Overall Guideline on Preparation Process Authorisation (PPA)

facilitatinG the Authorisation of Preparation Process for blood, tissues and cells

Laura Hickey and Ruth Barrio

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Previous steps…

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Previous steps

▷ Conclusions/Outputs:

- There should be common terminology
- VISTART principles should be used as a basis for Good Practice Guideline
- Seeking the possibility of adapting EUROGTP II in the framework of GAPP action, for blood should be considered
- The harmonized risk categorization described in VISTART and EUROGTP II might be used for determining the different steps required to authorise new products according to the risk level and its potential consequences for patients. Requirements for each level of risk should be described and established in the Overall Guidance.

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Previous steps

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WP5 Survey :

- 24 respondents
- 75% of CAs who responded specified that there was **no risk categorisation system** in place for application of changes to existing applications / or applications for authorisation of new or novel activities, products, processes or clinical indications.
- 84% of CAs who responded indicated that they did **not have a specific set of documents to provide guidance to CAs or other relevant bodies in relation to the review / evaluation of data** to be submitted to support an application for product authorisation
- 60% of CAs who responded indicated that they did **not have a definition** for what constitutes **novel activity / product / process / clinical application**

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Previous steps

- Desk based review of PPAs in Medical Devices, Medicinal products, ATMP's, Herbal and Homeopathic were reviewed
- Two MC workshops where held at European Commission
  - Tissue and cell CAs October 2019
  - Blood CAs February 2020

  Workshops generated a number of discussion points to consider with Guide and some decisions were agreed e.g. extension of EUROGTP II to blood

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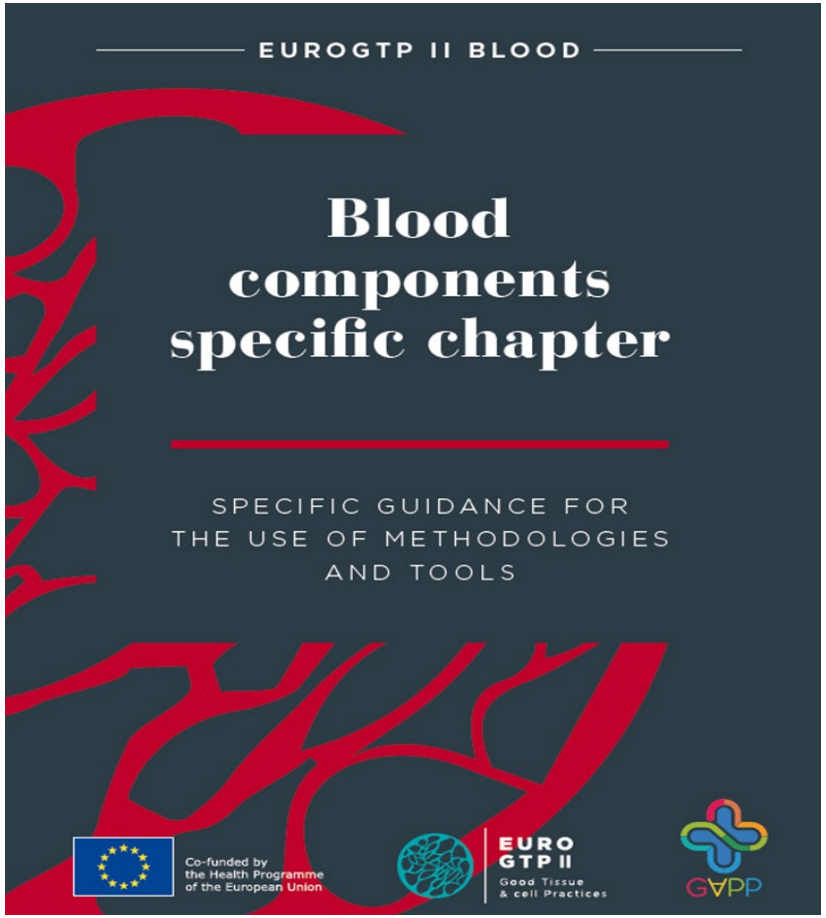
EUROGTP II Blood: Specific Guidance for the use of methodologies and tools



http://www.goodtissuepractices.eu/

HOME

E-Learning Blood

E-Learning BLOOD

Not registered yet?

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Send us your data to Eurogtpii@bst.cat: (Course (T&C or Blood) + Name + Surname + e-mail + Country + Organisation+ National ID card Number (optional - to be included in the certificate)).

http://www.goodtissuepractices.eu/index.php/2-uncategorised/58-e-learning

Interactive Tool

https://bloodtool.goodtissuepractices.site/

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Good practice guideline to authorisation on preparation processes in blood, tissues and cells establishments

▷ Scope

- Only PPAs under EU Directives BTCs
- To define how a PPA programme should or could be organised
- Uses the tool included in the EuroGTP II project to create a harmonized approach to risk categorisation in the PPA
- Definition of novelty and significant change
  - A **novelty** is ‘any change that might affect the quality and/or the safety of the blood, tissues and cells and/or the safety of recipients’. This change includes a new BTC, a new procedure designed by the BE/TE, a new procedure adopted from another centre that has shown scientific evidence or the application of the BTC to treat a new clinical indication.

  - A **significant change** is a ‘change that could significantly affect the quality and/or the safety of the BTC/or the safety of recipients and that is assessed as a moderate or high risk. A significant change will have been identified through initial identification as a novelty and the subsequent risk assessment process described in EuroGTP II.

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Good practice guideline to authorisation on preparation processes in blood, tissues and cells establishments

▷ Scope Contd:

- Guideline discusses the steps in relation to the PPA in detail and is divided into four sections:
  - Application process:
    - A proposed PPD template has been developed and CAs can create their own guidelines for applicants in relation to this.
  - Technical annexes
  - Review and evaluation
    - A proposed template to aid CAs in the review and evaluation of PPDs has been developed and can be found in appendix 3.
  - Framework for competent authority

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PPD – Proposed Application Process

Module 1: Applicant information

- BE/TE data.
- Data of the responsible person for the PPD.

Modules 2 and 3: Novelty and risk assessment

- Description of BTC.
- Novelty Questions.
- Activity information.
- Risk Assessment.

Module 4: Quality

- Updated SOPs.
- Validation.

Module 5: Preclinical studies

- *In-vitro*/*In-vivo* studies
- Performed studies.
- Bibliography.

Module 6: Clinical information

- General clinical information.
- Clinical indication.
- CIP.
- CFUpP

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Activities to which novelty may apply

- Donor Selection
- Donation/Collection/ Procurement
- Testing
- Processing
- Storage
- Transport and delivery
- Distribution/issue
- Exportation/importation
- New application/infusion method
- New clinical indication
- New anatomical site

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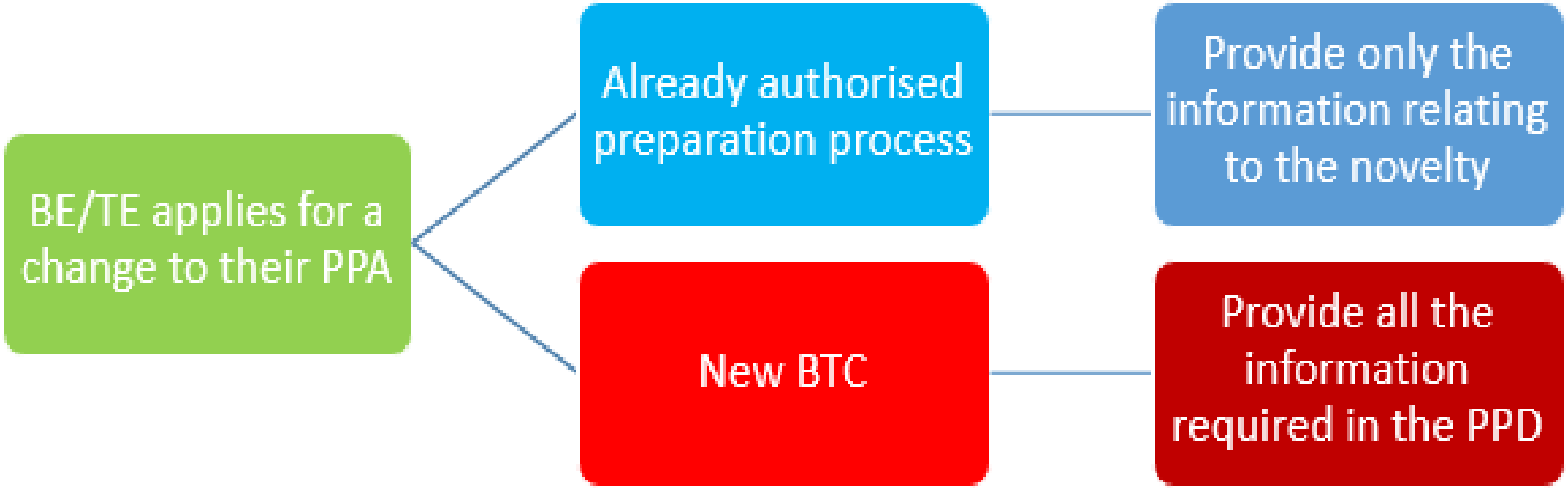
Information to be provided by the BE/TE according to novelty



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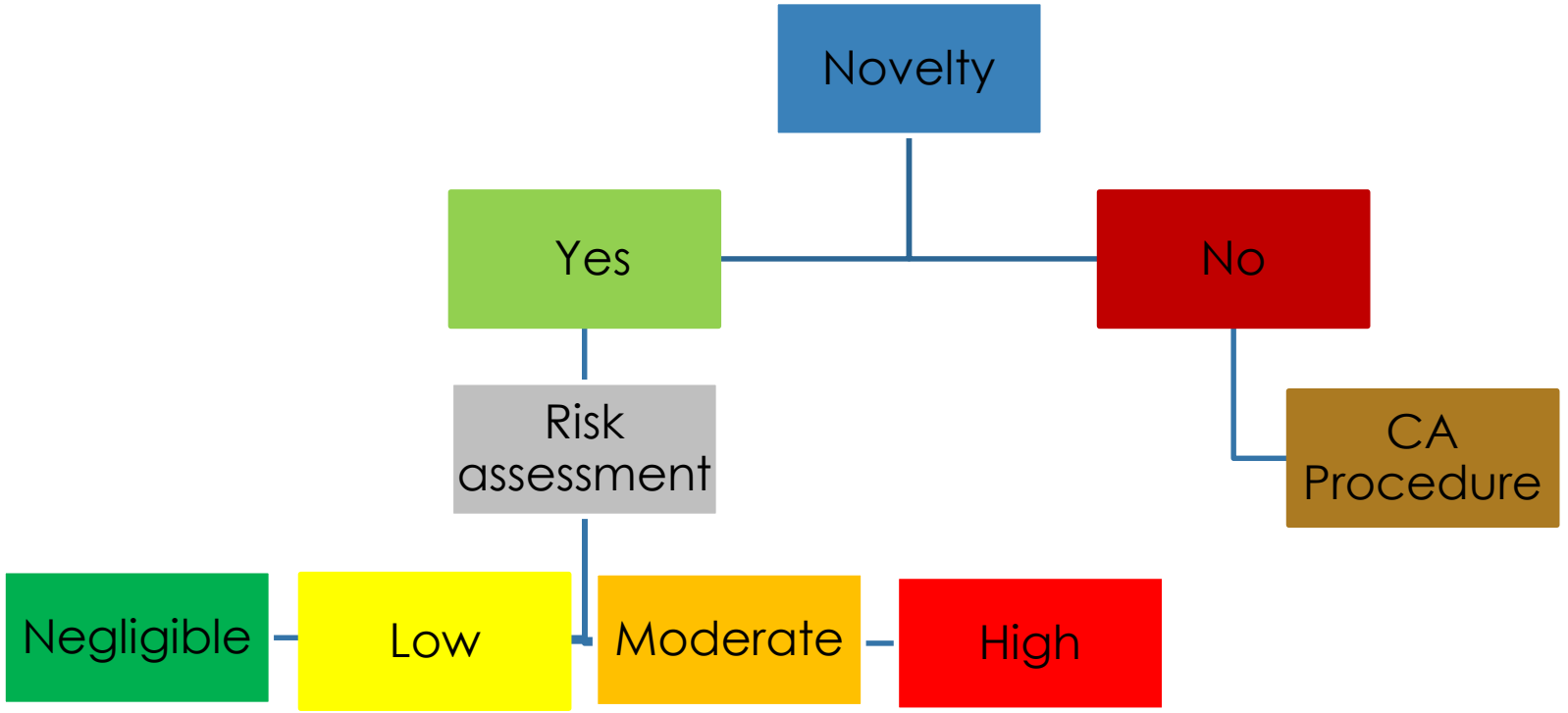
Novelty and RA flow chart



A CA will receive a PPD when a change is proposed to a BTC, which indicates novelty (as per EuroGTP II).

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Information to be submitted

Select the risk level assigned after performing the EuroGTP II risk assessment and provide the completed EuroGTP II tool template	The information below is required based on the indicated risk. To submit the required information proceed to module 4, 5 and 6 as appropriate.
Negligible □	Quality SARE reporting*
Low □	Quality Preclinical information SARE reporting* CFUpP
Moderate □	Quality Preclinical information SARE reporting* CFUpP CIP
High □	Quality SARE reporting* Preclinical information CFUpP CIP Comparison Study

** SARE reporting refers to the SARE SOP initially. SARE reports can be submitted as part of any interim reports and should be submitted to the CA as required by legislation.*

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Technical Annexes1 - 3

Technical annexes used as guidance to CAs on authorisation of changes in the different activities, including donor testing, pathogen reduction and sterilisation and the review of clinical data. Guide provides details on the modules these technical annexes relate to.

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Review and evaluation

- CA should firstly assess the admissibility of the application by verifying that all appropriate information has been provided, followed by a technical review relating to quality, safety and efficacy.
- CA to review novelty questions and risk assessment
- CA will complete the novelty questions and EuroGTP II risk assessment themselves to ensure that they are in agreement with the risk level assigned to the novelty by the BE/TE
- CA confirms that the application relates to a BTC which falls under the EUBTCDs. If not, they will return the application to the applicant or forward to the appropriate CA, and the assessment process for the BTC CA will end.

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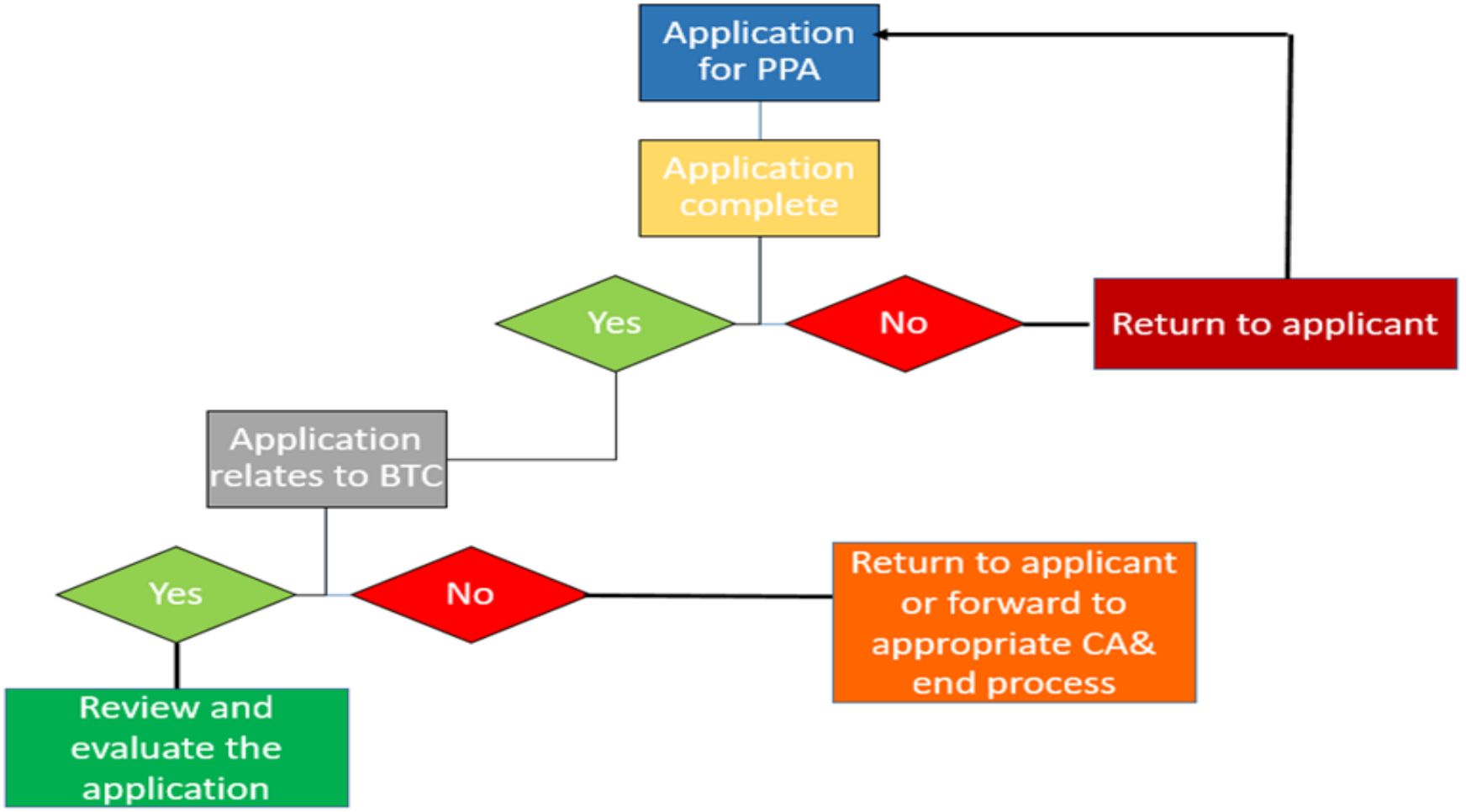
Compliance of the application



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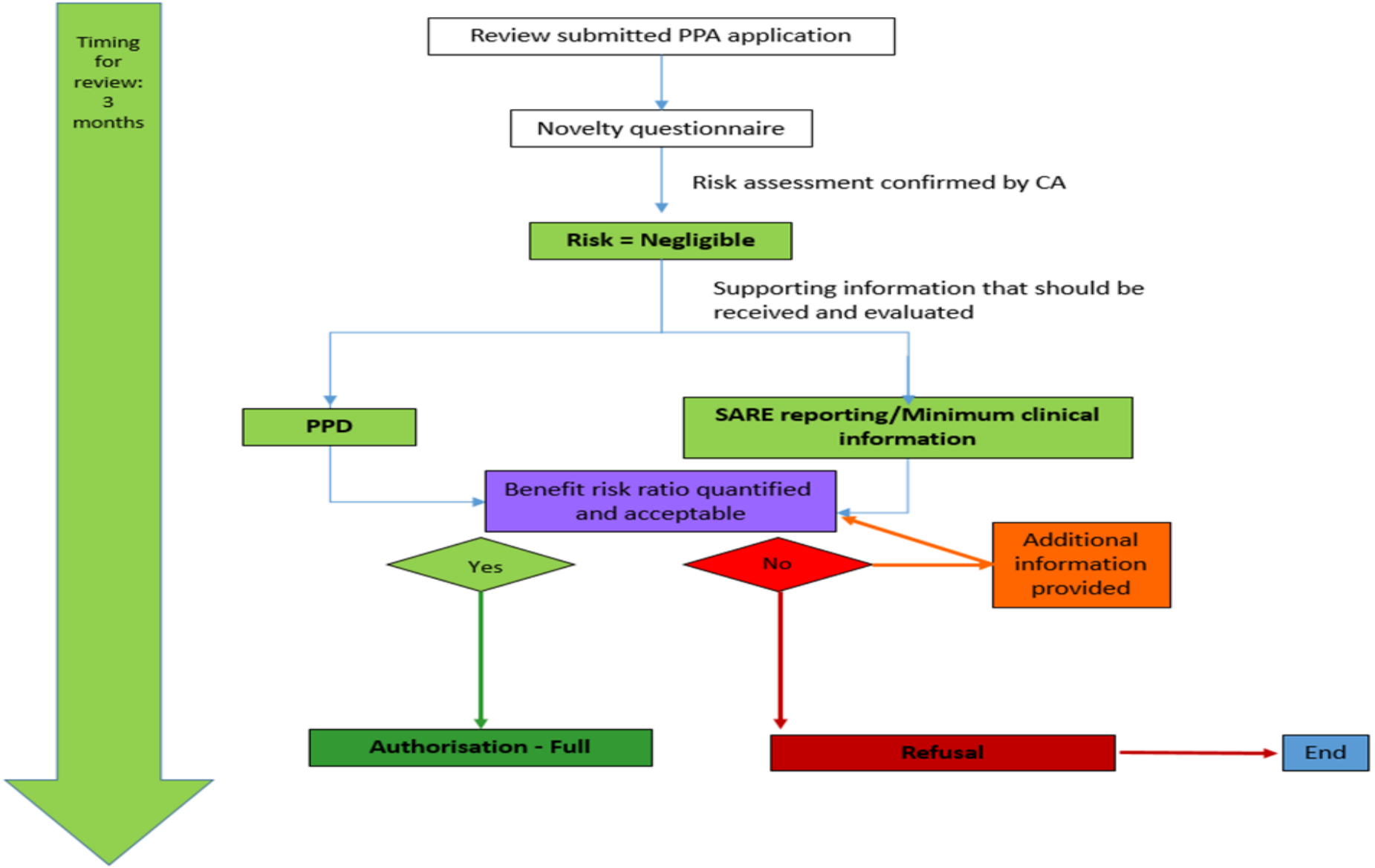
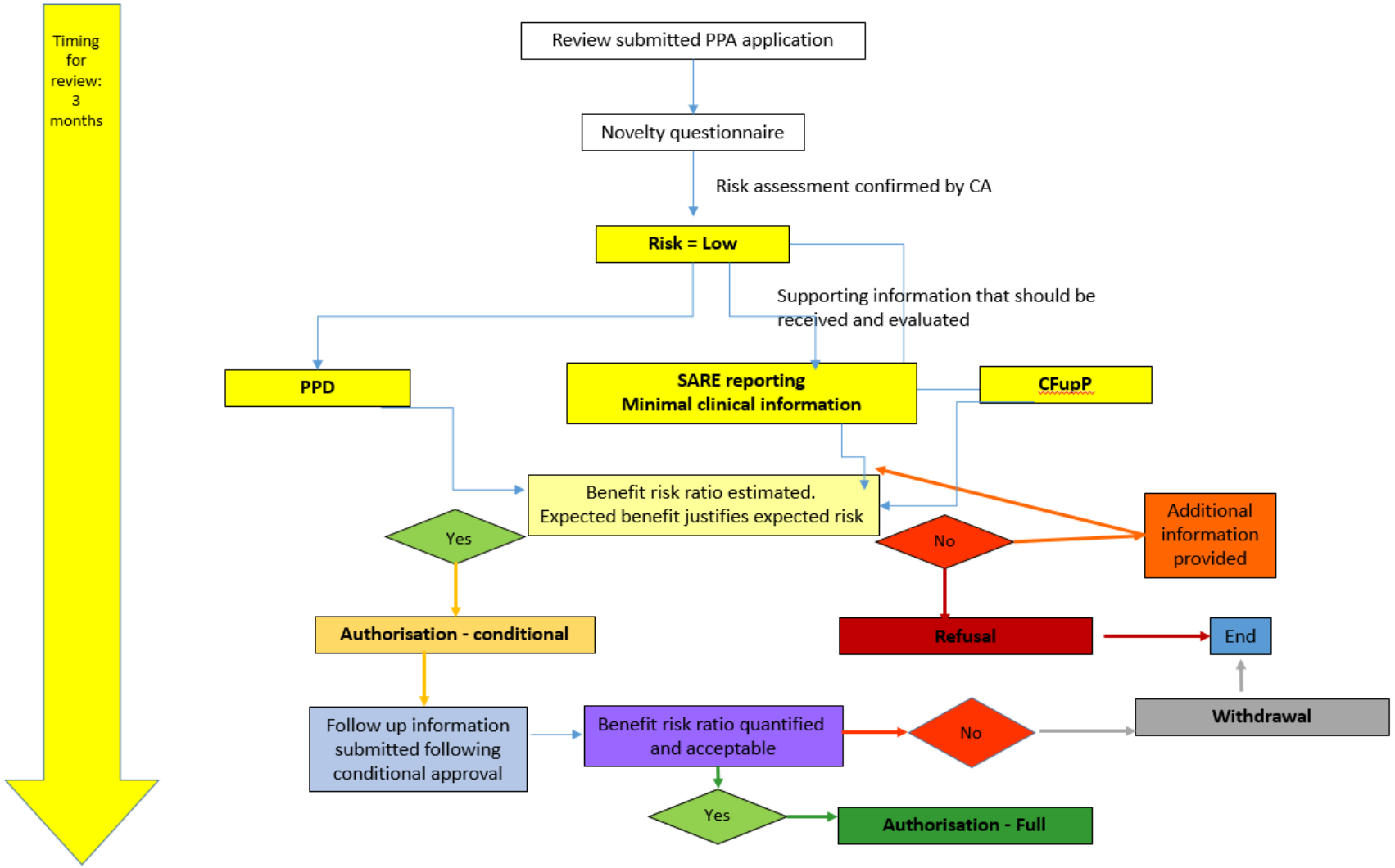
Evaluation process – negligible risk



Evaluation process – low risk



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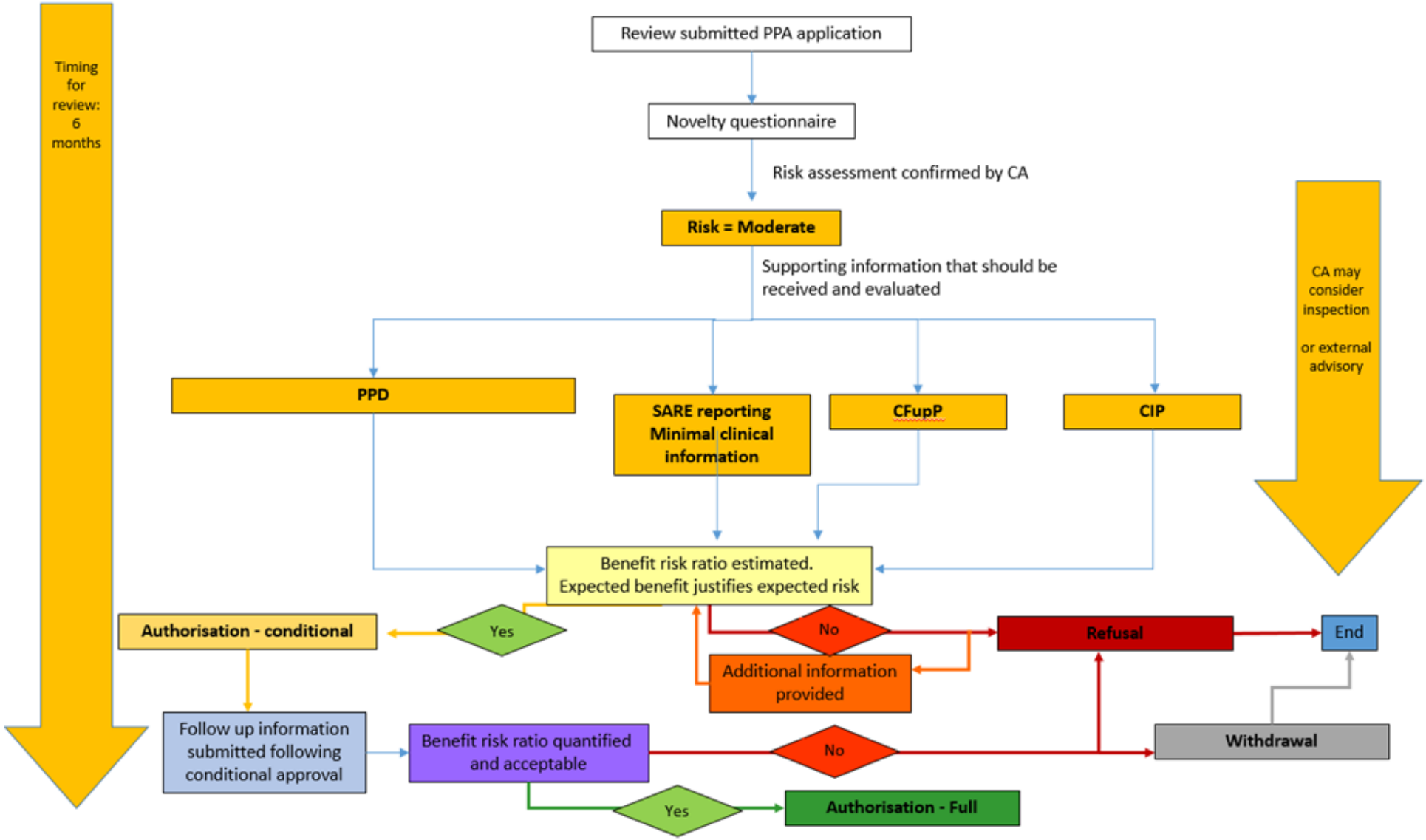
Evaluation process – moderate risk



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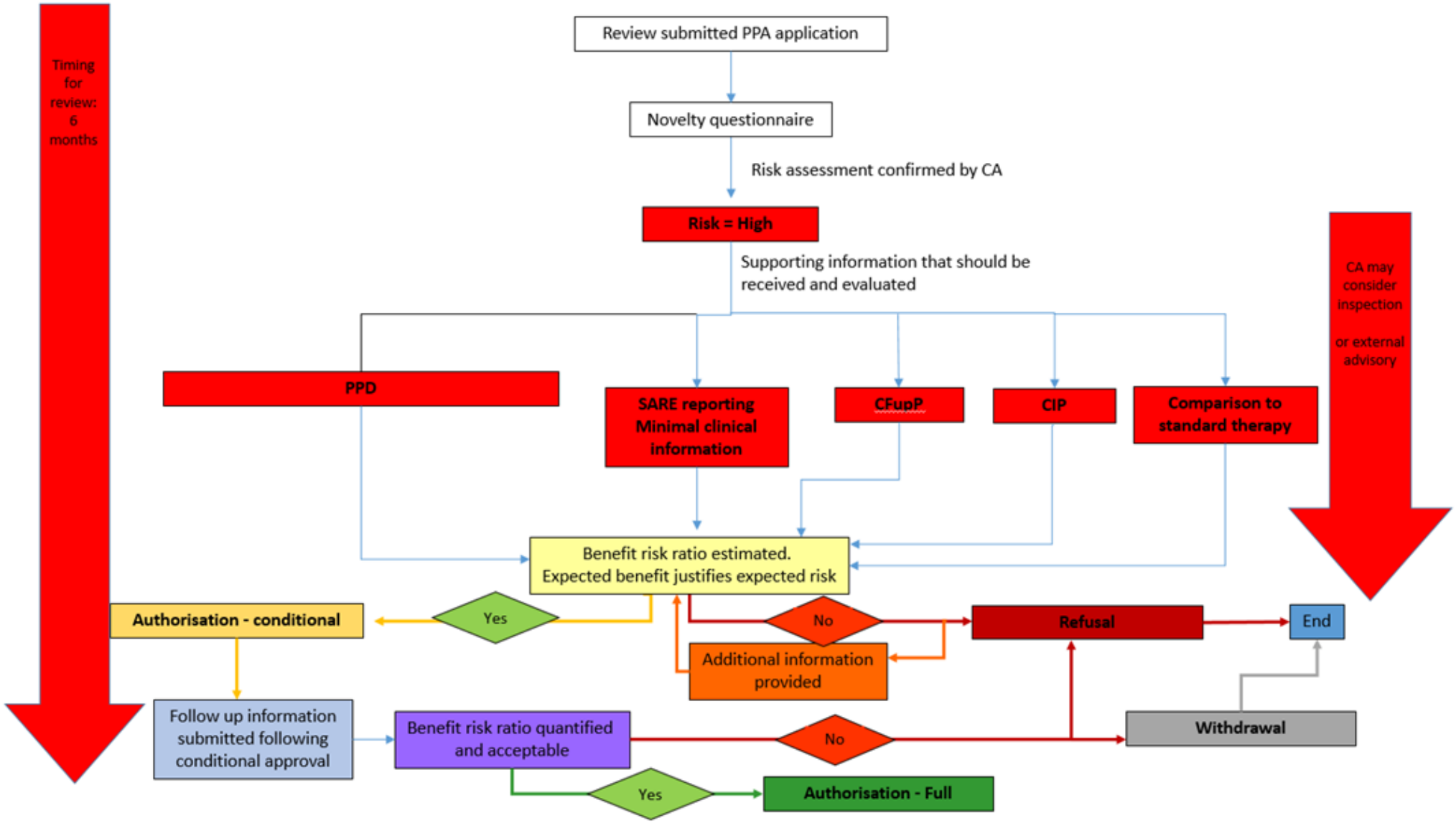
Evaluation process – high risk



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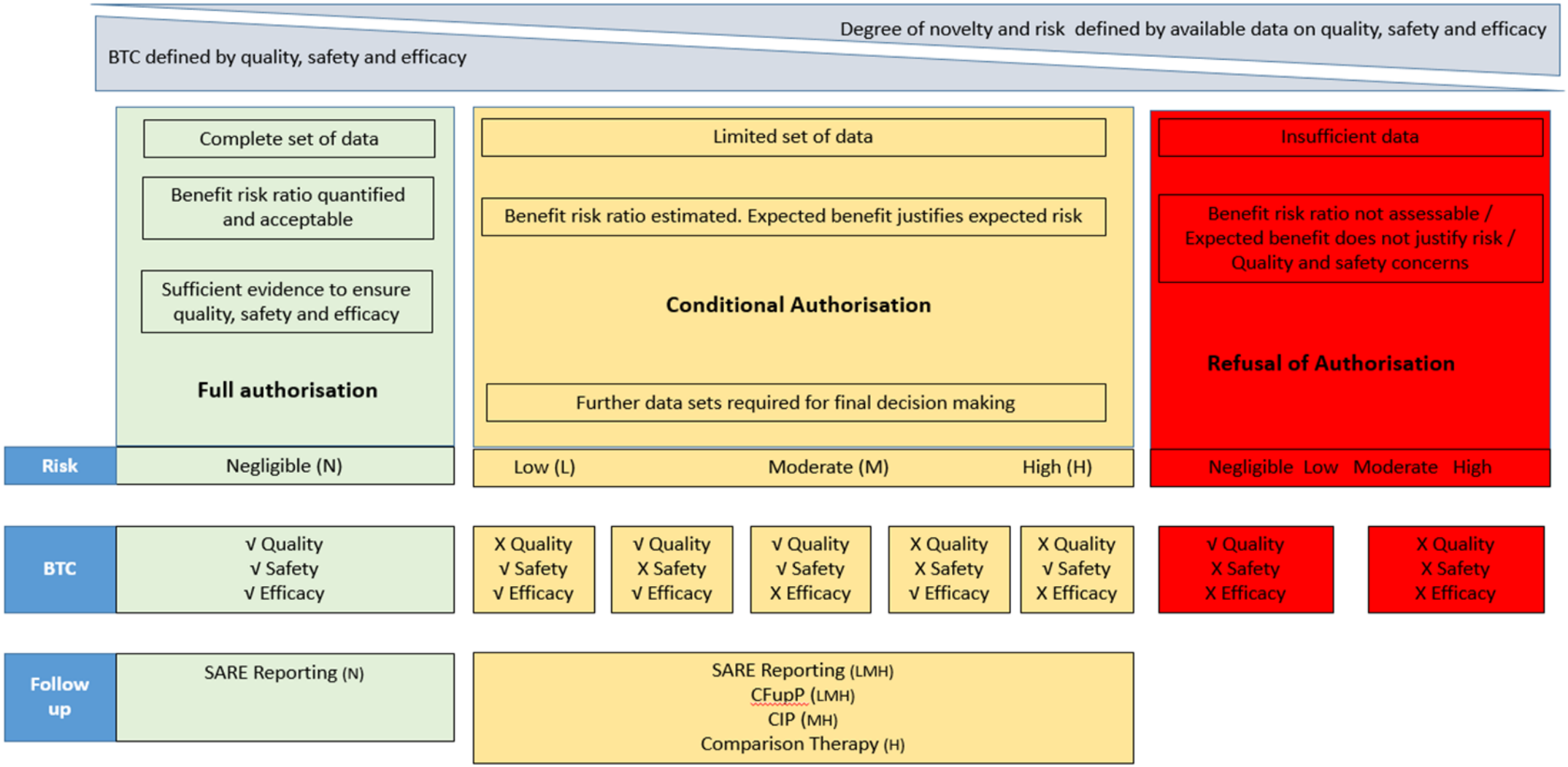
Review and evaluation - Risk/ benefit balance



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- Conditional Authorisation
  - expected benefit justifies the expected risk and no alternative options are available
  - define the further data sets that are required for further assessment and for final decision-making
- The conditional authorisation should detail the number of patients, the cohort of patients, and the centres that will manage the BTC. It is recommended that this authorisation is also linked to the CIP if possible.
- Once a conditional authorisation has been granted, the CA must define the timelines within which the applicant must submit the clinical data.

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- Full authorisation
- On evaluation of additional information following the granting of a conditional authorisation, the CA may grant a full authorisation, if the benefit justifies the risk and they have been appropriately satisfied that the quality, safety and efficacy of the novelty has been demonstrated.
- It is recommended that this authorisation for the preparation and clinical use of the novelty will be issued when there is sufficient evidence to assure the quality, safety and efficacy of the novelty.
- A full authorisation may also be granted for negligible risk BTCs / procedures, if all appropriate data is submitted with the application and is deemed appropriate by the CA.
- The benefit ratio should be quantifiable and acceptable in order for a full authorisation to be granted.

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- Refusal of an authorisation
- Competent Authorities shall refuse to issue an authorisation based on quality and safety concerns. If the expected benefit is not assessable, does not justify the risk, or if there are quality and safety concerns the authorisation should be refused.

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Recommended timing of review

Level of risk	Recommended timing of review	
Negligible risk	Three months	
Low risk		
Moderate risk		Six months
High risk		

Timings are recommendation only.

The applicant must receive an authorisation from the CA before implementing the novelty, particularly in relation to low, moderate and high risk applications.

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PPD template

- A proposed PPD template has been developed and CAs can create their own guidelines for applicants

Appendix 2 Preparation Process Dossier

The PPD is organised in modules as follows:

- Module 1: Applicant information
- Module 2: BTC novelty
- Module 3: Risk assessment
- Module 4: Quality
- Module 5: Preclinical studies
- Module 6: Clinical information

For applications submitted where novelty has been identified, only the applicant data as detailed below, and specific sections related to the novelty should be submitted to the CA to review. The information related to the novelty should be completed within the PPD. The PPD does not have to be completed for areas that the novelty does not affect, as the CA will have previously assessed these.

For BE/TE that have not previously been authorised, information in relation to the establishment, preparation process, materials and equipment, quality control testing, process validation and labelling will not have been provided before, therefore the complete preparation process dossier and all information should be provided to the CA

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Template for PPD assessment

- Template to aid CAs in the review and evaluation of PPDs

Appendix 3 Template for PPD Assessment

Module 1: Applicant Information	
Applicant Information section completed appropriately	□ Yes □ No Date: DD/MM/YYYY
If applicant information completed appropriately continue to Module 2 BTC Novelty	
If the applicant information is not completed appropriately, contact applicant and request information is resubmitted.	
Resubmitted general information completed appropriately	□ Yes □ N/A Date: DD/MM/YYYY

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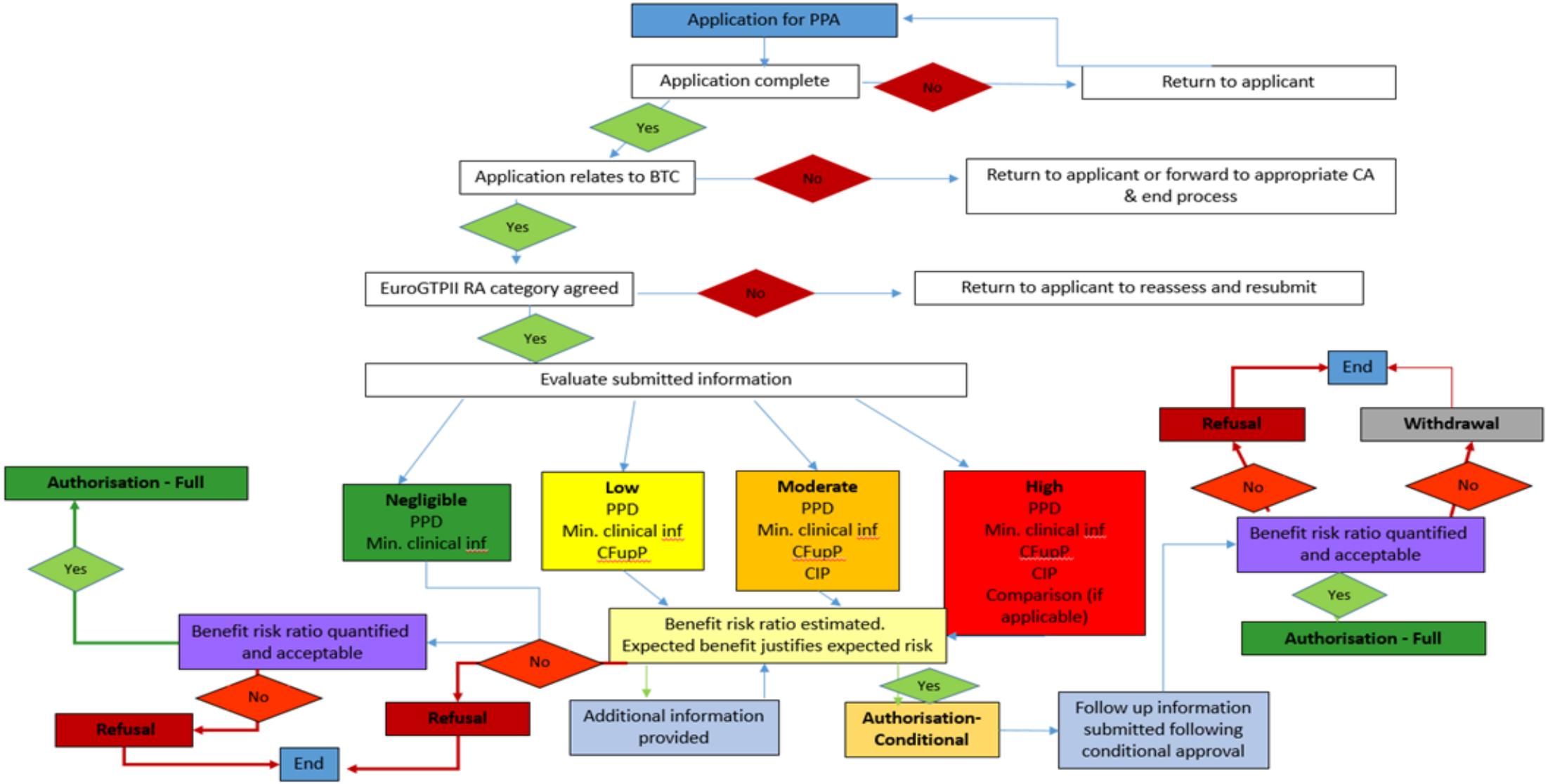
Process flow of the PPA application from receipt to authorisation / refusal / withdrawal



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Framework of CA

▷ Qualifications and training

- Successful completion of a university or a technical college degree or equivalent qualification in relevant studies, e.g. medicine, biological science or other relevant sciences
- Professional experience in relevant aspects of the field of BTC related activities, or regulation of such activities
- Knowledge of BTC legislation, including the general quality and safety and efficacy requirements
- Appropriate knowledge and experience of relevant standards and guidance documents; e.g. EDQM Guides
- Appropriate knowledge and experience of risk management principles and processes, e.g. EuroGTP II
- Appropriate knowledge and experience of clinical evaluation

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Framework of CA contd:

- Qualifications and training
  - Appropriate knowledge of the specific category of BTC which they are assessing;
  - Appropriate knowledge and experience of the assessment procedures / software relevant to the CA
  - The ability to maintain records and write reports demonstrating that the relevant assessment activities have been appropriately carried out
- Expert / expert panels
- Review and scientifically challenge the clinical data /clinical investigations
- Be able to scientifically evaluate and, if necessary, challenge the clinical evaluation presented
- Be able to ascertain the comparability and consistency of the assessments of clinical evaluations conducted by clinical experts
- Be able to make an assessment of the clinical evaluation and a clinical judgement and make a recommendation to the CA's decision maker

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- Some CA's may not have expertise available to assess all applications. For this reason, it may be beneficial to establish expert panels to assist in reviewing applications. The CA's decision to authorise or reject the application should be the final decision.

- The availability of a European panel of experts from within CA's would be beneficial, this would eliminate the need to engage the services of external experts who may have affiliations with BE/TE. The feasibility of establishing such a group, and possibility of sharing sensitive information between CA's would need to be investigated and is outside the scope of this project.

- It has been indicated in the revision of the BTC legislation that there is a proposal for an EU level mechanism to be set up to advise MS's on whether the BTC framework or other frameworks (in particular medicinal products and medical devices), should be applied for particular novel BTCs. It would be beneficial for a BTC CA to use this group for classification purposes.

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Thanks!

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