19 September 2025
EMA/305939/2025

Q&A Q3 2025 System Demo

Date: 17 September 2025

Location: Online, 09:00 - 12:30 Amsterdam time (CEST)

Link: https://www.ema.europa.eu/en/events/quarterly-system-demo-q3-2025

Disclaimer

This document contains a direct record of all questions asked through Slido.com during the System Demo and their written answers.

Questions not asked through Slido.com were not captured. Questions that did not receive written answers below where either responded to verbally or did not receive a response during the System Demo event. Questions asked in the "Plenary" room were generally taken as not addressing specific IT products and are not included below.

The responses represent the expert view of the development teams at the time of the System Demo and are not official statements by the European Medicines Agency nor its partners.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

Table of Contents

Research & Development Value Stream 3
Clinical Trials Information System (CTIS) modernisation 3
Trial Map 3
Scientific Explorer 3
Product Lifecycle Management Value Stream 5
Union Product Database (UPD) 5
Product Management Services (PMS) 5
Product user interface (PUI) 9
Electronic application form (eAF) 11
Electronic product information (ePI) 13
Regulatory Procedure Management (RPM) for Product Lifecycle management on IRIS 14
Monitoring Value Stream 16
EudraVigilance data analysis system (EVDAS) 16

Research & Development Value Stream

Clinical Trials Information System (CTIS) modernisation

Question	Reply
Please consider to implement an option to download the saMS overview (e.g. as an Excel file) if not already done.	The first version will be a Minimum Viable Product (MVP) covering the essential requirements, followed by an MVP+ by the end of 2026, which will include additional enhancements based on the experience with the initial MVP. We take note of this suggestion, to be considered - if not for the MVP, then at least for the MVP plus.
Please consider to give the NCAs the opportunity to test the system in detail prior to go-live.	We can confirm that this is the intention and that the process to prepare the User Acceptance Testing plan is underway.
Will the "right click/open in a new tab" functionality be enabled in the new ASR module?	Comment noted. The first version will be a Minimum Viable Product (MVP) covering the essential requirements, followed by an MVP plus by the end of 2026, which will include additional enhancements based on experience with the MVP. We take note of this suggestion, to be considered - if not for the MVP, then at least for the MVP plus.
When is the release of the New Safety Module planned for? Can you please provide the link to the New Safety Module? How will the access be managed?	The new safety Module is planned for deployment in early 2026. Discussions on access management are currently ongoing.

Trial Map

Question	Reply
[no questions received]	

Scientific Explorer

Question	Reply
Would you also include the EC approval date in this tool ?	Yes, EC approval date will be included in the tool.
When will the update (for the demo including MAs data) be available? Also, will the more detailed search that includes indication group terms be available for the scientific advice category as well?	The goal is to go live for the EMA and NCAs in Q1. Yes the grouping search [MedDRA AI] is already live and available in scientific advice, and will also be available for MA when this is released. The MedDRA AI search will operate on the proposed indications for both/either category.

Question	Reply
When is approximately scientific explorer available for public?	Scientific explorer contains confidential information, therefore it is available for the European medicines regulatory network only.

Product Lifecycle Management Value Stream

You can subscribe to the quarterly PLM Highlights Newsletter at
https://ec.europa.eu/newsroom/ema/user-subscriptions/3638/create

Union Product Database (UPD)

Question	Reply
Is it possible to search for consequential VNRAs for NCAs in the VNRA screen?	In Q4 2025 users will be enabled to browse and filter(as a new column) the VRA procedure number entered for the respective consequential VNRA(s) in the View VNRA Submission page.
What to do when in a lot of upd products terms are non-current or missing, eg. legal base ?	Currently, non-current referential terms in UPD do not prevent users from updating or creating products, so this is not causing any issues. The UPD Data Quality framework will be re-launched on Monday, 22 September 2025, and it will enable NCA users to identify products with non-current referential terms or missing legal bases and update them accordingly.

Product Management Services (PMS)

Question	Reply
Can you please provide an update and an estimate time when all the data quality issues in PMS will be solved? Our members find it difficult to invest resources in enriching data when it can all be reversed by changes in import rules.	*Question answered verbally during the demo.*
Can we get the timeline by when the xEVMPD sync issues will be resolved completely? Thank you	*Question answered verbally during the demo.*
It was mentioned in the previous Q&A session that both LLT and HLT can be used in PMS for MBOs for CAPs. Does this mean we can now start opening EMA tickets for correcting MBOs from HLT to LLT for CAPs to correct in PMS PUI?	*Question answered verbally during the demo.*
By when can we expect the publication of Chapter 4 "Data quality assurance" of EU IDMP IG?	*Question answered verbally during the demo.*

Question	Reply
The Manufacturing Activities RMS list values are different from the values available for selection in PMS PUI and from the list included in Chapter 3 - Annex II. When they will be aligned and fit for the ESMP enrichment?	*Question answered verbally during the demo.*
Could you please share if you are planning to provide a test/validation environment to test the write PMS API? And what the timelines are for this?	*Question answered verbally during the demo.*
For very old products where no eAFs are available, should we enrich data of manufacturers/MBOs based on 32S21 and 32P31 dossier sections alone?	*Question answered verbally during the demo.*
For how many records we can bulk update the pack size at a time?	*Question answered verbally during the demo.*
Currently we cannot see HLT in the dropdown for MBO's in PMS UI but available in RMS list. When this will be made visible?	*Question answered verbally during the demo.*
Did the Root number concept applicable for Non Caps also	*Question answered verbally during the demo.*
Are there any plans to have sandbox ?	*Question answered verbally during the demo.*
Can an overview of the National Health Authorities progress on the mapping of their national database with PMS be presented ? Some HAs are moving on (AT, LU...)	*Question answered verbally during the demo.*
How can we get the PMS ID of reference products of other companies to our Generic product that we have to reference in IDMP system?In the PMS we only see products related to user roles of connected companies.	*Question answered verbally during the demo.*
How often is data between the XEVMPD and the PMS database synchronised?	*Question answered verbally during the demo.*
In some cases one MA number is still captured at product level even if there different MA numbers at package level. In PMS document it is resolved in Q3 but not resolved is there an new timelines for that	*Question answered verbally during the demo.*

Question	Reply
Is there any training planned from EMA for 'Bulk update' feature?	*Question answered verbally during the demo.*
National IDs are not mandatory to be updatd in pack size. Please confirm whether this will be mandatory in future becoz right now we are not incorporating these IDs into packsize & later this will be daunting task becoz of large portfolio.	*Question answered verbally during the demo.*
The List of Manufacturing operations to select from in PMS doesnt include the First Level Term eg processing operations for Medicinal product. Will These Terms become available?	*Question answered verbally during the demo.*
A known issue with xEVMPD product updates not being reflected in PMS due to an older version of the EV code is sent to PMS. The expected resolution is in Q3-2025. Is it resolved now?	The root cause was fixed in Q3 but the data fix for the impacted products will be fixed in Q4.
Can you please explain PMS PUI data use of MBO Start Date & Manufacturing Authorisation Reference Number. Per "PMS data Matrix Cross Platform" doc these not used by ESMP, please confirm if used for shortages mitigations & prevention plans	The dates and reference number are not used for the moment by ESMP. We have also changed the conformance of these elements.
Could NCAs be committed to provide a country level recommendation for definition of national ID for pack sizes, to support consistency? Some NCAs have done so but many not.	We have asked the NCAs to provide this feedback and it is explained in the PMS Q&A document.
Could you please confirm the submission deadlines for products linked to ESMP: by the end of June 2026 (effective 1 July 2026) or by the end of July 2026?	The deadline has been extended 6 months from end of December 2025 to end of June 2026 (so effectively 1st of July 2026 the ESMP products should have been enriched).
For products not managed in XEVMPD for the moment (out of Art 16.2 scope for example), would a migration from National Authorities databases be possible ?	No. For the moment we don't expect NCAs to provide any product. We will need to discuss with them if these products are needed in PMS, what is the use case, etc.
How many number of products can be updated in Bulk in the PMS UI production?	For the moment, at go live, only 50. We will remove this technical limitation in Q4.

Question	Reply
Has the deadline for Manufacturers and MBOs been extended to give the industry more time, or is there a gap in the system? If we already have the data available, can we perform a bulk upload in PMS? When will be available?	Yes, the deadline has been extended and for products linked to ESMP, the deadline is now July 2026. The bulk update will be opened next week and you can start submitting data as soon as it is opened.
How to manage if pharmaceutical product strength in PMS if it is NOT available in the source documents?	the strength of the active substance should be available in the SmPC.
I open a CR in PMS for a MP but i'm not be able to finalize it due to warning of validation failed. I tried to refresh the product but the warning appears again	Please, open a ticket for the PUI team so they can check the specific case and what is the issue.
If there are problems with products with status "pending national phase", does this have any impact of use of these products in the new eAF?	Yes, the incorrect authorisation status is captured in PMS. You can submit a dummy update in XEVMPD (add a dot to the comment section) so PMS now takes the correct status. This way, you will be able to use it in the eAF.
in the material term list in RMS, the "composite" material is not listed ? should I ask to add it to the list or is there any rule for alloy of several materials ?	As we are not requesting the materials for the moment, the RMS team is not including these terms yet. Once we request this information, we will have a discussion with SMEs and the RMS team to check what is needed and if we need to add additional terms.
Is it possible to add a colomn for medicinal and packaging level MA number in the BI report ?	We can put this feature in our backlog to be picked up whenever we have the capacity but for the moment it is not possible. You can nevertheless need to combine the packages report and the products of my organisation report.
Is there any plan to implement full medicinal product report export in dynamic reports?	Not for the moment. The full medicinal product data is very big and with different relationships (multiple packages, multiple ingredients, etc). So building one single report with all the data is not manageable. For the moment, we have different reports that might need to be combined by the user to perform different checks.
One product has multiple EV codes, with same strengths for active substance. If EMA edits the strength in one of these records in Xevmpd, it leads to multiple PMS IDs? Shouldn´t EMA make sure to edit all EV codes belonging to one product?	Your assumption is correct. We have improved the validation process so EV Codes belonging to the same medicinal product should be validated together. If this is not the case for your product, you can open a ticket and ask the XEVMPD colleagues to perform the same validation.
Should products authorised with legal basis EUM4all (Art 58) be available in PMS and in XEVMPD? Is there a business scope for them in PMS?	As stated in Chapter 3.ii of XEVMPD, products with this legal basis are required in XEVMPD and therefore we are migrating them to PMS.

Question	Reply
PMS (BE/LU/FI): by when the duplicated Packaged PMS ID created from xEVMPD should be removed from PMS ? Even if the package description is updated in xEVMPD with the same text in English for all records, this doesn't fix the issue	We have this feature in our backlog but so far we have not had the capacity to work on it. Hopefully in Q1 2026 we will be able to start the implementation.
What does UX improvement in PMS Ui mean?	It means the changes we have done to the Product UI. You can see that the User Interface now looks a bit different as before, the colours have changed, some tables and accordeons as well.
What role should be assigned to use the Bulk update functionalty in PMS UI?	The qualified industry role would be the best one.
When will be the incorrect Marketing Authorisation Holder (MAH) name appearing in the PUI?	If a organisation name has been changed in OMS but IRIS has not picked up the update, then, the old version will be shown in the Product UI.
Which regulatory authority should be selected for Austria in PMS submissions — BASG or AGES?	The one that approved the product.
Will this Bulk update functionality be extended down the line to other fields let's say change in MAH name after submission of web based eAF in near future scenario.	Yes, but not for the moment. We will open at some point the full product edit. But so far, it is only for ESMP related fields.

Product user interface (PUI)

Question	Reply
Can you please elaborate on the problems with the linking of products to the wrong/old OMS data, causing MAHs to have problems retrieving the products in PLM portal?	*Question answered verbally during the demo.*
For how many records we can bulk update the pack size at a time?	*Question answered verbally during the demo.*
We have data discrepancy between Dynamic report and the Medicinal product details available at 'Product of my organization' in PMS. When do we expect the fix for this issue?	*Question answered verbally during the demo.*
Any news on the additional product reports that have been announced?	*Question answered verbally during the demo.*

Question	Reply
Can bulk update be used for multiple products with multiple data elements (eg. pack sizes, MBOs)?	*Question answered verbally during the demo.*
Can you create a stable URL from a MCA/industry IT system to PMS, enabling the showing of a product there, using the PMS ID? We'd like to go from out system to ons product in PMS with one click.	*Question answered verbally during the demo.*
Is there the intention to develop a bulk update functionality with extensive excel tables?	*Question answered verbally during the demo.*
the bulk edit functionality is available for all the data elements required to MAH: pack sizes, manufacturers, MBO and data carrier? or depending on the data element is recommended to use the PUI or the API?	*Question answered verbally during the demo.*
When will the incorrect Marketing Authorisation Holder (MAH) name appearing in the PUI be fixed?	*Question answered verbally during the demo.*
When you open the ESMP dynamic report, the manufacturer of active susbtance are in the drug product manufacturer column. Do you know?	*Question answered verbally during the demo.*
Will there be a training/test environment for the PUI?	*Question answered verbally during the demo.*
Would it be possible to check the legal basis (as per Directive 2001/83/EC) of approved, not-owned medicinal products in this PLM-PUI?	*Question answered verbally during the demo.*
Add Pack size via PMS and not xevmpd correct?	The pack size should be submitted through XEVMPD but the structured pack size data (10 tablets or 2 vials) should be done through PMS.
Can you please explain PMS PUI data use of MBO Start Date & Manufacturing Authorisation Reference Number. Per "PMS data Matrix Cross Platform" doc these not used by ESMP, please confirm if used for shortages mitigations & prevention plans	For the moment these two fields are not used by ESMP. We have also changed the conformance of these fields.

Question	Reply
How to manage if pharmaceutical product strength in PMS PUI if it is NOT available in the source documents? (edited)	The strength is coming from XEVMPD and the data from XEVMPD is coming from the SmPC. So the strength of the pharma product should be stated in the SmPC. For the excipients, please, do not include this data in XEVMPD as it is not required.
When preparing a web-based eAF few fields were spotted with blank values, but when reviewing PMS PUI the accurate expected values for those fields were present. Are you in awareness of synchronization issues between PMS PUI and eAF PLM?	We will check with eAF team, but I would recommend you to open a ticket with screenshots we can have a look at it.

Electronic application form (eAF)

Question	Reply
We cannot use eAF yet as data pulled from PMS is wrong. We cannot transition internal processes to eAF until we are assured that we do not run into constant problems	We fully understand that there are cases where the PMS data quality issues do prevent systematic use of the PLM Portal eAFs for certain products. We are pleased to see that the number of products with data quality issues is decreasing, but we understand that there are cases where the interactive pdf needs to be used. If you find errors in the data, please always report these issues so that we can ensure that the issue is already on the list to be fixed and is not a new finding.
Since the PMS eAF can be modified by different users and roles, is there an audit trail functionality available to track the changes made, and by whom?	There is an audit trail at the back-end of the system, however, this is not available for the end user or even the admin user of the system. If there are question on particular changes made in the system, the technical team can access the audit trail and provide details if needed.
Can we proceed with submitting the web eAF even if it reflects an old MAH name, considering the current legal entity name is not yet updated in PMS PUI and therefore not appearing in the eAF but up to date as per OMS?	Yes, in most cases that would be acceptable. You can mention the limitation in the cover letter and as the receiving regulators would normally look at the LOC-ID and ORG-ID the fact that the text is not correct should not cause issues. We are working on adding an ability to select the MAH name also directly in from OMS (as display value) and we're hoping to be able to deliver this improvement in Q4 2025.
For non-CAPs products, for a product which have multiple packagings, we can't choose a packaging in web based eAF for now, is it plan to be deblocked ? It is only available for CAPs only.	This is indeed as per design. During the design and analysis the business requirement that all changes impact all packages was given to the eAF team. For Centrally Authorised Products the user should indicate the impacted pack sizes/packages by selecting the relevant packages.

Question	Reply
How can eAF become mandatory when there are still so many bugs to fix? We have many problems with the display of the marketing authorisation number (the MA number field is empty or there are different MA numbers under one PMS ID).	The use of the PLM Portal eAF is not yet mandatory. We are in strongly recommended use for CAPs since May 2024 and we are planning to move to Strongly recommended use for non-CAPs at the end of the quarter. There is a difference between mandatory and strongly recommended use where the latter means that the form should be used in most scenarios, however, the interactive pdf is still available in case the users are not able to use the PLM Portal form. In mandatory use, the interactive pdf is no longer available and the PLM Portal must be used in all cases. We understand that it can be frustrating to the users to notice the data issues in the form and we work very hard with the PMS team to solve issues. However, we feel that it is important to gain experience and discover findings during this period before the mandatory use hence the strongly recommended use.
Can we do the switch to non-CAPs product for eAF even if there are some error in the datas (for example : for missing authorized dose form, will be corrected during Q3, but for some active subtance also) ?	You can do the switch already. If there are significant issues with the products, you may need to continue to use the interactive pdf in some cases, however, if you come across an issue, please do report it to the EMA, so that we can continue to fix the issues/address any bugs. Please also note that you might be able to use the PLM Portal eAF for some variations and continue the use of the interactive pdf eAF for other products/procedures. You do not have to move to use the portal for all your procedures/products at the same time.
For variations eAF - the list of CMSs takes up more than the first page. Is it possible the essential info of Type of application to be shown after the MRP number so it`s all in one glance? Or at least the CMSs are in drop down?	This is indeed how the list of the CMS countries is presented and if there are many selected, then the list is very long and can easily take 1.5 pages, exactly like in the interactive pdf eAF. The country of the product is additionally listed in the section 2. for each product. We would be really interested to hear an improvement proposal how to make the form more user friendly for the regulators. Please feel free to raise a change request either via 'comment' in service now or via email with as much details as possible and with a justification and examples if possible.
Is there a possibility to see changes that the Co-Author made to the eAF?	It is not obvious from the UI, however, at the back-end of the system the technical team can retrieve information where needed.
nonCAP, GR: In product details tab MAnum is visible. However GR HA have requested to use EOF product code in the eAF (code remains unchanged throughout the lifecycle of the MP).Can the EOF code be accommodated in eAF in place of MA number?	There is information on how to do this in the XEVMPD document for GR products; See question 5.10.1.7 Authorisation number: NAP in Greece. You are allowed to use either number: the product code OR the approval number. It may be necessary to include a code in the package description to ensure that not all packages have the same number so there is a distinction between different packages.

Question	Reply
Ongoing data migration issues with pack size details such as Missing and invalid EV Codes are affecting xEVMPD and PMS. These problems may result in inaccurate information being used in human variation electronic applications.	We are aware that there are some data quality issues in the eAF. Please do raise a service desk ticket if any new issues are detected so that these can be corrected. This will also help us to provide better user guidance and instructions to users in case issues are found in the middle of editing of the form.
Regarding strongly recommended use for non-caps of the web base eAf, do we need to specify the technical problem when using the pdf eAf from 29th of Sep? Can we receive a rejection of the variation if the pdf eAf is used from 29th of Sep?	You do not need to provide any explanation or justification why you continue to use the interactive pdf eAF. We understand that there may be various different reasons for not being able to use the PLM Portal eAF. However, if there are technical issues/limitations, please do report them via the Service Desk (ServiceNow tool) so that we can address them. You will not receive rejection if you continue to use the interactive form, please note that the Strongly recommended use is just that, it is a recommendation, not the mandatory use nor it is the transitional period towards the mandatory use. However, it is a very important step during which we would like to see a significant increase in number of the PLM Portal eAFs being created and submitted to the network.
The eAF does not allow the removal of manufacturers from an ASMF without including another one.When there are 3 mfx and 1 of them is removed, eAF does not allow the deletion of this mfx in the struct data unless a proposed mfx is included.	This is indeed correct and as per design, 'deletion' or removal of an organisation in the present and proposed section is not considered as a 'change in manufacturers' i.e. the tick box should be ticked to indicate that there is no change and details of the organisation to be removed should be added in the free text field. We recognize this is confusing and we are actually working on a solution that will all the user to indicate that the change is a 'deletion' of an organisation and this will allow the user to leave the 'proposed' organisation field empty. We have planned to deliver this change in Q4 2025.
When will all authorities accept the web-based eAF? We have recently received validation rejection and a request to use the interactive pdf after submitting the web-based one.	All NCAs have confirmed that they are now accepting the web based eAF. Would you be able to contact us via email or EMA's service desk tool to provide some more details. It would be really helpful to know which agency rejected the form and better understand the reasoning behind the rejection.

Electronic product information (ePI)

Question	Reply
Any insights from the recent reflection paper consultation?	The comments received are currently under consideration. The updated paper will be published in due course.
For some products, Headings for the leaflet differ from QRD standard headings	Yes, the headings are editable.

Question	Reply
(like for Fludeoxyglucose Core PI: "5. How X is stored"). Does ePI allow the update of Heading wording?	
Which are the methods to to print (if needed) EPI on a paper sheet?	The portal offers 'Export to Word'. The exported Word file can subsequently be printed.

Regulatory Procedure Management (RPM) for Product Lifecycle management on IRIS

Question	Reply
We are experiencing that for PSUR submission of MRP/National products, one IRIS case has been opened per country involved. Are there any plans to streamline, as it creates lots of workload and duplication	*Question answered verbally during the demo.*
We would like to reiterate our request to have a single button to download an entire IRIS case folder (not document by document, or screenshots as this is the case now). EMA acknowledged this as enhancement under review. Where do we stand?	*Question answered verbally during the demo.*
EMA has confirmed their intent to preserve the product number as a business identifier, and they are currently identifying opportunities for improvement. Can you please give updates on this ?	*Question answered verbally during the demo.*
Future developments for iMAA: does EMA plan to have a pilot for rolling out iMAA procedures in IRIS? How do EMA plan to roll out iMAAs in IRIS?	*Question answered verbally during the demo.*
Can EMA provide a clear process flow on document level (eCTD/gateway versus IR	This is a very good suggestion, we will include a process flow in the next release of the Q&A document.
As a complex and big pharma company, we would like to suggest disabling feature for „edit rip“ replacing it by a new submission type allowing to ''update RPI'', so we can have a track of who updated any product data	Thanks for your suggestion. We have taken note of it and will convey it to the relevant product owner.

Question	Reply
Communication: are there any more EMA Q&A webinars planned for iMAA feature? Are there further regular meetings planned with industry representatives? How is EMA going to communicate about developments?	Thank you for your question. The next webinar for Industry is scheduled for 30 September 2025. Please register here. We will have an additional demo in December 2025, including roadmap update (confirmation of the exact go live date). Trainings will be announced closer to the go live.
For Veterinary Medicine Eligibility Requests- from what time do we need to send the ER through IRIS? As this request is now still applied per Service Desk. KR	The intended go live is Q1 2026. An update to the roadmap will be provided in the next system demo (December 2025), to confirm the exact date.
How will it work if we want to submit a change in LoI / change in date of submission for example ?	For changes to the intended submission date, a notification of change request will need to be submitted via IRIS as well.
There is a section in the IRIS webform asking for an upcoming submission MAA date, but that can easily create misunderstandings when several procedures are running in parallel for the same product/RPI. Are there any plans to improve this?	The industry coordinator has this overview. There is an improvement currently under development to allow the industry coordinator to assign managers to closed cases to enable retrieval and overview of historical data. Expected release, early Q4 2025.
When is the Letter of Intent/ eligibility request features meant to go live ?	The intended go live is Q1 2026. An update to the roadmap will be provided in the next system demo (December 2025), to confirm the exact date.
As a complex and big pharma company, we would like to suggest disabling feature for „edit rip“ replacing it by a new submission type allowing to ''update RPI'', so we can have a track of who updated any product data	Hello, thanks for your suggestion. We have taken note of it and will convey it to the relevant product owner.
Communication: are there any more EMA Q&A webinars planned for iMAA feature? Are there further regular meetings planned with industry representatives? How is EMA going to communicate about developments?	The next webinar for Industry is scheduled for 30 September 2025. Please register here. We will have an additional demo in December 2025, including roadmap update (confirmation of the exact go live date). Trainings will be announced closer to the go live.
Can EMA provide a clear process flow on document level (eCTD/gateway versus IR	This is a very good suggestion, we will include a process flow in the next release of the Q&A document.
The e-business pipeline update has been canceled for June by EMA, mentioning ''due to recent technical developments with the EMA's IRIS platform'', can EMA please clarify what are the plans about e-business pipeline being handled in IRIS?	This question is out of scope of the presentation.

Monitoring Value Stream

EudraVigilance data analysis system (EVDAS)

Question	Reply
In the framework of Implementation Regulation 2025/1466: Amendment of Regulation No 520/2012 is the requirement for MAH for Signal Detection in EVDAS no longer needed?	This question is out of scope of the presentation. You can raise it via this page: https://www.ema.europa.eu/en/about-us/contacts-european-medicines-agency/send-question-european-medicines-agency