoofdstuk.

Het FAGG kan daartoe elke vraag stellen aan het ziekenhuis dat of aan de rechtspersoon die de erkenningsaanvraag heeft ingediend, eisen dat het College een bondige evaluatie verschaft van het Ethisch comité, met name van het kwaliteitscontrolesysteem en de naleving ervan en de naleving en coherente toepassing van de verordening, de wet, en haar uitvoeringsbesluiten, indien het reeds erkend was, en elke inspectie verrichten die het nuttig acht.

FR

Les missions des EC et du Collège concernant le contrôle de la qualité sont décrites dans la législation comme suit.

Loi 7 mai 2017

Section 2. - Des Comités d'éthique

Art. 8. Les Comités d'éthique assurent une haute qualité. Ils mettent en oeuvre à cet effet un système de contrôle qualité.

Le contrôle qualité repose sur une approche indépendante, objective, systématique et méthodologique sous la surveillance du Collège.

Les Comités d'éthique veillent en particulier, par ce système de contrôle qualité, à l'indépendance et à éviter les conflits d'intérêts, conformément à l'article 6, § 3, alinéa 2, 2°, de la présente loi.

Le Roi peut fixer les modalités du contrôle qualité.

Section 3. - Du Collège

Art. 9.

§ 3. Le Collège a pour mission :

5° de coordonner, d'harmoniser, de soutenir, d'évaluer et de suivre le contrôle de la qualité effectué par les Comités d'éthique. Le Collège peut adopter des recommandations à cet effet ;

Arrêté royal 9 octobre 2017

Sous-section 2. - Système de qualité

Art. 8. Le Comité d'éthique dispose d'un système de qualité pour l'application des principes et des lignes directrices en matière de bonnes pratiques cliniques, telles que rendues publiques par la Commission européenne en application de l'article 47, alinéa 3, du règlement.

Le Comité d'éthique rédige à cet effet des procédures écrites et leurs documentations qui concernent au moins :

1° la composition du comité d'éthique en indiquant les qualifications des membres et la façon dont il est composé et dont les membres sont nommés;

2° les obligations et les responsabilités de ses membres en fonction de leur qualité, notamment le suivi de formations pour l'évaluation d'essais cliniques, ainsi que les obligations et responsabilités du personnel administratif;

3° la planification, l'annonce à ses membres et l'organisation de réunions;

4° l'évaluation des demandes d'autorisation d'essais cliniques, de modification substantielle et d'élargissement ultérieur;

5° la formulation des avis, leur motivation expresse documentée, tant juridique que factuelle, et leur(s) forme(s);

6° le recours à des experts externes, des représentants de patients externes ou toute autre personne externe et leur désignation;

7° la procédure de décision pour rendre les avis ainsi que la procédure écrite visée à l'article 6, § 4;

9° la gestion des documents soumis au et rédigés par le Comité d'éthique ainsi que leur archivage;

10° la communication entre le Comité d'éthique et les autres intervenants dans l'autorisation des essais cliniques;

11° les règles de confidentialité;

12° la rédaction et la mise à jour des procédures.

Sous-section 1. - Procédure d'agrément

Art. 17. L'AFMPS s'assure que les renseignements fournis sont exacts en application de l'article 16 et que le Comité d'éthique répond aux conditions imposées par les articles 6, §§ 2 et 3, de la loi et la section 2 du présent chapitre.

L'AFMPS peut, à cette fin, poser toute question à l'hôpital ou à la personne morale qui a introduit la demande d'agrément, requérir du Collège une évaluation succincte du Comité d'éthique, notamment du système de contrôle qualité et du respect de celui-ci et de l'application cohérente du règlement, de la loi, et de ses arrêtés d'exécution, si celui-ci a déjà été agréé, et diligenter toute inspection qui lui semble utile.

Information on the Ethics committee	
Name of the Ethics committee:	*Name of the EC*
Date of completion:	*Date of completion*
Name of the person that completed the tool:	*Name, Firstname*
Function of the person that completed the tool:	*Function*

QC tool		
SECTION A. Legal requirements on Composition, responsibilities and training of the members of the EC	*Responses (green boxes)*	*Additional information/comment*
1. The requirements concerning the composition of the EC as described in the law of 7 May 2017 Art. 6. § 2. are met		
2. A list with starting date of all members, including his/her role is attached to this report.		
Note: The sheet "Ledenlijst/Liste des membres" can be used or an alternative document containing the same information.		
3. For each member an up-to-date CV is available		
4. For each member training in GCP, applicable (national and european) legislation and the EC's own procedures is documented.		
Note: This training can be organized by the EC or by an external partner.		
Note: It is recommended to have a training matrix for the EC. The sheet "Training matrix/Matrice de formation" can be used or an alternative document containing the same information. Training is preferably adapted to the role of the EC member.		
5. An overview of the trainings followed by the members of the EC as from 2023 is attached to this report. Please specify the trainings for each member individually.		
Note: Only trainings deemed necessary for the evaluation of clinical studies should be given, as stated in art. 8 of the Royal Decree of 9/10/2017. The sheet «Traininglist» can can be used or an alternative document containing the same information.		
6. For each member a signed and dated declaration of interest is available, which is yearly verified and updated when necessary		
7. For each external expert consulted a signed and dated declaration of interest is available		
Note: An external expert is a person that is external to the Ethics committee who receives the dossier and has no conflict of interest with the dossier. This person should also have provided its CV to the EC.		
8. For each member, the obligations and responsibilities are described		
Note: It is recommended to have an allocation matrix that defines which aspect of the dossier is reviewed per role of the members. This is merely an informative question that does not have a value judgment attached to it.		
9. It is documented that each member has received all EC procedures, this can be either by a signed agreement (may be an acknowledgment of receipt in case the procedures are provided by mail) or a documented training.		
10. Each member has signed an agreement to acknowledge that he will ensure confidentiality.		
11. Do you have KPIs to evaluate the functioning of your EC members, e.g. presence of the members at meetings, time interval until the delivery of an opinion, presence of an annual report, responsiveness of the EC members, …		
12. If KPIs are used, specify which KPI's are monitored.	KPIs monitored:	
Note: This is merely an informative question that does not have a value judgment attached to it.		

SECTION B. Document management	*Responses (green boxes)*	*Additional information/comment*
1. There is an up-to-date (< 2 years) quality manual for the EC available, this includes at least the requirements as given in the Royal Decree of 9/10/2017, Art. 8		
Note : The quality manual may be the rules of internal order of the EC, as long as it contains all the information given below.		
1.1° de samenstelling van het Ethisch comité met vermelding van de kwalificaties van de leden en de wijze waarop het is samengesteld en waarop de leden worden benoemd; 1.1° la composition du comité d'éthique en indiquant les qualifications des membres et la façon dont il est composé et dont les membres sont nommés;		
1.2° de verplichtingen en verantwoordelijkheden van de leden op basis van hun hoedanigheid, met name het volgen van opleidingen voor de evaluatie van klinische proeven, alsook de taken en verantwoordelijkheden van het administratief personeel; 1.2° les obligations et les responsabilités de ses membres en fonction de leur qualité, notamment le suivi de formations pour l'évaluation d'essais cliniques, ainsi que les obligations et responsabilités du personnel administratif;		
1.3° de planning, aankondiging aan de leden en de organisatie van vergaderingen; 1.3° la planification, l'annonce à ses membres et l'organisation de réunions;		
1.4° de beoordeling van aanvragen tot toelating van klinische proeven, substantiële wijziging en latere toevoeging; 1.4° l'évaluation des demandes d'autorisation d'essais cliniques, de modification substantielle et d'élargissement ultérieur;		
1.5° het formuleren van adviezen, hun gedocumenteerde, uitdrukkelijke motivering, zowel juridisch als feitelijk, en hun vorm(en); 1.5° la formulation des avis, leur motivation expresse documentée, tant juridique que factuelle, et leur(s) forme(s);		
1.6° het beroep doen op externe deskundigen, externe patiëntvertegenwoordigers en eender welke andere externe persoon en hun aanduiding; 1.6° le recours à des experts externes, des représentants de patients externes ou toute autre personne externe et leur désignation;		
1.7° de besluitvormingsprocedure om adviezen uit te brengen alsook de schriftelijke procedure bedoeld in artikel 6, § 4; 1.7° la procédure de décision pour rendre les avis ainsi que la procédure écrite visée à l'article 6, § 4;		
1.9° het beheer van de documenten ingediend bij en opgesteld door het Ethisch comité alsook de archivering ervan; 1.9° la gestion des documents soumis au et rédigés par le Comité d'éthique ainsi que leur archivage;		
1.10° de communicatie tussen het Ethisch comité en de andere belanghebbenden bij de toelating van klinische proeven; 1.10° la communication entre le Comité d'éthique et les autres intervenants dans l'autorisation des essais cliniques;		
1.11° de regels inzake vertrouwelijkheid; 1.11° les règles de confidentialité;		
1.12° het opstellen en bijwerken van de procedures. 1.12° la rédaction et la mise à jour des procédures.		
2. It can be demonstrated that all procedures established by the EC are re-evaluated on a systematic basis		
Were all procedures updated according to the predefined frequency?		
3. In the past year, for each clinical trial completed, subsequent documents were archived upon completion (according to the Royal Decree of 9/10/2017, Art. 9)		

SECTION C. Operational functioning of the EC (samples to be checked)	Responses (green boxes)	Additional information/comment
Select 5 dossiers that were evaluated by the EC in 2023 and answer per dossier all questions of section C. *If possible, select dossiers that are belonging to different categories, i.e. :* *1)CTA, initial dossier for which Belgium is RMS* *2)CTA, initial dossier for which Belgium is MSC* *3)CTA, substantial modification dossier (Belgium is RMS or MSC)* *4)CIA or PSA consolidated opinion pathway, initial dossier* *5)CIA or PSA consolidated opinion pathway, substantial modification dossier*		
Application 1	*application number (if applicable add _SM, _RMS, _MSC)*	
1. The decision-making procedure for the final advice is followed		
Criteria that must be checked:		
1.1. Specify which member(s) reviewed the dossier? Please specify only the role(s).	*role(s) of the member(s)*	
1.2. Was the selection of the reviewers done according to your procedure/allocation matrix ?		
1.3. If there is a deviation of the decision making procedure, were the reasons documented ?		
1.4. If an expedited procedure was used, were the reasons documented ?		
1.5. If an expedited procedure was used, how many EC members were involved in the decision ?	Not applicable/*Number of members involved in expedited procedure*	
1.6. Was it checked if an external expert was needed?		
1.7. If an external expert was appointed, which field of expertise was lacking ?	Not applicable/ *Field of expertise of external expert*	
Note: An external expert is a person that is external to the Ethics committee who receives the dossier and has no conflict of interest with the dossier. This person should also have provided its CV to the EC.		
1.8. Was the final advice checked by an EC member before it is provided to the sponsor? e.g. were the questions reviewed and are instructions for the sponsor clear		
1.9. If yes, specify by whom (which role of the EC member).	Not applicable/Who checked the advice (role)	
1.10. Is it checked if the ICF is in line with the protocol and Investigators' Brochure (using e.g. the Assessment report Part II or an equivalent checklist)?		
2. The criteria by which the vote is legally valid are followed		
Note: The validity of the vote is as described in art. 6 of the Royal Decree of 9/10/2017		
Criteria that should be checked:		
2.1. Was the quorum (regarding role and the right to vote) for the meeting met ?		
2.2. Was the voting procedure followed?		
2.3. Is a list of participants available?		
2.4. Was it documented who provided written comments ?		
2.5. Have all members assigned to review the dossier, provided comments (using the allocation matrix, if available)?		
3. All meetings are announced within the set timings		
Criteria that should be checked:		
3.1. How many days before the meeting was the dossier provided to the EC members?	*number of days*	
3.2. Was the dossier provided within the timelines given in your procedure?		
3.3. Was the dossier discussed during a plenary session of the EC or was a written procedure used?	plenary session / written procedure	
Note: With a plenary session we refer to Art 6 §1-3 of the Royal Decree of 9/10/2017; with a written procedure we refer to Art 6 §4 of the Royal Decree of 9/10/2017		
3.4. Was the EC meeting announced within the set timing?		
4. Minutes of the EC meetings		
Criteria that should be checked:		
Do the minutes of the EC meeting contain :		
4.1. - list of presence		
4.2. - possible conflicts of interest		
4.3. - written record of the discussion held		
4.4. - decision		
4.5. - justification of the opinion		
4.6. If one of the above criteria was answered with "No", please specify the reason.	The reason is…	
4.7. Who validated the minutes ?	member/chairman/…	
4.8. Were all communications archived, i.e. communications with the CT-College and other stakeholders involved in the decision process (e.g. external expert)?		

Application 2	*application number (if applicable add _SM, _RMS, _MSC)*	
1. The decision-making procedure for the final advice is followed		
Criteria that must be checked:		
1.1. Specify which member(s) reviewed the dossier? Please specify only the role(s).	*role(s) of the member(s)*	
1.2. Was the selection of the reviewers done according to your procedure/allocation matrix ?		
1.3. If there is a deviation of the decision making procedure, were the reasons documented ?		
1.4. If an expedited procedure was used, were the reasons documented ?		
1.5. If an expedited procedure was used, how many EC members were involved in the decision ?	Not applicable/*Number of members involved in expedited procedure*	
1.6. Was it checked if an external expert was needed?		
1.7. If an external expert was appointed, which field of expertise was lacking ?	Not applicable/ *Field of expertise of external expert*	
Note: An external expert is a person that is external to the Ethics committee who receives the dossier and has no conflict of interest with the dossier. This person should also have provided its CV to the EC.		
1.8. Was the final advice checked by an EC member before it is provided to the sponsor? e.g. were the questions reviewed and are instructions for the sponsor clear		
1.9. If yes, specify by whom (which role of the EC member).	Not applicable/Who checked the advice (role)	
1.10. Is it checked if the ICF is in line with the protocol and Investigators' Brochure (using e.g. the Assessment report Part II or an equivalent checklist)?		

2. The criteria by which the vote is legally valid are followed		
Note: The validity of the vote is as described in art. 6 of the Royal Decree of 9/10/2017		
Criteria that should be checked:		
2.1. Was the quorum (regarding role and the right to vote) for the meeting met ?		
2.2. Was the voting procedure followed?		
2.3. Is a list of participants available?		
2.4. Was it documented who provided written comments ?		
2.5. Have all members assigned to review the dossier, provided comments (using the allocation matrix, if available)?		

3. All meetings are announced within the set timings		
Criteria that should be checked:		
3.1. How many days before the meeting was the dossier provided to the EC members?	*number of days*	
3.2. Was the dossier provided within the timelines given in your procedure?		
3.3. Was the dossier discussed during a plenary session of the EC or was a written procedure used?	plenary session / written procedure	
Note: With a plenary session we refer to Art 6 §1-3 of the Royal Decree of 9/10/2017; with a written procedure we refer to Art 6 §4 of the Royal Decree of 9/10/2017		
3.4. Was the EC meeting announced within the set timing?		

4. Minutes of the EC meetings		
Criteria that should be checked:		
Do the minutes of the EC meeting contain :		
4.1. - list of presence		
4.2. - possible conflicts of interest		
4.3. - written record of the discussion held		
4.4. - decision		
4.5. - justification of the opinion		
4.6. If one of the above criteria was answered with "No", please specify the reason.	The reason is…	
4.7. Who validated the minutes ?	member/chairman/…	
4.8. Were all communications archived, i.e. communications with the CT-College and other stakeholders involved in the decision process (e.g. external expert)?		

Application 3	*application number (if applicable add _SM, _RMS, _MSC)*	
1. The decision-making procedure for the final advice is followed		
Criteria that must be checked:		
1.1. Specify which member(s) reviewed the dossier? Please specify only the role(s).	*role(s) of the member(s)*	
1.2. Was the selection of the reviewers done according to your procedure/allocation matrix ?		
1.3. If there is a deviation of the decision making procedure, were the reasons documented ?		
1.4. If an expedited procedure was used, were the reasons documented ?		
1.5. If an expedited procedure was used, how many EC members were involved in the decision ?	Not applicable/*Number of members involved in expedited procedure*	
1.6. Was it checked if an external expert was needed?		
1.7. If an external expert was appointed, which field of expertise was lacking ?	Not applicable/ *Field of expertise of external expert*	
Note: An external expert is a person that is external to the Ethics committee who receives the dossier and has no conflict of interest with the dossier. This person should also have provided its CV to the EC.		
1.8. Was the final advice checked by an EC member before it is provided to the sponsor? e.g. were the questions reviewed and are instructions for the sponsor clear		
1.9. If yes, specify by whom (which role of the EC member).	Not applicable/Who checked the advice (role)	
1.10. Is it checked if the ICF is in line with the protocol and Investigators' Brochure (using e.g. the Assessment report Part II or an equivalent checklist)?		

2. The criteria by which the vote is legally valid are followed		
Note: The validity of the vote is as described in art. 6 of the Royal Decree of 9/10/2017		
Criteria that should be checked:		
2.1. Was the quorum (regarding role and the right to vote) for the meeting met ?		
2.2. Was the voting procedure followed?		
2.3. Is a list of participants available?		
2.4. Was it documented who provided written comments ?		
2.5. Have all members assigned to review the dossier, provided comments (using the allocation matrix, if available)?		

3. All meetings are announced within the set timings		
Criteria that should be checked:		
3.1. How many days before the meeting was the dossier provided to the EC members?	*number of days*	
3.2. Was the dossier provided within the timelines given in your procedure?		
3.3. Was the dossier discussed during a plenary session of the EC or was a written procedure used?	plenary session / written procedure	
Note: With a plenary session we refer to Art 6 §1-3 of the Royal Decree of 9/10/2017; with a written procedure we refer to Art 6 §4 of the Royal Decree of 9/10/2017		
3.4. Was the EC meeting announced within the set timing?		

4. Minutes of the EC meetings		
Criteria that should be checked:		
Do the minutes of the EC meeting contain :		
4.1. - list of presence		
4.2. - possible conflicts of interest		
4.3. - written record of the discussion held		
4.4. - decision		
4.5. - justification of the opinion		
4.6. If one of the above criteria was answered with "No", please specify the reason.	The reason is…	
4.7. Who validated the minutes ?	member (role)/chairman/…	
4.8. Were all communications archived, i.e. communications with the CT-College and other stakeholders involved in the decision process (e.g. external expert)?		

Application 4	*application number (if applicable add _SM, _RMS, _MSC)*	
1. The decision-making procedure for the final advice is followed		
Criteria that must be checked:		
1.1. Specify which member(s) reviewed the dossier? Please specify only the role(s).	*role(s) of the member(s)*	
1.2. Was the selection of the reviewers done according to your procedure/allocation matrix ?		
1.3. If there is a deviation of the decision making procedure, were the reasons documented ?		
1.4. If an expedited procedure was used, were the reasons documented ?		
1.5. If an expedited procedure was used, how many EC members were involved in the decision ?	Not applicable/*Number of members involved in expedited procedure*	
1.6. Was it checked if an external expert was needed?		
1.7. If an external expert was appointed, which field of expertise was lacking ?	Not applicable/ *Field of expertise of external expert*	
Note: An external expert is a person that is external to the Ethics committee who receives the dossier and has no conflict of interest with the dossier. This person should also have provided its CV to the EC.		
1.8. Was the final advice checked by an EC member before it is provided to the sponsor? e.g. were the questions reviewed and are instructions for the sponsor clear		
1.9. If yes, specify by whom (which role of the EC member).	Not applicable/Who checked the advice (role)	
1.10. Is it checked if the ICF is in line with the protocol and Investigators' Brochure (using e.g. the Assessment report Part II or an equivalent checklist)?		

2. The criteria by which the vote is legally valid are followed		
Note: The validity of the vote is as described in art. 6 of the Royal Decree of 9/10/2017		
Criteria that should be checked:		
2.1. Was the quorum (regarding role and the right to vote) for the meeting met ?		
2.2. Was the voting procedure followed?		
2.3. Is a list of participants available?		
2.4. Was it documented who provided written comments ?		
2.5. Have all members assigned to review the dossier, provided comments (using the allocation matrix, if available)?		

3. All meetings are announced within the set timings		
Criteria that should be checked:		
3.1. How many days before the meeting was the dossier provided to the EC members?	*number of days*	
3.2. Was the dossier provided within the timelines given in your procedure?		
3.3. Was the dossier discussed during a plenary session of the EC or was a written procedure used?	plenary session / written procedure	
Note: With a plenary session we refer to Art 6 §1-3 of the Royal Decree of 9/10/2017; with a written procedure we refer to Art 6 §4 of the Royal Decree of 9/10/2017		
3.4. Was the EC meeting announced within the set timing?		

4. Minutes of the EC meetings		
Criteria that should be checked:		
Do the minutes of the EC meeting contain :		
4.1. - list of presence		
4.2. - possible conflicts of interest		
4.3. - written record of the discussion held		
4.4. - decision		
4.5. - justification of the opinion		
4.6. If one of the above criteria was answered with "No", please specify the reason.	The reason is…	
4.7. Who validated the minutes ?	member/chairman/…	
4.8. Were all communications archived, i.e. communications with the CT-College and other stakeholders involved in the decision process (e.g. external expert)?		

Application 5	*application number (if applicable add _SM, _RMS, _MSC)*	
1. The decision-making procedure for the final advice is followed		
Criteria that must be checked:		
1.1. Specify which member(s) reviewed the dossier? Please specify only the role(s).	*role(s) of the member(s)*	
1.2. Was the selection of the reviewers done according to your procedure/allocation matrix ?		
1.3. If there is a deviation of the decision making procedure, were the reasons documented ?		
1.4. If an expedited procedure was used, were the reasons documented ?		
1.5. If an expedited procedure was used, how many EC members were involved in the decision ?	Not applicable/*Number of members involved in expedited procedure*	
1.6. Was it checked if an external expert was needed?		
1.7. If an external expert was appointed, which field of expertise was lacking ?	Not applicable/ *Field of expertise of external expert*	
Note: An external expert is a person that is external to the Ethics committee who receives the dossier and has no conflict of interest with the dossier. This person should also have provided its CV to the EC.		
1.8. Was the final advice checked by an EC member before it is provided to the sponsor? e.g. were the questions reviewed and are instructions for the sponsor clear		
1.9. If yes, specify by whom (which role of the EC member).	Not applicable/Who checked the advice (role)	
1.10. Is it checked if the ICF is in line with the protocol and Investigators' Brochure (using e.g. the Assessment report Part II or an equivalent checklist)?		

2. The criteria by which the vote is legally valid are followed		
Note: The validity of the vote is as described in art. 6 of the Royal Decree of 9/10/2017		
Criteria that should be checked:		
2.1. Was the quorum (regarding role and the right to vote) for the meeting met ?		
2.2. Was the voting procedure followed?		
2.3. Is a list of participants available?		
2.4. Was it documented who provided written comments ?		
2.5. Have all members assigned to review the dossier, provided comments (using the allocation matrix, if available)?		

3. All meetings are announced within the set timings		
Criteria that should be checked:		
3.1. How many days before the meeting was the dossier provided to the EC members?	*number of days*	
3.2. Was the dossier provided within the timelines given in your procedure?		
3.3. Was the dossier discussed during a plenary session of the EC or was a written procedure used?	plenary session / written procedure	
Note: With a plenary session we refer to Art 6 §1-3 of the Royal Decree of 9/10/2017; with a written procedure we refer to Art 6 §4 of the Royal Decree of 9/10/2017		
3.4. Was the EC meeting announced within the set timing?		

4. Minutes of the EC meetings		
Criteria that should be checked:		
Do the minutes of the EC meeting contain :		
4.1. - list of presence		
4.2. - possible conflicts of interest		
4.3. - written record of the discussion held		
4.4. - decision		
4.5. - justification of the opinion		
4.6. If one of the above criteria was answered with "No", please specify the reason.	The reason is…	
4.7. Who validated the minutes ?	member/chairman/…	
4.8. Were all communications archived, i.e. communications with the CT-College and other stakeholders involved in the decision process (e.g. external expert)?		

Section D. Supplementary questions	*Responses (green boxes)*	*Additional information/comment*
1. Did you consult external experts in the past year?		
1.1. If yes, for how many projects in the past year did you consult experts external to the EC ?	*number*	
1.2. If yes, which fields of expertise were lacking ?	*fields of expertise of the external experts*	
2. Have you had an inspection of the FAMHP in the past year?		
3. Have you had an internal audit in the past year? If yes, please provide the executive summary of the report of this audit.		

Recommendations for the procedures (no answer is expected)
It is recommended that a back-up plan is in place in case the reviewer is unexpectedly unable to evaluate his part of the dossier.
It should be detailed in the procedure who evaluates the answers of the sponsor to the questions and takes the final decision for the dossier.
It is recommended to foresee an expedited procedure detailing the criteria for use, and who takes the decision of the application.
It is recommended that the EC proactively follows up on the timelines set by the College to ensure timely reporting.
It is recommended that even if a written procedure is initiated, an EC member can request a plenary meeting.

Naam	Voornaam	Geslacht	Hoedanigheid													plaatsvervangend lid	Voorzitter	Arts	Start datum
			deskundige inzake farmacologie, farmacotherapie en farmacokinetiek	lid met deskundigheid in de methodologie van het klinisch onderzoek	huisarts	arts houder van de bijzondere beroepstitel van geneesheer-specialist in de pediatrie	psycholoog	verpleegkundige	ziekenhuisapotheker	filosoof of vertegenwoordiger van de mensswetenschappen, onderlegd of gevormd inzake medische ethiek	jurist	patiëntenvertegenwoordiger	Lid met afdoende ervaring in klinische farmacologie	Lid met afdoende ervaring in beoordeling of uitvoering van klinische proeven van fase I	Vertegenwoordiger gezonde vrijwilligers				

Nom	Prénom	Genre	Qualité													membre suppléant	Président	Docteur en médecine	Date de début
			expert en matière de pharmacologie, pharmacothérapie et pharmacocinétique	membre ayant une expertise en méthodologie de la recherche clinique	médecin généraliste	médecin porteur du titre professionnel particulier de médecin spécialiste en pédiatrie	psychologue	infirmier	pharmacien hospitalier	philosophe ou représentant des sciences humaines, initié ou formé à l'éthique médicale	juriste	représentant des patients	Membre témoignant d'une expertise probante en pharmacologie clinique	Membre témoignant d'une expertise probante dans l'évaluation ou la conduite des essais de phase I	Représentant des volontaires sains				

Training to be followed	Hoedanigheid												
	deskundige inzake farmacologie, farmacotherapie en farmacokinetiek	lid met deskundigheid in de methodologie van het klinisch onderzoek	huisarts	arts houder van de bijzondere beroepstitel van geneesheer-specialist in de pediatrie	psycholoog	verpleegkundige	ziekenhuisapotheker	filosoof of vertegenwoordiger van de menswetenschappen, onderlegd of gevormd inzake medische ethiek	jurist	patiëntenvertegenwoordiger	Lid met afdoende ervaring in klinische farmacologie	Lid met afdoende ervaring in beoordeling of uitvoering van klinische proeven van fase I	Vertegenwoordiger gezonde vrijwilligers
GCP training													
Read and understand SOP xxx													
National legislation													
European legislation													

Training to be followed	Qualité												
	expert en matière de pharmacologie, pharmacothérapie et pharmacocinétique	membre ayant une expertise en méthodologie de la recherche clinique	médecin généraliste	médecin porteur du titre professionnel particulier de médecin spécialiste en pédiatrie	psychologue	infirmier	pharmacien hospitalier	philosophe ou représentant des sciences humaines, initié ou formé à l'éthique médicale	juriste	représentant des patients	Membre témoignant d'une expertise probante en pharmacologie clinique	Membre témoignant d'une expertise probante dans l'évaluation ou la conduite des essais de phase I	Représentant des volontaires sains
GCP training													
Read and understand SOP xxx													
National legislation													
European legislation													

Title of followed training, symposium, workshop	Organizing entity and/or speaker	Localisation	Date(s)	Name of EC member
GCP training			1 maart 2023	Member x
GCP training			15 maart 2023	Member y
Read and understand SOP xxx	Selfstudy	Selfstudy		
Read and understand National legislation	Selfstudy	Selfstudy		
Read and understand European legislation CTR	Selfstudy	Selfstudy		
Read and understand European legislation MDR	Selfstudy	Selfstudy		
Read and understand European legislation IVDR	Selfstudy	Selfstudy		

Name	Firstname	NL_Hoedanigheid	FR_Qualité	Documents of the dossier to be assessed												
				Cover letter	EU application form	Protocol	Investigator's Brochure	Scientific advice and PIP	Recruitment arrangements	Subject Info, ICF and ICF procedure	Suitability of the investigator	Suitability of the facilities	Proof of insurance	Financial and other arrangements	Statement on Data Protection	collection, storage and future use of human biological samples
		deskundige inzake farmacologie, farmacotherapie en farmacokinetiek	expert en matière de pharmacologie, pharmacothérapie et pharmacocinétique													
		lid met deskundigheid in de methodologie van het klinisch onderzoek	membre ayant une expertise en méthodologie de la recherche clinique													
		huisarts	médecin généraliste													
		arts houder van de bijzondere beroepstitel van geneesheer-specialist in de pediatrie	médecin porteur du titre professionnel particulier de médecin spécialiste en pédiatrie													
		psycholoog	psychologue													
		verpleegkundige	infirmier													
		ziekenhuisapotheker	pharmacien hospitalier													
		filosoof of vertegenwoordiger van de menswetenschappen, onderlegd of gevormd inzake medische ethiek	philosophe ou représentant des sciences humaines, initié ou formé à l'éthique médicale													
		jurist	juriste													
		patiëntenvertegenwoordiger	représentant des patients													
		Lid met afdoende ervaring in klinische farmacologie	Membre témoignant d'une expertise probante en pharmacologie clinique													
		Lid met afdoende ervaring in beoordeling of uitvoering van klinische proeven van fase I	Membre témoignant d'une expertise probante dans l'évaluation ou la conduite des essais de phase I													
		Vertegenwoordiger gezonde vrijwilligers	Représentant des volontaires sains													