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| European Medicines Agency |
| Q&A |
| Scientific Advice in IRIS |

Contents

[**Scientific Advice** 3](#_Toc47600910)

[1. Pre-submission consultations in veterinary Scientific Advice 3](#_Toc47600911)

[2. EEA/non-EEA important for SME fee reduction 3](#_Toc47600912)

[3. Only One contact allowed for final reference 3](#_Toc47600913)

[4. Are financial reference and contact points mandatory? 4](#_Toc47600914)

[5. Explanation for asterisks is missing 4](#_Toc47600915)

[6. Difference between “save and return” and “return” 4](#_Toc47600916)

[7. Greyed out fields 4](#_Toc47600917)

[8. Generate application form functionality 5](#_Toc47600918)

[9. Mandatory fields in enabling technologies 5](#_Toc47600919)

[10. Additional information on the RPI 5](#_Toc47600920)

[11. Procedural Information section : specific date not always known 5](#_Toc47600921)

[12. Procedural Information section - PRIME designation not part of SA 5](#_Toc47600922)

[13. ODD listed only type Initial/Follow-up Protocol Assistance 5](#_Toc47600923)

[14. Postponement of start of procedure possible and free of charge 6](#_Toc47600924)

[15. ODD listed only type Initial/Follow-up Protocol Assistance 6](#_Toc47600925)

[16. All countries to be shown in list 6](#_Toc47600926)

[17. MeDRA mandatory 6](#_Toc47600927)

[18. Significance of Medicine profile 6](#_Toc47600928)

[19. Terms with similar meaning 6](#_Toc47600929)

[20. Legal basis mandatory for SA 7](#_Toc47600930)

[21. Redundant information requested 7](#_Toc47600931)

[22. Documents from EMA section 7](#_Toc47600932)

[23. MedDRA terms list 7](#_Toc47600933)

[24. Non mandatory fields should be completed if required. 7](#_Toc47600934)

[25. Extension of tickbox options 8](#_Toc47600935)

[26. Look-up lists 8](#_Toc47600936)

[27. Abbreviated development programme 8](#_Toc47600937)

[28. Marketing Authorization-’Both’ option explained 8](#_Toc47600938)

[29. Field not mandatory 8](#_Toc47600939)

[30. Option for adaptive trial design 9](#_Toc47600940)

[31. Suggestion for free text fields for further explanations 9](#_Toc47600941)

[32. Difference between scientific innovation/Therapeutic/Technical innovation 9](#_Toc47600942)

[33. MedDRA code should always be provided. 9](#_Toc47600943)

[34. MedDRA term: is it mandatory? 9](#_Toc47600944)

[35. When should additional RPIs be provided? 10](#_Toc47600945)

[36. Contact HTAs 10](#_Toc47600946)

[37. HTA’s field not mandatory 10](#_Toc47600947)

[38. EDWP involvement 10](#_Toc47600948)

[39. Supported documents upload 10](#_Toc47600949)

[40. Zip files 10](#_Toc47600950)

[41. Documents to be included 11](#_Toc47600951)

[42. Follow-up has same structure as Initial SA 11](#_Toc47600952)

[43. Generation of application is not mandatory but advisable 11](#_Toc47600953)

[44. Downloading the submission package 11](#_Toc47600954)

[45. IRIS is less time consuming compared to previous system 11](#_Toc47600955)

[46. One or more Orphan Designations? 12](#_Toc47600956)

[47. IRIS to be used for SA post Go-Live 12](#_Toc47600957)

[48. Transitioning between systems: grace period? 12](#_Toc47600958)

[49. Parallel SA with FDA 12](#_Toc47600959)

[50. Letter of Intent replaced by IRIS 12](#_Toc47600960)

[51. Change in way of submitting SA applications 13](#_Toc47600961)

[52. Applicant / EMA interaction 13](#_Toc47600962)

# **Scientific Advice**

##  Pre-submission consultations in veterinary Scientific Advice

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| Question | **The process does not foresee the possibility to submit a draft package in view of a pre-consultation meeting with the Agency, before submitting an actual (veterinary) official scientific advice request.**  |
| Answer | While an application is locked after submission, it can always be reopened by EMA before validation/the start date. This is a feature that operates for all procedures in IRIS, including scientific advice for human and veterinary medicines, and orphan designations. A) If a pre-submission consultation is required by the applicant: if approved, the consultation is held; EMA will reopen the submission if necessary, and the applicant then revises the submission based on the outcome of the consultation and progresses to point B) below. B) When the SA request is submitted and no pre-submission consultation is requested, EMA starts its own validation process. If everything is ok, the request is validated, and the submission is locked. Otherwise, if there are validation issues, the SAWP-V secretariat will reopen the submission and contact the applicant, which will be able to revise their submission. A fee will be triggered at start date, or if a negative validation is concluded.Of note, if there seem to be insurmountable problems, the applicant may be reminded of the possibility to withdraw – no fee would be incurred if withdrawal occurs before the start date of the procedure. |

**Scientific Advice - Administrative Information**

##  EEA/non-EEA important for SME fee reduction

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| Question | **Why there are so many questions about EEA SME, in the Administrative Information section?** |
| Answer | Information on EEA/non-EEA applicants is very important for the determination of eligibility to SME fee reduction. This is only be mandatory to complete for applicants that declare that they are an SME. We are aware that the wording is complicated, and we have already worked on a modification of this field to make it clearer to the user. |

## Only One contact allowed for final reference

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| Question | **Is it possible to add more than one contact for the “Final reference” in Administrative Information section?** |
| Answer | We assume that Final reference stands for Financial reference. It is currently possible to add only one person as a financial contact point, as we only require one person for this purpose.  |

## Are financial reference and contact points mandatory?

|  |  |
| --- | --- |
| Question | **Why are the financial reference and contact point mandatory – could we include that this information is Non-Applicable?** |
| Answer | The financial contact point should be a person that is aware of a submitted application and can arrange payment of the invoice. The financial reference is used by several companies in the form of a Purchase Order number. If a Purchase Order number is not applicable the field should be pre-populated with the name of the person completing the application. This information is required by our accounts department for invoicing. Administrative and financial information are mandatory for all procedures, independently of any fee waivers that might be granted which could result in no fee payable. |

## Explanation for asterisks is missing

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| --- | --- |
| Question | **There are lots of asterisks, but no explanations for them.**  |
| Answer | An asterisk to the right of a field always means that compilation of the field is mandatory. |

## Difference between “save and return” and “return”

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| --- | --- |
| Question | **It is not intuitive to name buttons “save and return” and “return”. Once a section is filled, we would expect a button to take us further and not back. I understand that it takes you back to the overview where several sections must be filled, but it is still confusing when new to the portal.** |
| Answer | Other options for the names were explored in the past, but this was considered to be the most appropriate. |

## Greyed out fields

|  |  |
| --- | --- |
| Question | **Some fields that are greyed out can still be clicked into (e.g. “linked organization name”), but nothing can be filled in. Some fields that need to be filled by clicking on the magnifying glass icon also look greyed out first. This is confusing. It would be easier to navigate the page if the color code would be clear.**  |
| Answer | Greyed out fields should not be clicked as there is no need to provide information in them, based on previous declarations from the applicant. If a greyed out field allows entry of data, this is a bug that should be signaled to <https://servicedesk.ema.europa.eu>  |

## Generate application form functionality

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| --- | --- |
| Question | **I was confused again by the “Generate Application form” button and that after creating it I could not find it anywhere. Where is “Documents from Applicant” supposed to be?** |
| Answer | “Generate Application form” generates the word file of the application form filled online, which becomes available inside the section “Documents from Applicant". This information can also be found in “User guide for applicants”. |

**Scientific Advice - Additional Information**

## Mandatory fields in enabling technologies

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| --- | --- |
| Question | **None of the fields are mandatory (including no mandatory to fill enabling technology), so why do we have to confirm the below?** |
| Answer | While none of the possible choices is mandatory, at least one “enabling technology” should be added to the RPI. |

## Additional information on the RPI

|  |  |
| --- | --- |
| Question | **Additional information on Mechanism of action, Additional description of the product, and Enabling Technologies look redundant as this information was already specified in the RPI request.** |
| Answer | As the RPI remains the same across the lifecycle of the product, we ask applicants to update information on the RPI at every new scientific procedure undertaken at EMA, rather than only at the initial request for an RPI. |

## Procedural Information section : specific date not always known

|  |  |
| --- | --- |
| Question | **Why a specific date is mandatory for the foreseen date of submission of the Marketing Authorisation Application, as we might only know year/quarter of filing? What does it imply to give a specific date?** |
| Answer | The date is not binding in any way for the applicant, and it is just for information on the business pipeline. To specify a quarter or a year, it is just necessary to enter the last day of the quarter (or year) |

## Procedural Information section - PRIME designation not part of SA

|  |  |
| --- | --- |
| Question | **Priority Medicines (PRIME) scheme: are you thinking to also include in the portal the request for the KO meeting in relation to PRIME? Or this will be handled separately?** |
| Answer | Currently, PRIME designation is not part of the Scientific Advice office remit, therefore it will continue to be handled separately. Only Scientific Advice for PRIME designated medicines will be handled through IRIS.  |

## ODD listed only type Initial/Follow-up Protocol Assistance

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| --- | --- |
| Question | **Shouldn’t ODD be listed as well in Procedural Information section?** |
| Answer | An orphan designation is mandatory only for Protocol Assistance submissions.  |

## Postponement of start of procedure possible and free of charge

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| --- | --- |
| Question | **Could we include a wish/planned date for the SA to happen in Procedural information section?** |
| Answer | The start date for the procedure depends on the submission deadline linked to a specific start date that is published on the EMA website. Once a case is created by a certain submission deadline an automatic start date will be allocated. Following submission, applicants have the possibility to postpone if they realize that they are not ready to start the procedure on the initially planned date at any time prior to the start date (there is no charge for the postponement as long as it is requested prior to the start date). |

## ODD listed only type Initial/Follow-up Protocol Assistance

|  |  |
| --- | --- |
| Question | **Is previous national advice needed in procedural information section?** **And only for the indication in which SA is pursued?** |
| Answer | 1) Yes; 2) at the discretion of the applicant |

## All countries to be shown in list

|  |  |
| --- | --- |
| Question | **I couldn’t find the EU countries for national advice. Is this field for outside EU?** |
| Answer | All countries are included in this list |

## MeDRA mandatory

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| --- | --- |
| Question | **Why is a MeDRA term mandatory for a SA in Scientific Information section?** |
| Answer | This is already the case for orphan designations, and it is required by EMA for classification and reporting purposes. Also, the MedDRA term automatically determines the therapeutic area (MedDRA SOC). |

## Significance of Medicine profile

|  |  |
| --- | --- |
| Question | **Why is a medicine profile mandatory for a SA in scientific information section?**  |
| Answer | The intention of this field is to provide information about the type of product in a structured manner. The field is mandatory to ensure that one term is chosen by the applicant. It is expected that the list of terms is comprehensive and thus each product will have at least one applicable term.  |

## Terms with similar meaning

|  |  |
| --- | --- |
| Question | **What is the difference between “therapeutic” and “therapeutic medicine” ?** |
| Answer | Thank you for the feedback on the list, this is noted. The term is from a RMS list (SPOR) which needs to be amended.  |

## Legal basis mandatory for SA

|  |  |
| --- | --- |
| Question | **Why is the legal basis for the future MA mandatory for a SA in scientific information section?** |
| Answer | The intended legal basis allows the applicant to indicate the type of development programmed that is pursued by the Applicant. This provides EMA and SAWP with the context for the proposal and associated data requirements at time of MAA. The field is mandatory to ensure that one term is chosen by the applicant.  |

## Redundant information requested

|  |  |
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| **Question** | **Why do we need pick-up terms after we already provide a summary of questions in scientific information section?** |
| Answer | This field is required for the applicant to flag if the advice pertains to specific clinical aspects that require expertise within EMA or the network or require input from specific committees/working parties. This is as per the current Letter of Intent, for example where the applicant should proactively select “modelling and simulation” when it is applicable. These fields allow the same selection in the new form. |

## Documents from EMA section

|  |  |
| --- | --- |
| Question | **Why for a draft submission there is a category “documents from EMA” active?** |
| Answer | This the section where documents from EMA to the Applicant will be added during the procedure. It can be ignored while the submission is in draft status.  |

## MedDRA terms list

|  |  |
| --- | --- |
| Question | **Primary proposed medical condition/indication (MedDRA): is the list complete or will it be further populated? It seems to miss indications.** |
| Answer | The MedDRA list is filtered and contains all MedDRA terms for levels 2 (HLGT), 3 (HGT), and 4 (PT). It does not include level 1 (SOC) which is too broad, nor level 5 (LLT) as it is too narrow for a medical condition/indication. If you cannot find a level 2, 3 or 4 term, please raise it as bug with <https://servicedesk.ema.europa.eu> .  |

##

## Non mandatory fields should be completed if required.

|  |  |
| --- | --- |
| Question | **“Please add any additional conditions/indications for this procedure”: This field remains highlighted even if it’s not mandatory.** |
| Answer | This field is not mandatory and should only be completed if required. |

## Extension of tickbox options

|  |  |
| --- | --- |
| Question | **“This request contains question(s) about:” please confirm if the list will be further populated.** |
| Answer | At present it is not possible to determine whether additional points will need tobe added. |

## Look-up lists

|  |  |
| --- | --- |
| Question | **Will all the look-up lists be further expanded?** |
| Answer | Not all look up-lists are not finalised. For example, the look-up list for “quality questions on the following manufacturing activities” will be updated. The list is not exhaustive but intended to include high-level terms to describe common quality questions.Please note that most of the lookup lists in IRIS are integrated from RMS in SPOR. All stakeholders, including Industry, can request updates or additional terms in these lists; once updated in SPOR, the list will automatically reflect in IRIS.  |

## Abbreviated development programme

|  |  |
| --- | --- |
| Question | **Request related to abbreviated development programme: once one of the two fields is selected, it is impossible to unselect. It would be good to make it mandatory and have a third option with N/A.** |
| Answer | Thank you for your suggestion. |

## Marketing Authorization-’Both’ option explained

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| --- | --- |
| Question | **Type of marketing authorization: in which cases “Both” is applicable?** |
| Answer | As the criteria and the data requirements for each type of MA differ, it is expected that either but not both abbreviated programs would apply to the scientific advice proposal. This feedback is noted.  |

##  Field not mandatory

|  |  |
| --- | --- |
| Question | **Under medicine profile, there is a question called ‘this request contains questions about’ which has 2 options only digital therapeutics and orphan similarity. What is the purpose of this question and will this be limited to only these 2 choices.** |
| Answer | We need to collect this information if applicable. This field is not mandatory. |

##

## Option for adaptive trial design

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| --- | --- |
| Question | **Under “Trial scope”, there is no option for adaptive trial design, can that be added?**  |
| Answer | In principle, this information should be tracked under the “Enabling technologies” of the RPI, where this option is available, as it applies to the whole development of the product and not a single SA procedure. However, the option can be also added in the RMS list if desirable; please note that most of the lookup lists in IRIS are integrated from RMS in SPOR. All stakeholders, including Industry, can request updates or additional terms in these lists; once updated in SPOR, the list will automatically reflect in IRIS. |

## Suggestion for free text fields for further explanations

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| --- | --- |
| Question | **General question: all these field have drop down menu but there is no option for free text field in case the applicant needs to explain something?** |
| Answer | This is to simplify the submission form. It is always possible to add explanations in the scientific document, or other free-text fields. |

##

## Difference between scientific innovation/Therapeutic/Technical innovation

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| --- | --- |
| Question | **Type of innovation (in scientific information section): Please can you provide definition/example on what you mean by scientific innovation/Therapeutic innovation/ Technical innovation to ease our choice?** |
| Answer | This is at the discretion of the applicant. |

## MedDRA code should always be provided.

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| --- | --- |
| Question | **In the “other EMA procedure planned section”: it might be useful to define the abbreviation (i.e, ATMP certification SMEs and MUMS Classification) to ease the completion.** |
| Answer | The suggestion is noted. |

## MedDRA term: is it mandatory?

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| --- | --- |
| Question | **For the field “Primary proposed medical condition/indication (MedDRA)”: could a field named “Not-Applicable” be included, in case a perfect match for the indication/condition does not exist?** |
| Answer | No, a MedDRA term for the indication/condition should always be provided – please choose the most similar term, or a broader one if necessary. Terms from MedDRA levels 2 , 3 and 4 can be chosen. |

**Scientific Advice – Additional RPIs**

## When should additional RPIs be provided?

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| --- | --- |
| Question | **Please confirm when additional RPIs should be provided.** |
| Answer | Additional RPI (s) should be specified if the scientific advice is being requested for a combination treatment (not for a fixed-dose combination product), where more than one product from the same applicant will be used in the clinical trial(s). |

**Scientific Advice - Parallel consultation EMA / EUnetHTA**

## Contact HTAs

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| --- | --- |
| Question | **How to contact HTAs? Will they be contacted via EMA or separate? How is this working in IRIS?** |
| Answer | The process is currently being reviewed. All guidance and new developments on parallel consultations with EUnetHTA can be found [here](https://www.ema.europa.eu/en/human-regulatory/research-development/scientific-advice-protocol-assistance/parallel-consultation-regulators-health-technology-assessment-bodies). |

## HTA’s field not mandatory

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| --- | --- |
| Question | **It is not entirely clear to us how to define the field “participating HTAs”, as we do not know at this stage, which HTA’s are going to participate? Is this considered to be our choice of HTA’s, so the ones we are reaching out to?**  |
| Answer | This field is not mandatory. You can indicate HTAs that you would like to be involved, if any. |

## EDWP involvement

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| Question | **Regarding the question, ‘Is involvement of Early dialogue Working Party (EDWP) preferred?’ the intent is not clear. Isn’t EDWP party always involved as they are responsible for the approving the parallel consultation request?**  |
| Answer | The process is currently being reviewed. All guidance and new developments on parallel consultations with EUnetHTA can be found [here](https://www.ema.europa.eu/en/human-regulatory/research-development/scientific-advice-protocol-assistance/parallel-consultation-regulators-health-technology-assessment-bodies). |

## Supported documents upload

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| Question | **The supported documents for the upload are of broad range and might not be the ones which are uploaded during a Parallel HTA EMA SA. We would consider a review of those files. Also, would we need to upload those files within the Documents from Applicant section?**  |
| Answer | There is no requirement to upload any files other than the draft briefing document. |

**Scientific Advice - Documents from Applicant**

## Zip files

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| Question | **Is Zip file upload possible?**  |
| Answer | Yes, but it is NOT recommended. Please do NOT submit the whole application as a Zip file, and please do not include anything in a Zip file, except PDF documents for the literature references. A single PDF file combining all references is preferable to a Zip file.  |

##

## Documents to be included

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| --- | --- |
| Question | **Do References and Letter of Authorization need to be included?** |
| Answer | References should be uploaded, preferably as a single PDF file (or a ZIP file). There is no need anymore for a Letter of Authorization.  |

**Scientific Advice - Follow up procedures**

##  Follow-up has same structure as Initial SA

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| Question | **Do followup procedures have the same structure as the initial SA request?** |
| Answer | Yes, very similar, only some data are prepopulated (e.g. condition, RPI if known, etc.) |

**Overall**

## Generation of application is not mandatory but advisable

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| Question |  Do we need to generate the application form before finalizing submission? |
| Answer | Generation of the application form is not required for the submission. This option is available to applicants for their records. |

## Downloading the submission package

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| --- | --- |
| Question | **Can the whole package and documents be available at any time/any steps for downloading, as it would make it easier to align with internal functions/stakeholders for information to be provided as well as for archiving.** |
| Answer | Yes, that is already possible in the system. Just click on the uploaded documents to download them. For the data in the portal, you need to create the submission form first, which can then be downloaded. The submission can be created at any time during the drafting and submission states. |

##

## IRIS is less time consuming compared to previous system

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| Question | **As an overall impression it seems more time consuming to fill the form online in IRIS than current practice of compiling and sending a letter of intent and briefing package. I found the IRIS system overly complicated, requiring too many steps and too much information.**  |
| Answer | The fields in the IRIS form are not more than the fields contained in the previous letter of intent: some have been removed, and a few have been added. The main difference between the old PDF letter of intent and the new IRIS form is the automatic validation of mandatory fields, which prevents submission of incomplete applications and increases the chances of a speedier validation.  |

## One or more Orphan Designations?

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| Question | **Can we add more than one Orphan Designation, as currently one Orphan Designation is allowed?** |
| Answer | Protocol Assistance and relevant fee incentives can be provided for a single product on a single indication, therefore one designation is sufficient. |

## IRIS to be used for SA post Go-Live

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| Question | **Will the current system for SA request remain available post launch (i.e. during hyper care phase) or will it be mandatory as of go-live?**  |
| Answer | From go-live submission via IRIS is required (however see question 63 on the grace period). |

## Transitioning between systems: grace period?

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| --- | --- |
| Question | **With very few colleagues having IRIS access for now and launch date being shortly after summer period, it might be useful to allow for a transition period with both systems available for a smoother conversion from one system to the other.**  |
| Answer | During the “grace period” in case of technical problems with the submission through the IRIS platform that cannot be resolved within a reasonable timeframe it will still be possible to submit using the PDF Letter of Intent in the current fashion; these submissions will be entered manually in IRIS by EMA staff. Applicants should be aware that this may result in a delayed start date, particularly if their submission is received shortly before the deadline. |

## Parallel SA with FDA

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| Question | **Is the IRIS platform also expected to use for the joint SA between EMA and FDA? If yes, what would be the procedure followed for that.**  |
| Answer | The process for parallel SA with FDA remains the same. The part that will be handled through IRIS only relates to the submission of the application and draft briefing document. |

## Letter of Intent replaced by IRIS

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| Question | **Is the letter of intent not needed anymore? Especially within the grace period from October 2020 or December 2020?**  |
| Answer | The PDF “letter of intent”/application form will be replaced by IRIS. From 17 October 2020 submission via IRIS will be required. However during the “grace period” in case of technical problems with the submission through the IRIS platform that cannot be resolved within a reasonable timeframe, it will still be possible to submit using the PDF Letter of Intent in the current fashion; these submissions will be entered manually in IRIS by EMA staff. |

## Change in way of submitting SA applications

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| Question | **What is the general procedure EMA is outlining with SA via IRIS? As of now the Letter of Intent let to a draft Briefing book, which received input from EMA before finalization. Will this disappear?**  |
| Answer | There is no change in the process, but a change in way of submitting. The current letter of intent and draft briefing submitted via Eudralink in the sa\_submissions inbox will be replaced by the IRIS portal application, and the briefing document will have to be uploaded in IRIS |

##  Applicant / EMA interaction

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| Question | **What is general interaction during an SA? Will everything be handled via the IRIS platform (document exchange, advise, etc)**  |
| Answer | Yes. The portal contact (person who is submitting the application) will receive all communication from the IRIS system, and is expected to reply to the emails without changing the subject, to ensure proper routing of the email. We recommend to have at least two managers for every submission, to be able to change the portal contact should the initial one become unavailable. All documents from EMA will be made available in IRIS. Eudralink will not be used.  |

**Additional questions received**

* **A Rapid Scientific Advice programme has been made available for development programs to prevent or treat SARS-CoV2. Will this be included in the scope for mandatory use of IRIS SA? Or can we keep on relying on Eudralink submissions for that specific Rapid SA procedure?**
From 19 October, all Scientific Advice submissions are expected via IRIS. However, in the hypercare period (3 months) priority will be given to Rapid Scientific Advice procedures for SARS-CoV2.
* **For Scientific advice procedures initiated prior to 19 October, but with scientific document (briefing packages) due post launch: should these be transferred to IRIS, or can it be completed outside IRIS?**
It is possible that at least some or most of the ongoing procedures at 19 October will be transferred to IRIS by EMA staff. In this case, applicants may receive communications from IRIS, but will not be required to reapply via IRIS.
* **For RPIs already assigned, is it possible to extract a list (e.g. in Excel) of all RPIs already granted to a given Company (bearing in mind a company may entails several ORGs/legal entities)?**
EMA is considering publication of the list of all human RPIs in the public IRIS homepage, or access after login to the list of all RPIs assigned to the organisations to which the user is affiliated to. The function to download the list in Excel is easy to add, and will be implemented in both cases. However this is unlikely to be delivered at go-live date. Finally, for OMS a company (parent organisation) is a legal entity registered in a single country; there is no link between different parent organisations registered in different countries.
* **What are the constraints and impact of selecting an ORG when creating and sharing RPIs and Sc. Advice?**
For every IRIS submission (not just for Scientific Advice), an OMS location (address) of an OMS parent organisation (to which the user is affiliated to) needs to be chosen at first. The submission will then make reference to RPIs and pre-existing Regulatory Entitlements assigned to that particular location.
* **For companies with multiple ORG numbers, dependent on location, what ORG to choose for requesting RPI and then working on a SA? Should this be the organization of the potential, future marketing authorization holder rather than location of the manager? This is to avoid complications in situations where RPI is assigned to one location, a manager to another, and a scientific advice still addressed to the company/applicant (located at the third location).**
An IRIS User can create submissions on behalf of any of the Organisations he/she is affiliated to (and for all their locations). When creating a submission in the name of a specific location, the outcome of the procedure will be in the name of the specified location (for example, an Orphan designation will have that Location as the sponsor, and the SA Final Advice Letter will be issued to that Organisation/Location).