Information Management

October 2022

Digital application dataset integration (DADI) eAF Training Webinars (26 July 2022 & 2 September 2022)

Questions and Answers

Disclaimer

This Question and Answer (Q&A) document is for information only and is based on insights available at the time of the DADI eAF Training Webinars held on 26 July 2022 and on 2 September 2022. Nothing in this document should be taken as an explicit commitment on behalf of the EMA, or the DADI and PMS project teams.

For convenience, many technical terms are explained in the table of abbreviations at the back of this document.

For general inquiries, please contact the DADI project team via esubprogofficer@ema.europa.eu or the PMS project team via the EMA Service Desk. For questions or comments around the content of this Q&A document, please raise a ticket via the EMA Service Desk.

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Table of abbreviations

Abbreviation	Explanation
CAP	Centrally Authorised Product
CP	Centralised Procedure
DADI	Digital Application Dataset Integration
DCP	Decetralised Procedure
eAF	Electronic Application Form
EMA	European Medicines Agency
EU	European Union
xEVMPD	Extended EudraVigilance medicinal product dictionary
FHIR	Fast Healthcare Interoperability Resources
H	Human
IAM	Identity and Access Management
IDMP	Identification of Medicinal Products
IG	Implementation Guide
IRIS	EMA's Regulatory & Scientific Information Management Platform
ISO	International Organization for Standardization
MAH	Marketing Authorisation Holder
MHRA	Medicines and Healthcare products Regulatory Agency
MRP	Mutually Recognised Procedure
NAP	Nationally Authorised Product
NCA	National Competent Authority
NtA	Notice to Applicants
OMS	Organisation Management Service
PMS	Product Management Services
PoA	Proof of Authority
RA	Regulatory Activity
RMS	Referentials Management Service
SIAMED	EMA database for Centrally Approved Products
SPOR	Management Services for Substances, Products, Organisations and Referentials
Q&A	Questions & Answers
UAT	User Acceptance Testing

1. When will the final DADI requirements be made available? Is there an overview of what exactly will change compared to the PDF version (e.g. a free-text field in PDF versus a picklist in DADI coming from PMS)?

The EMA will publish the final Excel document with requirements. An updated version was published in early July. There will be a latest version published before the UAT starts. An overview of what will change compared to PDF forms: the fields are basically the same because the content is owned by NtA.

2. When will PMS go live?

PMS will go live in several steps. Currently, the product data available in PMS are already used to support the inspections activities at the Agency. Moreover, PMS will start make the product data available with the DADI release scheduled in October and, later on, in March, as announced at this event. The full PMS go-live will be announced at later stage as the EMA is working to developing the main components to allow user accessing and managing authorised product data directly in PMS.

3. What exactly are bug fixes?

A bug fix consists in a change to a system or product designed to handle a programming bug/glitch. Bugs may be discovered during the UAT (testing phase). If identified, these need to be fixed via implementing any suitable solution on the system to allow the correct functionality in production environment.

4. Is it mandatory to use DADI from October 2022? Is this still a transition period which is extended in March 2023 to align with second release?

The go-live for the form for CAPs is in October 2022 but that does not represent the start of the official transitional period. So, even though you can start using DADI forms for CAPs in October 2022, it is certainly not mandatory. The portal is there for applicants to use, but the EMA did not want to start the official transitional period before the form can cater for all procedures, especially in the view of mixed CAPs and NAPs procedures. Therefore, the transition will start in March when all procedures will be supported.

5. What does 'structured data support' in Q4 2023 mean exactly?

The structured data support means structured data fields will be added. So, the EMA will be reading structured data information as for IDMP compliant from its internal database for CAPs and from xEVMPD. For example, the ingredient or manufacturer data will be already filled in the form in the present and then the changes will reflect in the proposed. Then, the EMA will push this data back into PMS to be used in the next regulatory activity. There will be more information on structured data when other releases approach.

6. When is it planned to enrich/correct data information for CAPs and NAPs in case data in DADI eAF is incorrect?

The functionality to correct and enrich product data will not be available for the October go-live. However, DADI and PMS teams are already working with architecture experts to develop functionality and, most importantly, to design the user interface to allow this functionality. This should not be available before 2023. In any case, if users find product information are wrongly reported, the EMA recommends raising the issue by the Service Desk so that the issue can be addressed internally.

7. Should people already register to the portal when they are only using it for NAPs?

It will be possible to register from October 2022. However, unfortunately applicants using only NAPs will not be able to select any product yet until the second release scheduled for March 2023.

8. Which are the EMA internal databases used as source data in DADI?

The Agency's internal database SIAMED is the database used by the EMA to manage Centrally Authorised Products for which the available information are migrated to PMS and being retrievable in DADI eAF variation.

9. When can users begin requesting access to the production web portal eAF? Before or at go-live?

It will be possible to request access to the portal in production in the beginning of October.

10. Is it possible to start using the DADI portal in October when the transition period has not started yet?

Yes, it will be possible to start using the DADI portal for CAP products once it goes live.

11. Access with product records in PMS is being built from match and merge from SIAMED and Art. 57: may it imply that the display of CAPs at DADI initial go-live may change with subsequent DADI/PMS releases?

No, the product data as authorised are the same across both databases (SIAMED and xEVMPD). What will change is that one the delta to ensure the synchronisation between xEVMPD and PMS will be in place, more product data will be made available to populate other PMS attributes. PMS team released the EU IG V2.1.1. at the end of July 2022 to explain the above. We recommend reading Annex I to Chapter 7 of this document.

12. Which web browsers can people use to access the eAF portal?

Chrome and Edge work fine. The portal should also work with Firefox.

13. How can people attend the troubleshooting session?

The troubleshooting sessions currently organised are open to DADI UAT participants.

14. How shall smaller companies handle user management, if applicant and administrator is not supposed to be the same person? Is it mandatory or just recommended not to use the same people?

For a given ORG-ID, an account can have both an applicant and administrator role. However, users should not request 2 different applicant access levels (for example, applicant contributor and applicant manager).

15. How is DADI linked to the IDMP implementation and when can the FHIR templates be available to cross check systems?

DADI is linked to PMS because the latter is the main database to contain authorised product data. The link relies in the IDMP compatibility because the IDMP will be implemented soon.

The structure you will find in PMS has been aligned with DADI forms and the same will be done for the other forms to be delivered in the future. The link is in essence in the structure agreed between ISO IDMP colleagues, but also the FHIR. So, the data model was completely adapted across the 2 systems.

The EMA is working to make DADI FHIR templates available to be reusable into PMS database, to complete the circle. There is no timeline for when this can be used yet.

16. Who should sign the proof of authority (PoA)?

The PoA should be signed by an authority of an organisation. All the details are illustrated in the user administrator guide: https://register.ema.europa.eu/identityiq/help/useradmin.html.

17. If a manager selects a product of his/her organisation, does he/she have access to all applications of this product?

The manager role gives access to applications created by the user or applications where the user has been appointed as co-author. In order to have access to all applications for an organisation, a user should be granted with coordinator access.

18. Can people submit an EMA account request on behalf of another employee or must they individually submit the request?

You cannot submit the EMA account request on behalf of another employee. You will have to create the account separately. Same applies to the roles: you will have to access your EMA account management portal and ask for your own roles.

19. Are current IRIS admins automatically eAF admins?

Yes, the role has been combined. If you are an IRIS administrator, you can already manage eAF portal access.

20. How is it possible to obtain the proof of authority for IRIS-eAF admin user?

You can find the steps described in the user administrator guide: https://register.ema.europa.eu/identityiq/help/useradmin.html.

21. Can the Industry User Admin role be transferred to another person within the EMA Account Management System (e.g. if the person currently holding the role is leaving)?

The EMA recommends having multiple administrators per organisation in order to ensure business continuity. Additionally, access can be revoked if a user no longer needs to have the administrator role. This would fit the purpose of a role transfer.

22. After registering, do non-admin users need to request their role or can the Admin add all users to a role?

Applicants should request access. The administrator will then receive an access request which can be approved or rejected.

23. When PMS starts supporting DADI eAF product information, will the Art.57 data be previously migrated to PMS or will there only be a feedback loop between the databases?

The product data as authorised and submitted in xEVMPD will be loaded via delta sync to PMS in order to be made available for retrieving purposes in the DADI eAF Variation form to deal with the RA procedures. Once the RA procedure is completed, the user will still be required to submit the authorised data in art57. EMA data steward will capture the updated product data in SIAMED as per usual procedure. However, please note that, at the time of the first DADI release in October, product data will be loaded from the EMA internal database only.

24. Can the Administrator role grant access to Applicant roles (contributor, coordinator, manager)?

Yes, it is correct.

25. Why is the Admin role for DADI eAF named as IRIS/eAF Industry user Admin? Is it related to the Admin role for the IRIS portal?

Yes, it is the same role. IRIS and eAF administrators can manage user access for both IRIS and eAF applications.

26. Which authenticator settings would users need for login?

For the multifactor authentication step, users can configure either the Microsoft Authenticator App, or SMS.

27. How can admin users manage user roles?

The administrator role allows users to approve or reject admin roles request from your organisation. Additionally, it also allows users to revoke roles.

28. Is there any timeout time set in eAF portal? How long will users stay logged-in once they initially logged in in one session?

Yes, there is indeed a timeout which is quite long though. It is definitely longer than half an hour. Details on how long this time is will be added in the user guidance.

29. Will the recording and the slides be shared and when?

Yes. The recording and the slides will be made available via the 26 July 2022 webinar EMA event page and the 2 September webinar EMA event page, and the eSubmission website.

The recording will be also made available by e-mail and EMA YouTube channel in a few weeks.

30. Why can administrators select only one organisation at a time when submitting a request?

At the moment, administrators need to submit one request per ORG-ID. Additionally, this feedback was already reported to the Account Management team.

31. Can a colleague create an access for another?

At the moment, the requests must be individually submitted.

32. Can an applicant delete a wrongly created eAF (e.g. wrong MAH)?

Yes, this is possible. In the account management portal, go to "Manage My Access". There, you will see the option "Remove access", where you can select and revoke the role you no longer need.

33. Will a signed PoA still be needed if access is arranged in the EMA system?

PoA are required for all administrator roles.

34. Do applicants have to create every time a new eAF or is there the possibility to import eAFs already created and change the information?

In principle, applicants should create a new eAF each time. The EMA had a very highly-ranked feature or use case in the backlog to copy applications for past forms. The EMA is working on doing something similar now. However, since the basis of the form is selecting the marketing authorisation holder, if applicants have to change it, the point of copying the applications would not exist anymore. Therefore, the EMA was not able to come up with a feasible use case for copying application for now, and creating a new eAF remains the best option at the moment.

Note that creating the form should be much quicker than in the past, so it will be not such a demanding task anymore. However, if the EMA receives a lot of requests asking for a copying functionality, the EMA may rank it higher in the backlog.

35. For MAs in DC/MRPs that have multiple MAHs across MSs, would an applicant or person completing the form need to be associated with each MAH?

Yes, this is why sometimes, especially in those scenarios for DC and MRP, access management can be a bit complex. Global MAHs might have multiple companies under them in various countries. If one person in a company currently fills in forms for all these subcompanies, this person will need to be associated to all of them to have their products.

36. Does an Organisation need to have a coordinator role or can it only have manager roles?

It is up to the organisation to decide whether the organisation should have Applicant Coordinator(s) and/or Applicant Manager(s). At least one user should have one of these two roles so to be able to initiate (create) an electronic Application Form.

37. For eAF access, does the administrator give right to access to applicants like in OMS?

Administrator users can approve/deny access role requests. Administrators can approve applicant access requests as well as other administrator access requests.

38. Can users have an option to edit the form again after completing the finalisation step?

Yes, users can reopen the form.

39. Should the downloaded PDF eAF be signed via scanned signature? Is a signature mandatory?

No, scanned signatures are not required. EMA does not foresee mandatory signature requirements. The user decides how to sign the form. Nevertheless, users should also be able to sign it using a real digital signature.

40. Can the web-based Application Form be downloaded at any time during preparation? Can an interim version be saved at a local drive to be reviewed by others (e.g. by someone who has no access to DADI eAF portal)?

The EMA implemented a feature to share the eAF within the portal. Users can assign the form to anyone in the portal they want to share it with. This is especially useful for sharing eAF with third parties.

Users can also just download the form as a PDF and send it via e-mail. However, the EMA highly recommends using available in-browser features.

41. If present and proposed information is long, is it still possible to refer to an Annex in form which includes the information?

It would not be advised by EMA because data in the Annex could not be automatically imported into the systems. One of the main aims with the DADI form is to get the automation enabled. From the procedural point of view, if there is a high number of pages, users can refer to an Annex.

EMA tried to incentivise the use of new user-friendly system features instead of the Annex. For example, the system supports rich texts, copy-pasted material, and tables.

42. Will a DADI guide similar to the eAF registration guide that has been released recently be provided?

Yes. A similar guide on how to use the web UI will be released. The EMA is also planning to record short videos on different sections of the form in order to make the search of the desired topic easier. More guidance materials will be provided.

43. For present and proposed change apart from manual texting and adding pictures, can applicants attach the present and proposed document?

Yes, it is possible. Users would just include it in the relevant section of the eCTD sequence, namely in the same section where the forms are included (section 1.2 on the human eCTD).

However, the EMA does not encourage that, even though it is necessary in certain scenarios where it is not possible to include all the changes. Nevertheless, it should not be attached to the form using the paper clip, but just added as a separate document.

44. Is the progress in the DADI portal saved automatically? In case of poor performance, broadband issues, etc., will users have to re-do the form, or will it be automatically saved for recovery?

In DADI, there are various save-points when a user fills in the procedure. The document is not only saved when the user clicks on "save" button, but the system makes an auto-save after almost every action taken by the user. This is a standard power feature, which is used in the background, and makes it very unlikely to lose data in case of a system crash.

45. As long as the UK MHRA uses EMA eAF, what is the plan for DADI? Will the UK MHRA continue to use the web-based DADI form? Will the UK MHRA have access to PMS? How will data updates be handled?

Unfortunately, due to the BREXIT, EMA is not working together with MHRA hosting the form since it is a EU application form. MHRA may continue using the PDF form, which will remain available through the website for some time even after the transitional period has ended because variations applications may have started while the transitional period was still ongoing. Indeed, applicants might need to update the forms might. Therefore, the EMA will not completely remove the forms or eliminate the web services for some time even though not officially working with MHRA anymore.

For what concerns product availability, following the BREXIT, there is a protocol on Ireland and Northern Ireland. If there is any product that has been authorised at national level within the UK via the national procedure (DCP, MRP) meant to be sold in the Northern Ireland under the same protocol, PMS will follow the same rules applicable to xEVMPD. The same applies in case of medicinal products which are centrally authorised or products that have to be sold in Northern Ireland. Therefore, the formal agreement is not changing, but there are some changes from a UK perspective.

46. What can users do if xEVMPD data is incorrect? How does the eAF take information from xEVMPD?

This issue is expected because EMA performs the UAT migration of information from xEVMPD and SIAMED. EMA recommends every user to check XEVMPD data to make the corrections directly in the system. With the use of DELTA, it will be propagated to PMS database and user will see it already reflected in the relevant DADI form. This is relevant mostly to the XEVMPD. In the future, EMA is planning to release a user's interface and the full connection with the API. In this way user will be able to directly correct and reach the data straightforwardly in PMS.

47. When will the MA transfers be supported in DADI?

In some NCAs, the variation form is used for MA transfers. The same should be possible using DADI. However, this has not been tested yet, as the non-CAPs are not yet available in the system. Once the UAT for the NAPs release planned for March 2023 starts, the EMA will be able to confirm how feasible the use of the web form is for this purpose.

In the long term, the EMA can review if a specific MA transfer form is needed.

48. How will users understand which values are in the internal system as base for DADI field values for them to prepare the forms and link it with their RIM systems?

The DADI form uses lists from SPOR where possible. In certain cases, it may be a combination of multiple lists. The SPOR list IDs are being added to the data excel file.

49. Will users be able to select any of the products from their organisation during the UAT, or will they only be able to test on a limited number of products?

All products associated to a given MAH organisation should be available for selection/ testing in the form.

50. Are there plans to include MRP/DCP in DADI forms?

The Nationally Authorised Products (NAPs) will be included in the web form in the next scheduled release in March 2023. NAPs generally also include the MRP/DCP products, as these are also authorised through a non-Centralised route.

51. Will the second Beta UAT (including NAPs) also be coordinated by Trade Associations secretariats and allow a large number of participants?

The experience from the first Beta UAT with the coordinators worked very well. The EMA is currently internally exploring the best way to facilitate a larger number of testers that are likely to take part in the next UAT, considering that the number of NAPs is considerably higher than CAPs.

52. Should consultancies register by their own for each MAH or should the MAH register them?

Each MAH has to affiliate the necessary consultancy to its organisation and grant a suitable role for the consultancy colleagues.

53. How and where can applicants register to use the DADI application form? What are the requirements?

To sign in to the eAF Portal, users are required to have (1) an active EMA user account and (2) user access role(s) assigned to that account. For further information, please consult the eAF Guide to Registration.

54. If a procedure started with current PDF eAF is still ongoing after March 2023, will applicants need to switch to web form?

No, the procedure will run until end with the form that it started with. The EMA always strongly discourages changing the form/version of the form during an ongoing procedure. It is also expected that if a procedure has started using the PDF eAF just before the end of the transitional period, and there is a request for validation-response, the form will not be changed at that point and the procedure will run until the end with that PDF eAF.

Exceptions to this rule, if any, will be announced well in advance.

55. Should consultancies request the access in the EMA Management Portal as often as they support different

MAHs? Does the MAH need to give access to the Consultancy company?

Yes, this is correct. Each MAH has to affiliate the consultancy to its organisation and grant the relevant access to the relevant colleagues from that consultancy.

56. How can people get access to the Access Management troubleshooting sessions?

Here below are the recordings from the two Access Management troubleshooting sessions:

- 1st Access Management Troubleshooting Session (21 Jul 2022) Recording (YouTube)
- 2nd Access Management Troubleshooting Session (23 Aug 2022) Recording (YouTube)

57. Should service providers register for the MAHs for which they submit dossiers/variations?

Yes, this is correct. Each MAH has to affiliate the service provider to their organisation and grant the relevant access to the relevant colleagues from that service provider.

58. Which data for CAPs will be coming from EMA internal database at go-live? Can this data be corrected in the eAF? If not, how?

The data coming from the EMA internal database is the product data held for each product. This includes, for example, the ingredients and manufacturers data. If incorrect information is found, this should be corrected by contacting the EMA through the usual channels.

59. Can only one person per organisation cover a specific role?

There is no such restriction. The EMA's Access Management is a decentralised process i.e. organisations are invited to self-manage their own accesses. For instance, the EMA advises to have at least two User Administrators per Organisation.

60. When users log into DADI, do they see a list of the MAHs for which they have been authorised? How can they select the MAH they need at a certain moment?

Yes, DADI users will be able to see and to select only the MAHs that they are affiliated to.

61. In case of a mid-sized company, is it sufficient for the eAF Industry User Admin to approve an employee for the eAF Applicant Coordinator role to fully use DADI?

The number of required users and which roles would be appropriate for each of them depends on the internal structure of each organisation.

62. Do users need an EMA account for each organisation they act on behalf of?

No, users only need a single EMA account. However, each MAH has to affiliate the user to its organisation and grant the relevant access to the colleague.

63. Country regulatory colleagues may need to act as a contributor for some applications such as MRP/DCP and, at the same time, may need to act as a coordinator for other applications such as national ones. How is this going to be managed?

The NCAs colleagues will be able to register as NCA users and they will be able to see all products authorised in their relevant Member State.

64. If the new eAF is used for a variation, is there the possibility to use the old one for the next variation?

Yes, this is possible. Following the initial launch, and even during the transitional period, it is possible to use the web eAF and the PDF eAF in parallel for different procedures. However, the format of the form should not be changed during an ongoing procedure. If applicants start a procedure using the interactive PDF eAF, they should not shift to the web-based form in the middle of that procedure and, conversely, if applicants start a procedure with the web-based form, they should ideally not revert back to the interactive PDF form, unless unresolvable issues without a suitable workaround are found.

65. Is it correct that both MS authenticator as well as SMS verification code require a mobile phone?

Yes, it is correct.

66. Do users need to have a business mobile phone or they can use their private telephone number for authentication? Can computer certificates be used as well?

A business or a private mobile phone are required to complete the multifactor authentication. Computer certificates are not applicable for authentication.

67. When will it be possible to register for the DADI UAT for NAPs in December/January?

Details of the timing and approach to the second Beta UAT will be published as soon as possible. However, the EMA is not able to provide the exact timing yet.

68. If the incorrect MAH is selected in the first section of the eAF, can applicants correct this information or do they have to create a new eAF?

In this situation, users would have to create a new eAF.

69. Can users create a template for their eAFs or use an existing eAF as a template for a new one?

At the time of the initial launch, the 'copy' function will not be available yet. This means that if a form from a previous submission is modified, that document is then lost, and the user will not be able to retrieve the original form. For this reason, it is not recommended reusing the forms for other submissions.

The feature to do a simple copy of the form is in the product backlog and it has been ranked high priority, meaning that it will be implemented as soon as possible.

70. Is the list for classification of Variation types populated from RMS list?

Yes, this is the same RMS list which is used in the current interactive PDF eAF. The only difference concerns how the Type IB unforeseen classifications are managed using the business rules vs extended attributes. This may lead to some classification scopes not having this procedure type available initially as this has to be added to each classification manually. If such a case is detected, please raise a service desk ticket to add this procedure type (as per the usual existing procedure).

71. Would you consider adding an information icon describing the information required to each page on the eAF?

The team is currently working on adding information buttons and tooltips in the web form. Even though an info button might not be available at the time of the initial launch, if the EMA receives requests to add these, they could be implemented at a later stage to make the UI as easy to use as possible and reduce the need for the users to consult the Portal navigation guide.

72. Will the EMA review DADI forms in draft, i.e. to estimate incoming workload? How long will completed forms be retained and visible through the DADI portal?

It is currently not planned to use the system to forecast the number of future submissions/variations. A retention period has been discussed and will be reviewed once the users' needs are better clarified.

73. Will the eAF be visible by all users of the same organisation or is there a confidentiality by country?

Users with the eAF Applicant Manager role for a given organisation can create/ access/ edit applications created by themselves; users with the eAF Applicant Coordinator role for a given organisation can create/access/edit all applications created for that organisation (i.e. created by him/herself or created by other users within that organisation).

74. Is the EMA Variation procedure number assigned when the form is created or when the form is validated?

As per the current workflow, the variation procedure number is assigned upon receipt of the form/upon validation. The introduction of the web-based form alone does not change this workflow.

75. Where is the grouping justification/unforeseen classification justification added in the DADI Form?

The Type IB unforeseen classifications are managed in the web form using extended attributes instead of business rules like in the interactive PDF. This may lead to some classification scopes not having this procedure type available initially as this has to be added to each classification manually. If such a case is detected, please raise a Service Desk ticket to add this (as per the usual existing procedure).

76. Why are the scopes and background separated out while they were together in the old PDF format?

This was implemented based on a business change request from the regulators.

77. Where is the FHIR message?

The FHIR xml message is contained within the exported PDF. Once you open the PDF and click to the 'paper clip' icon in the side navigation bar, the xml attachment is shown and can be opened for viewing.

78. How can the final form be downloaded?

To download the final form, hit the Export button within an eAF.

79. Can a draft of an eAF which is no longer used be deleted?

Yes, users with the eAF Applicant Manager or the eAF Applicant Coordinator role for a given Organisation may delete eAFs with Draft, Deactivated or Completed status.

80. Can applicants expect any test environment apart from UAT to experience the portal before going live?

As the go-live does not trigger the transitional period, the registered users can use the production environment to experiment and to test the form(s).

81. How many accesses as a co-ordinator role can a single company have?

The number of coordinators per company is not limited. Each organisation can decide autonomously how many users are needed and which access rights each user should have.

82. After issuing a PDF file, will it be necessary to include it in Module 1 as it is currently done?

Yes, there is no change to the way the forms are included in the submission package and how these submissions are submitted. The PDF rendition should be included in the section 1.2 of the EU M1 as it is currently done.

83. As soon as a section or the whole eAF is validated, can an applicant make changes (e.g., type of change, product selection) to the form?

Yes, you may always edit/update already saved/validated sections. Please note that eAF sections are interconnected so that editing/updating already saved/validated sections may result in making already completed sections back to uncompleted status.

84. Is it possible to print the eAF, even though it is not yet final and validated?

An eAF can be exported at any stage of the eAF filling.

85. Is there any limit to view already submitted or processed applications?

It is possible to open previously filled in and finalised forms. The retention period, namely how long these forms will remain available, will be discussed with the stakeholders.

86. Once the eAF is completed and you have added the details for the signature and you click "Validate", is it closed? Should it be signed with Adobe or simply exported and included in the eCTD structure?

Validating the form does not close it. The user can use the 'finalise' button to indicate that the form is now finalised and export the PDF for signature (if the MAH wishes to include a digital signature) in the PDF. Once the exported PDF is considered ready by the applicant, it should be included in the eCTD submission (section 1.2 of M1).

87. Normally the EMA can create a Procedure Number when the procedure starts: is this true with the web-based eAF?

As per the current workflow, the variation procedure number is assigned upon receipt of the form/upon validation. The introduction of the web-based form alone does not change this workflow.

88. Is there a date to select - upon approval?

It is possible to either select a date from a calendar or to include a note, which can for example be a text reading 'upon approval'.

89. Which tools are involved to develop the DADI web form?

The web form has been developed with MS365 PowerApps technology with as little customisation as possible.

90. If Type IA (TIA) is selected but a condition or document is missing, does the eAF web-based application change from TIA to TIB for example?

No, the form does not automatically change the procedure type. If a condition is not filled or if a document is not provided, it is possible to add a justification in the form, just like in the interactive PDF form. If users wish to upgrade the variation to Type IB, they can remove the procedure type (as opposed to removing the whole classification (scope)) in the interactive PDF form.

91. Can you add multiple co-authors?

Yes, multiple co-authors can be added.