

| Name • Organization • Role  | Vote                | Use Case Section          | Comment  | Disposition  |
|---|---------------------|---------------------------|--|--|
| Rhonda May • OneHealthPort • Committed Member                               | Yes (with comments) | 11.0 Dataset Requirements | <p>In the response section of the data requirements, the document shows that the HIE does not use the Strength and Form of the drug. This is not the case. It is use and should be checked. In the WA DOH transaction, the strength and form are coming in the same data stream as the name of the drug, but it is data that is required and should be checked.</p> <p>In the Date written field the HIE should have the box checked. This is a data field that is used.</p> <p>In the Refill Number field, the HIE should have the box checked. This data field is used.</p> <p>My understanding is that there was going to be a Product code data element added to the response and it would have appropriate qualifiers to provide information as to which code was submitted (i.e. NDC) There was discussion about a different coding system that is also used because of the deficiencies in the NDC numbers being reused, I don't recall the name of that coding system.</p> | Add "X" in HIE column for Strength and Form of Drug, Date Written, and Refill Number. The Product Code data requirement is listed as the Drug Identifier data requirement.   |
| Cynthia Coulter • TN Office of eHealth Initiatives • Committed Member       | Yes                 |                           |  |  |
| Cathy Graeff • National Association of Chain Drug Stores • Committed Member | Yes                 |                           |  |  |
| Shelly Spiro • Pharmacy HIT Collaborative • Committed Member                | Yes (with comments) |                           | <p>These are overall comments from a pharmacy/pharmacist prospective. This initiative is addressing current processes related to what occurs now within a pharmacy that affects downstream use by pharmacists dispensing information captured by PDMPs. We should look toward a future solution in identifying medication information in real-time including bi-directional exchange of information between providers. This is an important patient safety perspective especially but not limited to substance abuse. I encourage the formation of sub-group to identify future processes not identified in the use case that can lead to real-time bidirectional exchange for managing medication information including PDMP information between pharmacies, pharmacists, HIEs and those receiving incentives for the MU of EHR program.</p>  | Thank you for your comment. While we understand that the patient safety perspective is an important aspect, the formation of sub workgroups are for in-scope items. We encourage pilots to provide feedback on real-world challenges that they experience during testing of the implementation guide which could include recommendations for future projects. As we're in the development of the IG we may need a pharmacy WG for the pharmacy workflow. |

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| Michele Davidson • Walgreen Co • Committed Member                                     | Yes (with comments) | 3.2 Out of Scope                        | While this initiative has addressed the current process, it has failed to address future needs of the pharmacy industry to curb drug abuse and diversion as this was deemed out of scope. I would encourage ONC to consider the formation of sub-group to identify future processes that were not identified in the current use cases. These processes can lead to real-time solutions to resolve workflow issues, prescription drug abuse and diversion, as well as patient matching.   | Thank you for your comment. While we understand that the patient safety perspective is an important aspect, the formation of sub workgroups are for in-scope items. We encourage pilots to provide feedback on real-world challenges that they experience during testing of the implementation guide which could include recommendations for future projects. As we're in the development of the IG we may need a pharmacy WG for the pharmacy workflow.  |
| Roger Pinsonneault • RelayHealth-Pharmacy • Committed Member                          | Yes (with comments) | 2.0 Initiative Overview                 | The deliverable fulfilled the initiative scope. However, the outcome mostly aligns with current processes and doesn't significantly advance a solution addressing the current short comings or future needs for PDMP data exchange. I recommend the committee members focus their efforts on: (i.) how these business functions interface with practice management systems (i.e. within workflow), (ii.) how to make the process seamless across state PDMP programs, and (iii.) contemplate how existing technologies and standards can be used to lower development and support costs. | We encourage pilots to provide feedback on real-world challenges that they experience during testing of the implementation guide which could include recommendations for future projects. Additionally, S&I Initiatives are narrowly focused but have broadly applicable goals, which allows implementers to take what we've done and build on that. Our Use Case is meant to be a document outlining the business requirements; these considerations can be added to the parking lot for future initiatives. |
| Donna Peterson • Montana Prescription Drug Registry • Committed Member                | Yes (with comments) | 10A.3.2 System Requirements             | This comment also applies to sections 10B.4, 10C.3.2, and 10C.4. My understanding was that we were going to remove all references to a hub or HIE transforming the request/response, which implies that the hub or HIE will have direct access to the detailed data contained in a PDMP's response. Montana can allow our data to pass through a hub or HIE, but the hub or HIE cannot have direct access to the detailed data (they can only access the "package wrapper" information).   | The community agreed on the community call to include transformation as part of the system requirements; transformation does not necessarily require access to the content but could be as simple as repackaging into a new format (e.g. putting an envelope around it). States determine who have access to their PDMP data, and our Implementation Guide will not specify any policy choices.   |
| Donna Peterson • Montana Prescription Drug Registry • Committed Member                | Yes (with comments) | 11.0 Dataset Requirements               | Please check the PDMP box for the following data elements for requests: City and Gender in the Patient Information section. The MPDR allows searches using these parameters.<br>Please check the PDMP box for all data elements in the General section for responses. Since the PDMP initiates the response, it makes sense that we would establish these values in each response.   | Put "X" in the above boxes.   |
| Tim Tannert • SoftWriters, Inc. • Committed Member                                    | Yes (with comments) | 10A.0 Scenario #1: HIT to PDMP directly | We need to outline a scenario where multiple patient matches are returned from the PDMP. We must ensure that the healthcare professionals do not need to work within multiple systems in order to secure an exact match.   | Our Use Case assumes that the healthcare professional has already identified the subject of the request. This is listed in our assumptions: "While it is understood that a request is sent by the HC Professional through the Health IT system to the PDMP, the PDMP may return a number of positive patient matches back to the Health IT System; our Use Case assumes, the HC professional or Health IT system positively identifies the subject of the request (POI)."                                     |
| Bill Lockwood • American Society for Automation in Pharmacy (ASAP) • Committed Member | Yes (with comments) | 10A.3 Functional Requirements           | This is becoming far more complicated than need be. We have to be cognizant of the implementation costs to PMPs. Also, need more active participation in the process by the PMPs.  | Thank you for your comment. We will continue to do outreach to PDMPs and other stakeholders.  |

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| Lester Keepper • SHAPE HITECH, LLC • Committed Member                               | Yes                 |  |  |  |
| Holly Walpole • INSPECT • Committed Member  | Yes                 |  |  |  |
| Danna Droz • National Association of Boards of Pharmacy • Committed Member          | Yes (with comments) | 11.0 Dataset Requirements                  | This is difficult to evaluate in a vacuum of experience. It appears to me that very few of the committee members have real world experience with which to compare and make recommendations. We are looking at data elements and many of them seem valuable in the abstract. However, in my experience, some data turns out to have less value in actual practice. This time next year there will be a good pool of experience from which to draw and evaluate proposals.       | Thank you for your comment and we expect to receive feedback from our pilots. Additionally, this table represents the perspectives of various stakeholders but has not been fully validated. |
| Lynne Gilbertson • NCPDP • Committed Member   | Yes (with comments) | 3.1 In Scope                               | Item 2 minor - 2.If standards do not exist, identifying the gap in the current standards and working with the Standards Organizations (SDOs) to address the gap - Modify to Standards Development Organizations (SDOs) since the acronym is SDO.   | Modified to read, "...working with the Standards Organizations (including Standards Development Organizations)"  |
| Lynne Gilbertson • NCPDP • Committed Member   | Yes (with comments) | 3.3 Communities of Interest (Stakeholders) | Suggest Standards Organizations - since the above section uses the acronym of SDO, either remove acronym SDO from document in favor of Standards Organization, or change this to SDO.<br><br>Professional Associations - suggest (AMA, Pharmacy Associations) be removed for consistency. Examples are not given for others and for the two examples, one is citing an organization and one is citing a concept, so they are not consistent. Better to remove for consistency. | The communities of interest table consist of Standards Organizations (to be consistent with the disposition for the above comment)   |
| Lynne Gilbertson • NCPDP • Committed Member   | Yes (with comments) | 5.0 Use Case Assumptions                   | Bullet 2. Suggest "All" be removed. The assumption is that the Healthcare Professional has appropriate .... do not need to assume "All".<br><br>Bullet 4 spell out HC - Healthcare. POI is not defined explicitly.   | Accepted   |
| Lynne Gilbertson • NCPDP • Committed Member   | Yes (with comments) | 6.0 Pre-Conditions                         | 2.If an intermediary, such as a Hub, is used it provides necessary technology infrastructure to allow PDMP data exchange from the PDMP to the Health IT system - to be concise with our drawings below, please modify to<br>2.If an intermediary, such as a Hub, is used it provides necessary technology infrastructure to allow PDMP data exchange from the Health IT system to the PDMP and back  | The data exchange originates with data that is stored within in the PDMP which is why it is written the way it is.   |
| Lynne Gilbertson • NCPDP • Committed Member   | Yes (with comments) | 10B.1 User Stories                         | Just for ordering, suggest 7 become 4.<br>Same change to user story #2 for the sentence A patient arrives at the pharmacy to have a prescription filled.   | Reordering comment - accepted<br>Accepted  |
| Andrew Holt • Tennessee Controlled Substance Monitoring Database • Committed Member | Yes                 | 3.2 Out of Scope                           | While some items are considered out of scope it must be understood that some items in this section may limit participation in pilots by an undetermined number of states.  | Acknowledged   |

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| Lynne Gilbertson • NCPDP • Committed Member | Yes (with comments) | 10A.1 User Stories                           | <p>Suggest that if the "package response" cited in multiple rows in section 8.0 Actors and Roles, that we have a use case that explains what this means. We do not appear to define what this activity is.</p> <p>User Story 2. Suggest to make it more generic so that other pharmacy settings are supported.<br/>Change from A patient arrives at the pharmacy to have a prescription filled.<br/>to<br/>A prescription is sent to the pharmacy for dispensing.</p>  | <p>Package response seen in the interchange requirements is used for the Hub and HIE/Ph. Intermediary since they will collect and package the responses from multiple states. The community agreed to keep this as an interchange requirements and in the functional requirements we have package to mean to be able to put together the request in a standardized format</p> <p>User Story 2 - accepted</p> |
| Lynne Gilbertson • NCPDP • Committed Member | Yes (with comments) | 3.3 Communities of Interest (Stakeholders)   | Do we need to have a statement in the Hub description that shows they may also perform some kind of packaging? To support 10B.   | The definition provided for Hub is posted on the initiative glossary. The more technical aspects of the hub are detailed in the system requirements.   |
| Lynne Gilbertson • NCPDP • Committed Member | Yes (with comments) | 10B.1 User Stories                           | <p>In 10B.0 Scenario #2: Healthcare Professional requests patient history of controlled substances from PDMP via a Hub, does the Hub hold the PDMP data? I believe the Hub sends the request onto the PDMP, right? If so, we need to add:</p> <p>. At the appropriate point in the workflow, the request is sent to a Hub through the Health IT system to obtain patient history of controlled substances dispensed. The Hub receives the request and sends the request to the PDMP. The PDMP processes the request and sends a response to the Hub. The Hub sends the response back to the Health IT system where the request originated. After receiving the response(s),</p> <p>Also would need to add this to the pharmacy User Story #2. (and make the same change to the prescription being sent versus the patient showing up...)</p> | For the purposes of this use case, we will be focusing on the transactions originating from the HIT to the next end point, which would be the PDMP, Hub, or HIE/Pharmacy Intermediary.   |
| Lynne Gilbertson • NCPDP • Committed Member | Yes (with comments) | 10B.3.1 Information Interchange Requirements | <p>Need 2 more rows interjected.<br/>Row 2 Hub has to send the request to the PDMP<br/>Row 3 PDMP sends response to the Hub</p>  | For the purposes of this use case, we will be focusing on the transactions originating from the HIT to the next end point, which would be the PDMP, Hub, or HIE/Pharmacy Intermediary.   |
| Lynne Gilbertson • NCPDP • Committed Member | Yes (with comments) | 10A.3.2 System Requirements                  | <p>We use the term package in HIT system. In 8.0 we do not have the health IT system doing "package").</p> <p>Missing the Hub has a system involved.<br/>We need definition of "package".</p>  | Package, as listed in the system requirements, is the ability to put together the request in a standardized format.  |

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| Tom Bizzaro • First Data Bank Inc. • Committed Member                               | Yes (with comments) | 3.2 Out of Scope          | <p>I commend this group and those that have done so much work to develop the current PDMP's currently implemented. These programs are providing benefit in allowing healthcare professionals access to helpful information on the use of drugs with potential for abuse. It is now imperative to look past the limited scope of this initiative to a real-time solution that can be embedded in the physicians and pharmacists work flow. Data now flows bidirectionally from physicians to pharmacists to third parties in real-time millions of times a day. This data transfer happens within the workflow and the end user is not required to leave their healthcare management system to accomplish the exchange.</p> <p>If we are truly looking for a national solution to a national epidemic of abuse and we want to provide information that could allow healthcare professionals to help those with problems of abuse; we must look past our current methods.</p> <p>It is my hope that this initiative is a first step. National standards exist that would allow states the independence they want to develop their PDMPs and provide a real-time exchange of data within the workflow.</p> <p>I look forward to future discussions and additional work on this issue.</p> | Acknowledged  |
| Andrew Holt • Tennessee Controlled Substance Monitoring Database • Committed Member | Yes (with comments) | 10B.2 Activity Diagram    | <p>This is also in the out of scope section, but there are multiple places that may imply that data is opened between the PDMP and the end user. Many state privacy laws do not allow this process and therefore it should be removed from the diagrams to allow maximum participation from the state PDMP's.</p>  | States determine who have access to their PDMP data, and our Implementation Guide will not specify any policy choices.  |
| Carl Flansbaum • New Mexico Board of Pharmacy • Committed Member                    | Yes (with comments) | 11.0 Dataset Requirements | <p>I'm voting Yes with the assumption that there may be changes to these Data Elements as we work through the Standards Gap Analysis and Harmonization sections. I also believe that some of these Use Cases may not be able to be supported by the PMDPs if the data elements are outside of those that are part of the PMIX architecture which is what the PDMPs use now and from which most will be unable to modify.</p>   | Thank you for your comment and we expect to receive feedback from our pilots. Additionally, this table represents the perspectives of various stakeholders but have not been fully validated. |
| Lynne Gilbertson • NCPDP • Committed Member   | Yes (with comments) | 10C.1. User Stories       | <p>Change the first sentence in User Story#2 to the recommendation from above.</p>   | Accepted  |
| Lynne Gilbertson • NCPDP • Committed Member   | Yes (with comments) | 10A.4 Sequence Diagram    | <p>Not quite sure of consistency. In the Sequence Diagram it says the HIE/Ph. Intermediary routes the request to the appropriate end points (4). But in all the sections above, it treats the HIE/Ph. Intermediary as the end point (the entity that has PDMP data). Is it the diagram that should change, or is it the sections above need to include the PDMP as the source of the data?</p>   | For the purposes of this use case, we will be focusing on the transactions originating from the HIT to the next end point, which would be the PDMP, Hub, or HIE/Pharmacy Intermediary.        |

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| Jeff McMonigal • Surescripts • Committed Member                        | Yes (with comments) |                           | <p>The purpose of this initiative is to bring together the PDMP and health IT system communities to standardize the data format, transport, and security protocols to exchange patient controlled substance history information between PDMPs and health IT systems. Doing so would enable health care professionals to make more informed clinical decisions through more timely, effective and convenient access to PDMP data in an effort to reduce prescription drug misuse and overdose in the United States.</p> <p>As an outcome if this initiative, we have failed to address the future opportunities that will help reduce prescription drug misuse and overdose in the United States. Rather, we've focused our efforts on documenting current workflows that exist today that are not designed to support a national solution.</p> <p>I would also encourage ONC to consider the formation of sub-group to identify future processes that were not identified in the current use cases. These processes can lead to real-time solutions to resolve workflow issues such as:</p> <ul style="list-style-type: none"> <li>•Patient Matching</li> <li>•Providing data consistently to multiple settings</li> </ul> <p>All of this, of course, with the intention of standardizing the exchange of patient controlled substance history information between PDMPs and health IT systems.</p> | <p>Thank you for your comment. While we understand that the patient safety perspective is an important aspect, the formation of sub workgroups are for in-scope items. We encourage pilots to provide feedback on real-world challenges that they experience during testing of the implementation guide which could include recommendations for future projects.</p> |
| Lynne Gilbertson • NCPDP • Committed Member                            | Yes (with comments) | 11.0 Dataset Requirements | <p>Concern with this section and the X. For example, if the pharmacy system is performing the query, then many of the boxes checked EHR would be checked for pharmacy system. For example, Date of Request.</p> <p>An intermediary would not generate a Date of Request, they would pass what they received from the EHR or pharmacy system initiator. Likewise HIE or Hub. They take what is sent them. When they respond, they echo back what was requested.</p> <p>I suggest we have to review this much more before the check boxes would stand.....I hate to formally object but concerned.</p>  | <p>We created this table to make sure that each data element mapped to at least one system. We will look at this further down during harmonization, but we wanted to make sure there were no extraneous data elements. Add disclaimer: This table represents the perspectives of various stakeholders but have not been fully validated.</p>                         |
| Wayne Burrows, MD • SHAPE HITECH, LLC • Committed Member               | Yes                 |                           |   |  |
| Barbara Carter • MN Prescription Monitoring Program • Committed Member | Abstain             |                           |   |  |
| Marty Singleton • Kansas State Board of Pharmacy • Committed Member    | Yes                 |                           |   |  |

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| Ralph Orr • Virginia Prescription Monitoring Program • Committed Member   | Yes (with comments)        | 11.0 Dataset Requirements                  | <p>I am very concerned that we spent a lot of time developing user stories and then rushed to completion when discussing dataset requirements. I think we need more work done on this as we go forward because I have seen too many instances where something that was supposed to be "optional" becomes a de facto requirement. It also seems that there is a lot of data elements included that may only be used at one end of a transaction and are not necessary for all parties to a transaction.</p> <p>This entire process is tremendously time consuming and then we encounter a rush to judgment. I suggest that when it is time for consensus in the future that more time be given for careful review and opportunity to inform leadership of certain issues that may be considered to be of vital interest in our states.</p> | Thank you for your comment; conformance criteria such as optionality will be included in the Implementation Guide.  |
| Timothy Davis • Beaver Health Mart Pharmacies • Committed Member<br>Dave Johnson • Kentucky Cabinet for Health and Family Services • Committed Member | Yes (with comments)<br>Yes | 10A.3 Functional Requirements              | I'm concerned with cost associated with intricacies. Community independent pharmacies are very cost sensitive and the more complexity is layered on currently operating PMPs, potential costs to operate will be driven upward. Simplification of processes need to be a priority. We also need to be mindful of cost neutrality and business effects of this initiative.   | We will take that into consideration as we collect the standards for the harmonization phase.   |
| Ben Loy • PDX, Inc. • Committed Member  | Yes (with comments)        | 3.3 Communities of Interest (Stakeholders) | I am still concerned with the level of participation by the PMP/PDMP entities. As the holders of the information needed this is one of if not the critical stakeholder group for this initiative. Initially, less than 50% of this group was participating in the initiative and although this has improved with the addition of three or four of these entities 100% participation by this group of stakeholders should remain the goal.   | Thank you for the comment, we'll continue to do outreach to PDMPs and other stakeholder groups.   |
| Eriko Farnsworth • Substance Abuse and Mental Health Services/DHHS • Committed Member   | Yes (with comments)        | 10C.4 Sequence Diagram                     | I concur with comments made by Donna Droz, NABP, and Carl Flansbaum, NM BoP, regarding the Data Elements. This is very difficult at this time to completely comprehend and agree to all the data elements without the necessary time to evaluate/study them.  | This table represents the perspectives of various stakeholders but have not been fully validated.   |
| Ben Loy • PDX, Inc. • Committed Member  | Yes (with comments)        | 10A.3 Functional Requirements              | I am concerned with the direction the group has taken and the resulting complexity in the standard selected that may result. Although cost is not a primary consideration in standards development the creation of an overly complex process could result in non-adoption or use and ultimate failure of the initiative.  | This will be addressed during harmonization process where we will incorporate potential barriers to adoption as part of the standards selection criteria. |

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| Tammy Devine • QS/1 • Committed Member  | Yes (with comments)        | 5.0 Use Case Assumptions  | In #4 of Assumptions it states the PDMP may return a number of positive patient matches. Can we handle this in the standard? We should not require HealthCare professionals to maintain multiple systems for identifying patients. How is this addressed if a hub is involved?   | We're not expecting HC professionals to maintain multiple systems for identifying patients. Also, we are not specifying how a HC professional identifies a patient but are accommodating the different ways Health IT systems do that today. We would not expect the standard to adjudicate possible matches with the actual person of interest. |
| Ben Loy • PDX, Inc. • Committed Member  | Yes (with comments)        | 11.0 Dataset Requirements | I am concerned with the data element selection process and the issues that are being pushed-off to be addresses in the future such as the use of Create Date. I was also very surprised to hear that the determination of a minimal required data set may not be possible. It was my understanding that the ultimate goal of this group, after determining the various requirements by the consensus process, would be to select an existing standard or create a standard to fulfill the need of communication available prescription drug information in the PMP/PDMP systems to prescribers and dispensers. If we are unable to even determine a minimal required data set then I fear that it will be impossible to complete this ultimate task. | Thank you for the comment; we will refine the dataset throughout this process as we move forward. Additionally, this table represents the perspectives of various stakeholders but have not been fully validated.  |
| Charlie Oltman • Target • Committed Member<br>Ernest Grove • SHAPE HITECH, LLC • Committed Member | Yes (with comments)<br>Yes | 11.0 Dataset Requirements | Item 5. We have created a laundry list of data elements but we still need to create a minimum required data set required to request and retrieve PDMP data to complete .<br><br>Also add for pharmacy systems:<br>Patient Section:<br>Patient Gender<br><br>Prescription Information section:<br>Payment Method<br><br>Dispenser Section:<br>DEA Number DEA<br>NCPDP Provider ID<br>National Provider Identifier (NPI)   | Thank you for the comment; we will refine the dataset throughout this process as we move forward. Additionally, this table represents the perspectives of various stakeholders but have not been fully validated.  |
| Charlie Oltman • Target • Committed Member  | Yes (with comments)        | 6.0 Pre-Conditions        | As discussed what needed to added after last week's call:<br><br>7. A risk alert rigger has occurred notifying the provider to access PDMP data.   | Added risk trigger as an example in the out of scope item #1   |

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| Charlie Oltman • Target • Committed Member   | Yes (with comments) | 4.0 Value Statement | <p>The purpose of this initiative is to bring together the healthcare community to standardize the data format, transport, and security protocols to exchange patient controlled substance history information between PDMPs and health IT systems. Doing so would enable health care professionals to make more informed clinical decisions through more timely, effective and convenient access to PDMP data in an effort to reduce prescription drug misuse and overdose in the United States. While this initiative has addressed current processes, its scope has not address future needs of the industry to curb drug abuse and diversion.</p> <p>We still need to look toward a future solution in identifying risk prior to writing and dispensing controlled substance medications in real-time including bi-directional exchange of information between providers and controlled substance history. I want to ensure that future steps include an initiative to identify these future processes not in scope for these use cases.</p> <p>ONC may have plans for additional discussions on moving access and transmission of PDMP data into the workflow of the physician and pharmacist, on providing access to PDMP data on a national level and in real time. However, the scope of the current discussions does not allow for those discussions. Without a national solution we cannot address a national problem.</p> | Defining standards for EHR systems to access PDMP data will increase utilization of PDMP data. |
| Christie Frick • SC DHEC, Bureau of Drug Control, Prescription Monitoring Program • Committed Member | Yes                 |                     |  |  |
| Chris Baumgartner • WA State Dept. of Health • Committed Member                                      | Yes                 |                     |  |  |

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| John Odden • Collaborative For Universal Health • Committed Member | Yes (with comments) | 3.2 Out of Scope | <p>The general picture art shows live end users starting the transaction flows. If the intent is to allow "Admit Triggers" or other automated interfaces, then it may serve to delete "1. Defining the trigger" from 3.2 Out of Scope. This suggested change would open the possibility that transactions may be staged and report into a patient chart without imposing needless end user workflow. Where permissible under local law and regulation, this type of use case is working very well today. Between 3.2.1 and the diagrams, we may needlessly "rule out" a very convenient and well accepted method of operation.</p> <p>I'm not asking that trigger events be put in scope - merely suggesting that implementers be given enough leeway to apply sophisticated trigger tools that save "clinical user transaction time" in venues where staff is already stretched.</p> | <p>Acknowledged - Out of Scope Item #1 is there to enable the type of workflows suggested; it is intended to allow this Use Case to be more encompassing</p> |