Projet Antilope

Revue des livrables

Sommaire

1 Préambule

Ce document est une fiche de relecture.
Elle permet de tracer d'une part les remarques, questions et commentaires des participants lors de leur analyse d'un document.

2 Suivi du document

Synthèse: **JDR / Jean-Charles DRON**

Suivi des documents cités dans la présente fiche de travail (ajouter tout document cité) :

Code	*Nom fichier*	*Désignation*	*Qui*	*Commentaire*	*Date*
WP1	D1.1_RefinementofAntilopeUseCases_v0.9g.pdf	**D1.1: Refinement Definition document Revision: 0.9g**	JDR		02/04/14
WP2.1	D2.1_Quality_Management_System_for_Interoperability_Testing-v09.pdf	**D2.1: Quality Management for Interoperability Testing Revision: 0.9**	JDR		02/04/14
WP2.2	D2.2_Interoperability_Testing_Processes_v09.pdf	**D2.2: Interoperability Testing Processes Revision: 0.9**	JDR		02/04/14
WP3	D3.1_Testing_tools_overview_v0.90.pdf	**D3.1: Testing tools overview: Testing tools gap analysis with description of required new tools Version: 0.90**	JDR		02/04/14
WP4	D4.1_V08_Certification_Processes.pdf	**D4.1: Interoperability label/certification Processes Revision: 0.8**	JDR		02/04/14

Suivi des intervenants sur le document:

Trigramme	*NOM Prénom*	*Coordonnées (email / Tél.)*	*Commentaire*	*Date*
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3 Relecture et prise en compte

N°	Qui	Code Doc.	Chap.	Page	Remarques / Questions / Commentaires
1.	FMA	WP1	4	P.15	**Fr** Commentaires généraux sur le chapitre 4 du WP1 : • Dans les scénarios de réalisation, la classification des profils sélectionnés entre les catégories « overall », « infrastructure », « security », « workflow », « information » est inappropriée et n'est justifiée ni dans le modèle d'interopérabilité ni dans les templates de scénarios (page 14). De plus, un même profil fluctue d'une catégorie à l'autre selon les use cases : Par exemple, PIX, PDQ, CT sont classés tantôt en « overall » tantôt en « infrastructure » tantôt en « security ». • Nous suggérons de définir les catégories de manière formelle dans le template « realisation scenario » (§ 3.2.2 p 15), puis de reclasser convenablement les profils dans chaque scénario, en fonction de cette définition formelle. Proposition de catégories : ○ Domaines IHE (ITI, PCC, LAB, CARD, RAD, ...) + différenciation entre profils orientés workflow et profils orientés contenu **En** General Comments on Chapter 4 of WP1: • In « Realisation scenarios », the classification of categories "*overall*", "*infrastructure*", "*security*", "*workflow*", "*information*" of selected profiles, is inappropriate and should have been defined ahead in the scenario template (§ 3.2.2). More over, profiles are classified erratically from one category to another depending on the use cases: For example, PIX, PDQ, CT are sometimes classified as "*overall*" sometimes as "*infrastructure*" sometimes as "*security*". • We suggest to define the list of categories of profiles in the formal template of Realisation scenario (§ 3.2.2), and then to properly reclassify profiles in each scenario, based on this formal definition. The simplest choice of categories would be the IHE domain of the profile (ITI, PCC, LAB, RAD ...), with a possible subdivision between content profiles (such as XD-LAB) and workflow profiles such as SWF.
2.	JCC	WP1	4	P.15	**Fr** Commentaires généraux sur le chapitre 4 du WP1 : • Un diagramme de séquence illustrant les scénarios, et indiquant, pour chaque use case les profils concernés apporterait une meilleure compréhension à l'ensemble du chapitre. **En** General comments regarding Chapter 4 of WP1: • A sequence diagram illustrating scenarios, and indicating, for each use case concerned profiles would bring a better understanding to the whole chapter.
3.	FMA	WP1	4.1.2	19	**Fr** • Cas d'usage et scénario 1b (circuit médicament - échelle régionale/nationale) : Profil XDS oublié. A réinsérer. • Remarque EPO : Il est fait mention de CMPD qui s'appuie sur XDS (implicite) **En**

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					• Use case and scenario 1b (Use Case 1b: e-Prescription and e-Dispensing on a national/ regional scale): XDS profile was forgotten. • To be added explicitly (even if implied by CMPD)
4.	FMA	WP1	4.2.2	23	**Fr** Cas d'usage et scénario 2b (examens d'imagerie - échelle intra-hôpital) : • Copier/coller malheureux depuis un autre scénario. Il ne faut pas du partage de document (XDS). Il faut ajouter des profils de workflow (PAM, SWF, REM, ce dernier - l'enregistrement de la dosimétrie - étant ajouté en vertu du cadre réglementaire européen depuis 2004) **En** Use case and scenario 2b (Use Case 2b: Requests and Results sharing workflow for radiology on an intra- hospital scale): Looks like a Copy / Paste from another scenario. • Remove XDS, which is irrelevant in an intra hospital context • Add the workflow profiles PAM, SWF, REM. (REM, fulfills a requirement for recording dosimetry, in place in the EU regulatory framework since 2004)
5.	FMA	WP1	4.2.2	25	**Fr** XWF ? → SWF (Erreur). Le profil XWF n'existe pas. **En** XWF = typo. Replace by SWF.

6.	FMA	WP1	4.3.1	25	**Fr**
					Cas d'usage et scénario 3a (Résultats de labo - échelle régionale/nationale) :
					• Le titre du cas d'usage est incorrect. Il s'agit de partager les seuls comptes rendus de laboratoires, et non pas les demandes d'examens.
					  ○ Titre suggéré : ~~Request and~~ « results sharing workflow for laboratory on a National/regional scale » ;
					  ○ Ou bien rajouter toute la partie associée à la gestion de la demande d'examen, qui n'est pas présente dans le scénario).
					• Le profil de contenu XD-LAB qui était bien présent dans le eHealth EIF a été oublié. A réinsérer.
					• Le profil RID est hors sujet pour voir un compte rendu CDA. Le supprimer.
					• Process flow. Point 3 faux.
					En
					Use case and scenario 3a (Use Case 3a: Request and results sharing workflow for laboratory on a National/regional scale):
					• Improper title for this use case. This use case is addressing only the sharing of laboratory report / resultts, not the lab requests. Suggested title: « Results sharing workflow for laboratory on a National/regional scale ».
					• The content profile XD-LAB (CDA template for lab report) which was present in the eHealth EIF has been forgotten. Add it.
					• RID profile irrelevant for viewing a CDA report. Remove it.
					• Process flow: Point 3 is incorrect. Replace by "*Results are shown in a viewing format as instructed in the "View" option of the XD-LAB profile*".

7.	FMA	WP1	4.3.1	26	**Fr**

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					Realisation Scenario description du UseCase 3a : Request and results sharing workflow for laboratory on a National / regional scale • Titre peu compréhensible • Proposition « Cross entreprise sharing of laboratory report » à la place de « Cross-entreprise workflow for laboratory requesting and results viewing » **En** • Realisation Scenario of Use Case 3a: Title "*Cross-enterprise workflow for laboratory requesting and results viewing*" is obscure. • Proposed title: « Cross entreprise sharing of laboratory reports »
8.	FMA	WP1	4.3.2	27	**Fr** Cas d'usage et scénario 3b (Résultats de labo - échelle intra-hôpital) : • Le profil de diffusion du catalogue des examens de laboratoire LCSD qui était bien présent dans le eHealth EIF a été oublié. A réinsérer en tant que profil, ainsi que dans les « Actors », « Transactions », « Process flow » du scénario. • Compléter et corriger le « Process flow » : Les prélèvements sont plus souvent réalisés par le personnel soignant que par celui du laboratoire. • Il manque le flux d'examens ajoutés par le laboratoire (« reflex tests »). A compléter. **En** Use case and scenario 3b (Use Case 3b: Request and results distribution workflow for laboratory within a hospital): • LCSD (Laboratory Code Sets Distribution), used to distribute lab exams catalogues, was present in the eHealth EIF, but has been forgotten in this presentation. • Add LCSD profile as well as its Actors and Transactions, and materialize it in the "Process flow" of the scenario. • Complete the Process Flow: Samples are more often collected by the nursing staff of the hospital rather than by the laboratory staff. • Complete the Process flow: Transaction for lab reflex tests is missing (see LTW profile, transaction LAB-2).
9.	FMA	WP1	4.4.2	29	**Fr** Cas d'usage 4a (Volet médical de synthèse - échelle transfrontalière) : • Le pavé « Context » du cas d'usage donne une référence erronée à epSOS : « More extensive information about this use case and Patient Summary requirements can be found in **epSOS Deliverable 3.1.2.** ». Ce livrable décrit en fait les requirements de la ePrescription. Corriger en **epSOS Deliverable 3.2.2.** • La référence **epSOS D3.A.1** dans le même pavé ne semble pas correspondre à un livrable epSOS disponible. Corriger la référence ou la supprimer s'il ne s'agit pas d'un document publié par epSOS. **En** Use Case 4a: Patient Summary sharing on a cross-border scale • "Context" paragraph has an incorrect reference to epSOS: "*More extensive information about this use case requirements and Patient Summary can be found in epSOS Deliverable 3.1.2.* ". Replace by reference to epSOS Deliverable **3.2.2**. • The epSOS D3.A.1 reference in the same paragraph does not seem to be an epSOS deliverable (not found in the epSOS project). Remove it.

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10.	FMA	WP1	4.4.3	32	**Fr** Cas d'usage 4b (Volet médical de synthèse - échelle régionale/nationale) : • Le titre du cas d'usage « Patient summary sharing on a national scale » oriente vers une fausse piste de mise en partage de résumés médicaux à l'échelle d'un pays, alors que le cas d'usage et ses deux scénarios de réalisation (1 et 2) ne traitent que l'échange point à point entre deux hôpitaux A et B. Corriger le titre : « Inter-hospital exchange of patient summary on a national scale » • Ajouter le profil XDM pour le scénario 1 (mode « push »). XDM correspond aux envois par messagerie de A vers B. C'est le choix retenu en France. • Les parties « Process flow » et « Associated profiles » du scénario 2 semblent être un copier/coller du scénario 1. Le profil XDR est inapproprié pour gérer le mode « pull ». Pour information : le profil BPPC n'est pas mis en œuvre en France. Dans le contexte du DMP, le consentement du patient n'est pas géré de cette façon : Il est recueilli comme une donnée structurée et non comme une document. **En** Use case 4b (Use Case 4b: Patient Summary sharing on a National/regional scale) : • The title of the use case " Patient Summary sharing on a National/regional scale " deals with the approach for sharing medical summaries on the scale of a country, while the use case and two scenarios Realisation (1 and 2) only treat the point to point exchange between two hospitals A and B. Correct the title into « **Inter-hospital exchange of patient summary on a national scale** » • Add the **XDM** profile for scenario 1 (" push"). XDM is related to email exchanges between two actors. This is the choice made in France for email exchanges. • « Process flow » and « Associated profiles » parts related to Scenario 2 seem to be a copy / paste of scenario 1 . XDR profile is irrelevant to manage the "pull" mode.
11.	FMA	WP1	4.5.2	40	**Fr** Cas d'usage 5b (résumé de sortie - échelle régionale/nationale) : • Pavé « business case » du cas d'usage commence par « For the referral of a patient ... ». Copier-coller du 5a ? Ce devrait être « For the discharge ... » • Pavé « information » du cas d'usage contient « Referral letter ». Ce devrait être « Discharge summary ». • Pavé « Workflow steps » copier-coller du 5a. Ne correspond pas à ce cas d'usage. • Le scénario de réalisation est une copie intégrale de celui du 5a. Il ne correspond pas à ce cas d'usage. **En** 5b use case: Discharge report from secondary care. Copy/paste issues: • "business case" use case paragraph begins with "For the referral of a patient ...". Copy and paste from 5a. It should be "For the discharge ..." • "information" use case paragraph contains "Referral letter." It should be "Discharge summary". • "Workflow steps" is a copy paste from 5a. Does not match this use case. • Scenario Realisation is a complete copy/paste of the one of 5a. It does not refer to this use case.
12.	FMA	WP2.1	Part 1 : QMS	---	**Fr**

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					Commentaire général : Le livrable reste évasif sur les organisations ciblées par ce QMS. Il faut impérativement une dénomination constante d'un bout à l'autre du document, en l'occurrence « the interoperability testing entity » est la dénomination majoritaire mais il y en a au moins trois autres dans le document pour désigner le même objet. Il faut impérativement donner une définition en tête du document de ce que représente « interoperability testing entity », même si cette définition est très large. En l'état actuel on ne sait même pas si l'organisation cible du manuel inclut les éditeurs de produits à tester, les clients utilisateurs des produits ou seulement les organisations chargées d'organiser et d'évaluer les tests d'interopérabilité entre produits. Préciser de qui on parle. **En** • General comment: The deliverable is not clear enough regarding organizations targeted by this QMS. A consistent denomination should be used throughout the document, « **the interoperability testing entity** » is the main denomination but there are at least three other variants in the document to refer this same object. • Provide a definition of the expression « **the interoperability testing entity** » (a reference to an ISO definition might be fine) at the begining of the document, and then stick to this expression in the remainder of the document.
13.	FMA	WP2.1	Part 1 : QMS	---	**Fr** Distorsion entre la liste de normes sous-jacentes introduites aux chapitres 2.1 « Quality Manual » et 2.2 «Quality Management System » , et le chapitre 3 « Normative references » qui omet **ISO 9000** et lui substitue **ISO 13485:2012**. **En** • Discrepancy between the list of underlying standards introduced in chapters 2.1 "Quality Manual" and 2.2 "Quality Management System" and Chapter 3, "Normative references" that doesn't mention ISO 9000 but mentions ISO 13485:2012. • Restore consistency between those lists.
14.	FMA	WP2.1	Part 1 : QMS	---	**En** Some typos to be corrected.
15.	FMA	WP2.2	Part 2 : Process test interop.	7	**En** Typo: "The Interoperability Testing Processes are based on IEEE 829 and European Best practice and includes: »
16.	FMA	WP3		---	**Fr** • Problème de génération de la table des matières (chapitres 5 et 5.2) • Compléter l'investigation des outils en ajoutant les profils oubliés par le WP 1 : XD-LAB • Que signifie cette affirmation au § 6.3 page 42 : " For laboratory use cases profiles XDS-I and XUA are not covered with appropriate test tools." ? Les cas d'usage concernant la biologie n'ont pas besoin de XDS-I. Et XUA est externe à tout cas d'usage métier (A priori, erreur de copier / coller) • question similaire pour XUA et la radiologie (§ 6.2 sur la même page). **En**

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					• Error in the Table Of Content (Chapters 5 and 5.2) • Complete investigation of available tools by adding profiles forgotten in WP1: XD-LAB • § 6.3 on page 42: What does this statement mean? : « *For laboratory use cases profiles XDS-I and XUA are not covered with appropriate test tools.*" The use case for biology does not need XDS-I. And XUA is external to any business use cases (looks like a copy / paste error) • Similar question for XUA and radiology (§ 6.2 on the same page).
17.	JCC	WP4	Appendix b	45	**Fr** • Homologation du DMP : N'a pas seulement porté sur le test de la conformité des transactions techniques mais a également porté sur la validation que le logiciel affichait bien certaines informations nécessaires à l'homologation. **En** • DMP certification: This certification did not just focus on technical and transaction conformance testing but also on validating that mandatory data were adressed consistantly by the software.
18.	FMA	WP4	General comment	-	General comment: A global polish of the English language used in this document will significantly improve the understanding of the text.
19.	FMA	WP4	Glossary	4	Missing abbreviation definitions in the glossary page 4: ○ AHA ○ ASIP Santé ○ CAB : Conform~~ance~~ity Assessment Body (as introduced on p 14) ○ DMP ○ EA ○ EHR-Q is there with no definition ○ EIP ○ IAF ○ ICT ○ MRA ○ QL&C – by the way improper. It's not QL AND C it's QL OR C. How about QL/C instead?
20.	FMA	WP4	1.2	8	○ to describe the field of ~~the~~ assessment of ~~the~~ solutions ○ is discussed in ~~the~~ section 3. ○ Concrete examples allow~~s~~ a better understanding but also demonstrate~~s~~ ○ for the benefit of ~~the~~ healthcare providers and Industry
21.	FMA	WP4	2	9	○ 2) Terms and Definitions ○ body ~~that~~ who performs conformity assessment services (ISO/IEC 17000)

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22.	FMA	WP4	3.1	11	○ A quality label or a certification processes define all requirements, (...) that want to seek this quality label of certification. Don't you mean "a certification or quality label process defines ..." rather? ○ Then if QL&C means "quality label and certification" it is different from "quality label OR certification". thus the abbreviation QL&C seems inappropriate, throughout the document. QL/C may be better ○ organi~~z~~sation ○ A~~n~~ functional decomposition is shown in ~~the~~ figure 1 ○ Note that the right hand side of this figure introduce~~d~~s ○ Last line: "For example:" and then, nothing? page layout issue?
23.	FMA	WP4		12	○ delegates to the ~~to the~~ ○ the Conformity Assessment Bodies ~~that the~~ whose role is to ○ Model-1: The same organisation define~~d~~s (...) organises ... ○ only the testing services are organised by the conformity assessment bodies ~~that are or not accredited bodies~~ , which may be accredited or not for this activity. ○ Last line: this model is used by the epSOS project ...
24.	FMA	WP4	3.3	13	○ ~~It is not a certificate recognized at the international or European level that is issued but the goal is to answer to the regulation of the country.~~ This certificate or label or seal does not aim to have an international recognition. Its goal is to fulfil the country legal and regulatory framework.
25.	FMA	WP4		14	○ The ~~QL and C~~ QL/C processes are ~~then not so distinct between them~~ ??? and are adapted for each purpose. *I can't grasp the meaning of that sentence.* ○ *3.4 1st paragraph:* ~~This process is launched by a Conformity Assessment Body (CAB) generally played by a testing laboratory or inspection body that the role is to perform tests or audit for the assessment of the interoperability requirements implemented by the solutions.~~*Please rephrase completely this sentence. I don't understand what you want to express.* ○ *last paragraph:* The equivalenc~~y~~e
26.	FMA	WP4		15	○ Table at the top. *The ~~ISO/IEC 15189:2012~~ standard is out of scope of the ANTILOPE project. This standard has no value in the processes described throughout all Work Packages (It is not interoperability testing but in vitro diagnostic testing). I suggest to remove it from the table.* ○ 3.5 (~~that the~~ whose role is to define ...), and delivers a consisten~~cy~~t and impartial ... ○ 3.6 EA (European co---operation for Accreditation ~~that the~~ whose main mission is ...
27.	FMA	WP4		16	○ 1st line: in the case of a certification process
28.	FMA	WP4	5.4.2	25	○ 5.4.2 The French QL process called "DMP-compatibility homologation" ○ described in detail in ~~the annex II~~ Appendix B ○ The goal of the "DMP-compatibility homologation" is to validate ~~that the healthcare software connected to the DMP (French National PHR) is conformed with the DMP specifications~~ the capability of the software to interact consistently with the DMP, in conformance with the technical specification of the DMP interfaces. ○ The specification~~s~~ describes the external interfaces of the DMP system to be used ~~to connect~~ by any software that needs to interact with this system. ~~to the DMP~~ This specification is ~~and are~~ available at ...
29.	FMA	WP4	5.4.2	26	○ Top sentence to be replaced by: This specification is based on a set of IHE profiles: XDS, XUA, DSG, ATNA, CT, XD-LAB, APSR and the PCC content profiles. The specification also leverages a set of HL7 v3 messages for the administrative management of the patient record.

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					○ ~~The process is more an quality label process than a certification process launched by the national agency called ASIP Santé.~~ The process carried by ASIP Santé is a labelling process, which ensures that each labelled software is capable to establish correct and consistent transactions with the DMP system. ○ ~~ASIP Santé founded in 2009 by the French authorities, is a national agency that the role is to strengthen public ownership of the Information System developed in the Healthcare sector~~ ASIP Santé was founded in 2009 by the French authorities. This national agency is driven by the Ministry of Health and its main missions are: ▪ Foster the development of shared information systems in the fields of health and social care, for a better coordination and quality of care. ▪ Build and run national e-health services (e.g.; the DMP, the national PKI for healthcare providers, secured health messaging services ...) ▪ Define, promote and homologate profiles of standards contributing to interoperability, security and usage of healthcare IT and e-health. ○ ~~The national agency~~ Asip Santé provides specifications, ... ○ ~~The~~ Asip Santé is neither a ... ○ However ~~the~~ Asip Santé provides ... ○ The coverage ~~with~~ of the eHealth European Framework is quite ~~satisfied~~ fulfilled regarding the use cases. The products homologated as "DMP-compatible" ~~could be well accepted by~~ are likely to fit easily in other European projects.
30.	FMA	WP4	6	28	1st paragraph is obscure: ~~The recommendations and guidelines have the objective to support any national/regional organisation to define its own processes of QL&C processes. It is structures on 4 main steps (...)~~ The recommendations and guidelines provide support to any national/regional organisation in the definition of its own QL/C process. This definition includes 4 major steps described below.
31.	FMA	WP4	Appendix B	45	Objective of the homologation scheme : ○ The goal of the "DMP-compatibility homologation" is to validate ~~that the healthcare software connected to the DMP (French National PHR) is conformed with the DMP specifications~~ the capability of the software to interact consistently with the DMP, in conformance with the technical specification of the DMP interfaces. ○ The specification~~s~~ describes the external interfaces of the DMP system to be used ~~to connect~~ by any software that needs to interact with this system. ~~to the DMP~~ This specification is ~~and are~~ available at ... ○ Several ~~profiles and~~ services are described: ▪ Access to the ~~DMP~~ record of a patient ▪ INS (national patient identifier) ▪ Creation and management of the ~~PHR~~ patient record ▪ ~~registration of medical documents in the DMP~~ Feed a patient record with new or updated content ▪ query and retrieve content from the patient record ~~Consultation of the DMP~~ ▪ Manage the visibility and/or status of content in a patient record ▪ Other services ... ○ These services are combined into three profiles: ▪ Create ("Création") ▪ Write ("Alimentation") ▪ Read ("Consultation") ○ ○ A "homologation" scheme is defined by ~~the~~ ASIP Santé ...

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					~~o The list contains 139 records (July 2013)~~ As of February 2014, 126 distinct software are registered and labelled as "DMP-compatible"
32.	FMA	WP4	Appendix B	45	Certification scheme : o The type ~~of certification~~ is ~~based on~~ a quality label process. All the steps of the QL procedure ~~is led~~ are carried by the national agency ASIP Santé ... o ... and ~~the~~ Asip Santé did not have ~~audited~~ their own processes audited by an external auditor at the time (although ~~the~~ Asip santé ~~did not pass any certification scheme for itself (ISO 90000, ISO 17025,...)~~ is currently applying for an ISO 9001 certification for a part of its activities)
33.	FMA	WP4	Appendix B	46	Content/requirements : o The main use case is the ~~connexion~~ connection ... o The DMP system ~~used~~ leverages the national interoperability framework ~~based on,~~ which selects and further constrains (through the process of national extension) these IHE profiles: XDS, XUA, DSG, ATNA, CT, XD-LAB, APSR and the PCC content profiles. This interoperability framework provides also a selection of HL7 v3 messages, which are used to administer the patient record in the DMP.
34.	FMA	WP4	Appendix B	48	d/Methodology, tools, test criteria : o 4 educational environments are available ~~that~~ to simulate healthcare ~~and patient DMP~~ applications in interaction with the DMP system. Tools and Test criteria are not available publicly. The tools were developed by ~~the~~ ASIP Santé and are proprietary.
35.	FMA	WP4	Appendix B	49	Target : o To be recognized at the European level, ~~the~~ Asip Santé has to separate the specification activities ~~to from~~ the testing validation activities ~~by assigning this second activity~~ and to assign the latter to an accredited ~~lab~~ testing laboratory. o ~~In France, IHE ATNA is not required. The profile IHE – XDS is coupled with IHE ATNA.~~ The DMP XDS transactions do rely on the ATNA profile: Those transactions are pursued between mutually authenticated nodes, in full conformance with the "NA" part of the ATNA profile. However, ASIP Santé does not require the "DMP-compatible" softwares to be capable of exporting their audit trails to a central audit trail repository per the "AT" part of the ATNA profile.