Smart Open Services for European Patients

Open eHealth initiative for a European large scale pilot of

Patient Summary and Electronic Prescription

D3.B.2 - epSOS Phase 2 Common Components Prototype

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ABSTRACT

"**D3.B.2 - epSOS Phase 2 Common Components Prototype"** represents the release of the software components developed by WP3.B as Open Source, to allow the implementation of the Open Source National Contact Point by the Participating Nations.

The document provides the high level specifications, the adopted implementation and release methodologies, the release plan and the release notes of the already released version of OpenNCP.

Version 1.1, not foreseen in the DoW, substitutes Version 1.0. It includes the achievements of the OpenNCP team (KT3.B.2) in 2013, considerations on the sustainability of the OpenNCP Community and the summary of the activities performed in KT3.B.3 in support of OpenNCP national implementations.

Appendix A: lists abbreviations and definitions.

Appendix B: provides the OpenNCP design and Release notes.

Appendix C: describes the Patient Access (PAC) service design and engineering details

Appendix D: refers to the Health Care Encounter Report (HCER) design and implementation

Appendix E: provides details on the Medication Related Overview (MRO

Appendix F: includes Continuous Integration (CI) and Conformance Testing design and implementation

Appendix G: VPN problems tracking and resolution

Appendix H: includes the document provided by Christian Lovis, requested by the EC Officier and epSOS Project Management Team on the analysis of Open Source License model impacts

Appendixes C, D, E, F and G were added in version v1.1 of D3.B.2.

Change History

Version	Date	Status Changes	From	Details	Review
V0.1	14/01/2013	Draft	Lombardy	Initial Structure of D3.B.2	KT3.B.2-CT

V0.2	21/01/2013	Draft	Denmark	Contributions from Steen	
V0.3	31/01/2013	Draft	Lombardy	Contributions from Marcello	
V0.4	7/02/2013	Draft	Portugal	Contributions from Licinio	
V0.4.1	10/02/2013	Draft	CH	Contributions from Patrick Ruch	
V0.5	27/02/2013	Draft	Portugal	Contributions from Licinio	
V0.6	28/02/2013	Consolidated Draft	Lombardy	Version for internal review	
V1.0	31/03/2013	Final	Lombardy	Released	
V1.1	31/12/2013	Final	Lombardy Portugal	Revision to include last achievements of OpenNCP Team and Technical Appendixes	
V1.1.1	22/05/2014	Final	Lombardy Portugal	Revision to include quality assurance process and EC reviewer comments	
V1.1.2	30/06/2014	Final	APM	last edits, line numbering, version number	

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1 Introduction

1.1 Scope of the Document

This deliverable describes the implementation activities performed in the Key Task 3.B.2 addressing:

- Relation with the implementation strategies (Chapter 1).
- Methodologies adopted in the OpenNCP implementation (Chapter 2).
- High level design criteria and architecture and release plans (Chapter 3).
- Analysis of achieved results and conclusions (Chapter 4).
- Detailed OpenNCP design (Appendix B, oriented to technical experts).
- Document on “Assessment of the epSOS licensing policy”, by Christian Lovis (Appendix H).

Version 1.1 includes the achievements of the OpenNCP team (KT3.B.2) in 2013, considerations on the sustainability of the OpenNCP Community and the summary of the activities performed in KT3.B.3 in support of OpenNCP national implementations.

The main document and Appendix H are addressed to PNs middle management and technical co-ordination, while appendixes B – G are addressed to the technical staff.

1.2 Background

The overarching goal of epSOS (Smart Open Services for European Patients) remains “to develop a practical eHealth framework and ICT infrastructure that will enable secure access to patient health information, particularly with respect to a basic Patient Summary and ePrescription, between European healthcare systems.”[1]

epSOS 2 related activities enlarge the scope of epSOS 1, extending the defined services, the coverage of the European Large Scale Pilot (LSP) with many more participating countries and raising epSOS 2 to a more maturity of the operated pilot services.

The basic Pillars established for epSOS 1 implementation remain valid:

- epSOS has identified means of interoperability which will allow to connect services and architectures, potentially different in every Participating Nation (PN), to provide Patient Summary (PS) and ePrescription/eDispensation (eP/eD) cross-border services.
- epSOS has defined, and is currently operating services to allow a patient from the Country of Affiliation (Country A) while being in the Country of Care (Country B), to exploit eP and PS services available in Country A.
- epSOS LSP is based on legal, functional and technical pre-requisites that represent the pillar for the definition of the services and the architecture of epSOS.
- epSOS has enabled the Participating Nations to integrate their national solutions and validate them for Cross-border interoperability of eP and PS.
- epSOS has not developed European eP / PS services.
- epSOS eP and PS Cross-border interoperability are based on already existing National eP and PS services,

[1] Annex I, Ch. B1.1.2.1

- epSOS LSP should not interfere with National eP/eD and PS services or request their modification,
- epSOS LSP services must be based on a Legal and Regulatory framework which includes the signature of contractual agreements among the Participating Nations to commit to their legal responsibilities and to assure the adequate level of trust.
- The National Contact Point (**NCP**) is the fulcrum of cross border interoperability, exploiting the role of connecting the National technical, organisational and legal environment to the European Level environment.
- epSOS implementation strategy is based on the paradigm: "Design centrally, implement locally".
- Sustainability is one of the most relevant requirements to be adopted.

Those basic pillars are representing the compulsory, binding boundary conditions for all the activities of epSOS 1 and most likely epSOS 2.

epSOS 1 implementation (see D3.9.1 Chapter 8.4 for details) saw the development by a epSOS funded team to (1) reuse/adapt from vendor provided catalogue of SW Components, (2) develop SW Components if needed, and integrate them as an NCP-in-a-box. This team was led by two epSOS beneficiaries and includes vendor contributors from the Industry team. PN developped their interfacing to this NCP.

The main reason for going for a centralised development of the NCP-in-a-box was mainly the level ofimplementation of eHealth services in the EU Countries and their suitability for cross-border interoperability.

Joining efforts, adopting commercial closed source backbone, implementing a common solution (the NCP-in-a-box based on Common Components (CCD) from Fraunhofer - Elga Team (FET) has allowed everal PNs to complete the implementation, to pass the validation phase and to start the operation with minimal development effort.

Among the three epSOS 1 defined implementation strategies[2], all the PNs opted for jointly develop the full proof of concept, minimizing the risk of non-interoperability and covering the lack of the National Infrastructure.

This solution, valid for epSOS 1, shows some limits as for medium long term sustainability.

WT3.B.1 identified that epSOS core responsibility is and remains to specify and support testing for compliance to the epSOS Interoperability Architecture.

The open question is whether epSOS 2 should consider supporting the definition of an "informal" epSOS Software Architecture which includes the specification of a "back-interface", towards the National Infrastructure.

The implementation strategies for epSOS 2, proposed in D3.B.1 offer opportunities to create/enforce the eHealth interoperability ecosystem (through the establishment of a Consortium or through the open competition) to assure market opportunities which might allow sustainability for PNs and Vendors.

The challenge is to be able to create an environment in which industry can compete and PNs can choose their preferred way forward (together or apart) and how we provide specifications, tools and support to enable this in a way that allows for future growth.

[2] 1) leave to PN the role of specifying and implementing, 2) leave complete freedom to the market opportunities and open competition, 3) jointly develop the full proof of concept

1.3 Scope of the task

In application of the policy:

- Specify Centrally / Develop Locally

and of the implementation strategy:

- Foster the establishment of the eHealth ecosystem through the development and release of Open Source Components, made publicly available through an Open Source Community

the following methodological approach was adopted:

1. Confirm / reinforce Implementation Strategies and medium-long term sustainability criteria with WP2.2 (see 1.4).
2. Adopt Open Source based implementation model, re-using, wherever possible, existing Open Source Components (see 2 epSOS OpenNCP Implementation Strategy and Methodologies) to implement components usable by PNs and Vendors to build NCP and Portal solutions.
3. Define the OpenNCP components release plan in several phases, to allow incremental adoption by PNs.
4. Revise NCP architecture, identifying the clusters of components developed in common and PN specific ones.
5. Adopt efficient and effective development methods, allocating the clusters of components (mini-projects) to PNs / Vendors willing to co-operate.
6. Perform Units test and demonstrate / test the possibility to integrate the developed Open Source Components.
7. Identify the suitable Open Source Community to deploy and disseminate (see 2.3 OpenNCP and JoinUp).
8. Release OpenNCP components according to the release plan and publish on JoinUp.
9. Provide support to PNs for OpenNCP components adoption, upgrade, integration and testing.

All the described steps imply the **Engagement of industry** and of **PN administrations/competence centres** with the goal of establishing a permanent mechanism and an ecosystem for secure **technical and organisational sustainability.**

1.4 Implementation Strategy and sustainability: Relations with WP2.2 and WP3.D

In order to achieve an effective development, the KT3.B.2 considered the close relationship with Work Package 2.2 in terms of synergies and coherence of outputs.

Under Work Package 2.2 three main aims are envisaged:

1. To update and then maintain the set of policies for epSOS2, building on the work of epSOS1, and in view of a medium – long term sustainability of interoperability and semantic assets (T2.2.1 epSOS Policy development and maintenance);
2. To provide a comprehensive epSOS service description addressing legal, semantic, and organizational issues. This will aid local implementation activities (T2.2.2 epSOS Service Description);
3. To support stakeholder liaison and engagement both globally and in Europe through a programme of openness, transparency and validation (T2.2.3 Openness, Transparency and Validation).

To achieve OpenNCP implementation goals in view of the eHealth Ecosystem support, it has been fundamental to understand Industry Team Go-to-Market strategy in short (within the project time frame), medium (5 years) and longer term (10 years) nd Standardisation Bodies plans. WP3.B and WP3.D are co-operating to collect this information relevant to take the correct design decisions.

2 epSOS OpenNCP Implementation Strategy and Methodologies

2.1 OpenNCP Implementation Strategy

In the summer of 2012, concrete plans for forming an open source project focusing on delivering the software components necessary to run a National Contact Point (NCP) manifested in an international implementation team forming.

The project, named OpenNCP, took its vantage point in code contributed from SRDC – licensed under GPLv3, and the epSOS Common Components (ECC) developed by various sources in support of the proprietary NCP back-bone offered by TIANI-Spirit. These components were licensed under ASLv2.

The focus point of the development within OpenNCP is the Protocol Terminators; the connection endpoints implementing the IHE profiles XDR, XCA and XCPD. The aim was to make a generic backend to the national infrastructure while maintaining strict compliance to the epSOS specifications.

Version 1.0 was the first usable version and Version 1.1 is a hardened release, ready for general public exploitation. Version 2.x have provided epSOS phase 2 services.

The last release in December 2013 has been OpenNCP2.1.0 Gold, also ready for general public exploitation.

2.2 OpenNCP Implementation Methodologies

With a distributed development setup as one of the basic conditions[3] the development practices have to be transparent and easily communicable. At the onset of development, this manifested itself with the choice of tooling and development principles in OpenNCP.

2.2.1 Development principles

As the distributed and concurrent nature of code development in the project needs fast and up-to-date communication of the changes done in the project, a decision to build on agile approaches, such as Scrum[4], was made. All non-trivial changes in the code repository must be annotated with an issue identifier, making concise communication of the context of code changes possible. Furthermore all software components released from OpenNCP must be readily deployable, which put strict qualitative demands on the build tools as well as the discipline of the developers when committing code to the project. Information regarding setup, prerequisites and tools needed to obtain, build, develop and contribute to the project should be easily obtainable and understandable.

[3] The core development team prior to 1.0 comprised 10 countries, spanning three time-zones

[4] Scrum Development **http://en.wikipedia.org/wiki/Scrum_%28development%29**

2.2.2 Development tools

The choice of development tools was done according to the above mentioned considerations. In the following, knowledge concerning Java development and general development skills is presumed.

- Programming Language (Java)
- **Knowledge Sharing** (Atlassian Confluence)
- **Code Sharing** (Google Code + GIT)
- **Development Management** (Atlassian Jira & GreenHopper)
- **Build** (Maven[5] + Semantic Versioning)
- **Quality Assurance** (Jenkins - Continuous Integration)

2.2.2.1 Maven

As build tool, maven was chosen. The main reasons for this choice was ease of code distribution, ease of inter-component version management and ease of build, test and release processes. The use of maven also allowed for the publication of OpenNCP artefacts through the frameworks of the European Commission (more on that below).

2.2.2.2 Git

In order to facilitate the distributed and non-sequential nature of developments within the OpenNCP project, and to ensure that all contributions would equally fit in the repository, the de-centralized and distributed version control system git[6] was chosen. Furthermore, the development team has adopted the git-flow development model, which clearly states how feature development can be separated from production code and how to handle so-called “hot-fixes”; bug-fixes of so severe character, that their solution must be developed directly on the production code.

2.2.2.3 Versioning

To ensure a common understanding and a frictionless communication of what is entailed in version numbers and version bumps, the OpenNCP team uses Semantic Versioning[7]. Semantic Versioning has a well-defined set of rules describing which types of code changes warrants which types of version number changes.

2.2.2.4 Issue tracking

The heart of coordinating and focusing development work is an issue tracker. Several issue trackers were evaluated and tested before the OpenNCP team decided on Jira and its accompanying wiki platform Confluence. Using an issue tracker that is integrated with a wiki allows for easy communication of the larger flows of development, which is represented by the individual issues, but for which most issue trackers does not have means for tying together.

[5] http://maven.apache.org/

[6] http://git-scm.org

[7] **http://sem-ver.org**

2.2.2.5 Quality Assurance

When code is checked in by a developer, we assume the developer is able to compile the code and successfully run the unit tests. But that does not necessarily mean that other developers checking out the code are able to replicate this, which would leave them unable to directly develop further on the codebase. In order to avoid such a situation, the OpenNCP team decided to have a continuous integration server, assuring that a greenfield setup is able to compile and test the code. The CI server furthermore ensures the publication of development snapshots, such that new developers are always able to work on the newest versions of the code.

2.3 OpenNCP and JoinUp

JoinUp[8] is a collaborative platform created by the European Commission to, amongst other things, support open source development work done by government agencies in Europe. epSOS agreed to use JoinUp as the correct environment to create and make growing the Open Source Community for eHealth interoperability.

The OpenNCP project uses JoinUp to disseminate the official releases as well as the development snapshots created by the development work. Once development documentation reaches a stable level, JoinUp also offers dissemination spaces for hosting documentation.

[8] **www.joinup.europa.eu**

3 epSOS OpenNCP Architecture and Releases

3.1 OpenNCP Architecture

The contents of the OpenNCP are mostly independent from national infrastructures.

As such, the implementation of the OpenNCP common components is scoped by:

- In the one end: the IHE profiles specified in the D3.A.1 document;
- In the other end: the integration points to the local infrastructure.

The NCP follows the general SOA paradigm, and each component in the OpenNCP must operate as a service, which is externally scoped by the NCP, but internally available to the other components.

While the OpenNCP as a whole is mandated to operate in a synchronous manner, the individual services that the components implement may operate asynchronously. For instance, the issuing of instructions to log audit events should not halt the processing of the message, only guarantee for its own completion.

As an additional component the OpenNCP gently provides a standard Portal that a PN can adopt and adapt in order to accomplish more rapidly the country B use cases.

The following figure presents the main building blocks from the OpenNCP components architecture. Each component and their interactions are deeply described in the D3.B.2 Open Source NCP Design - APPENDIX B.

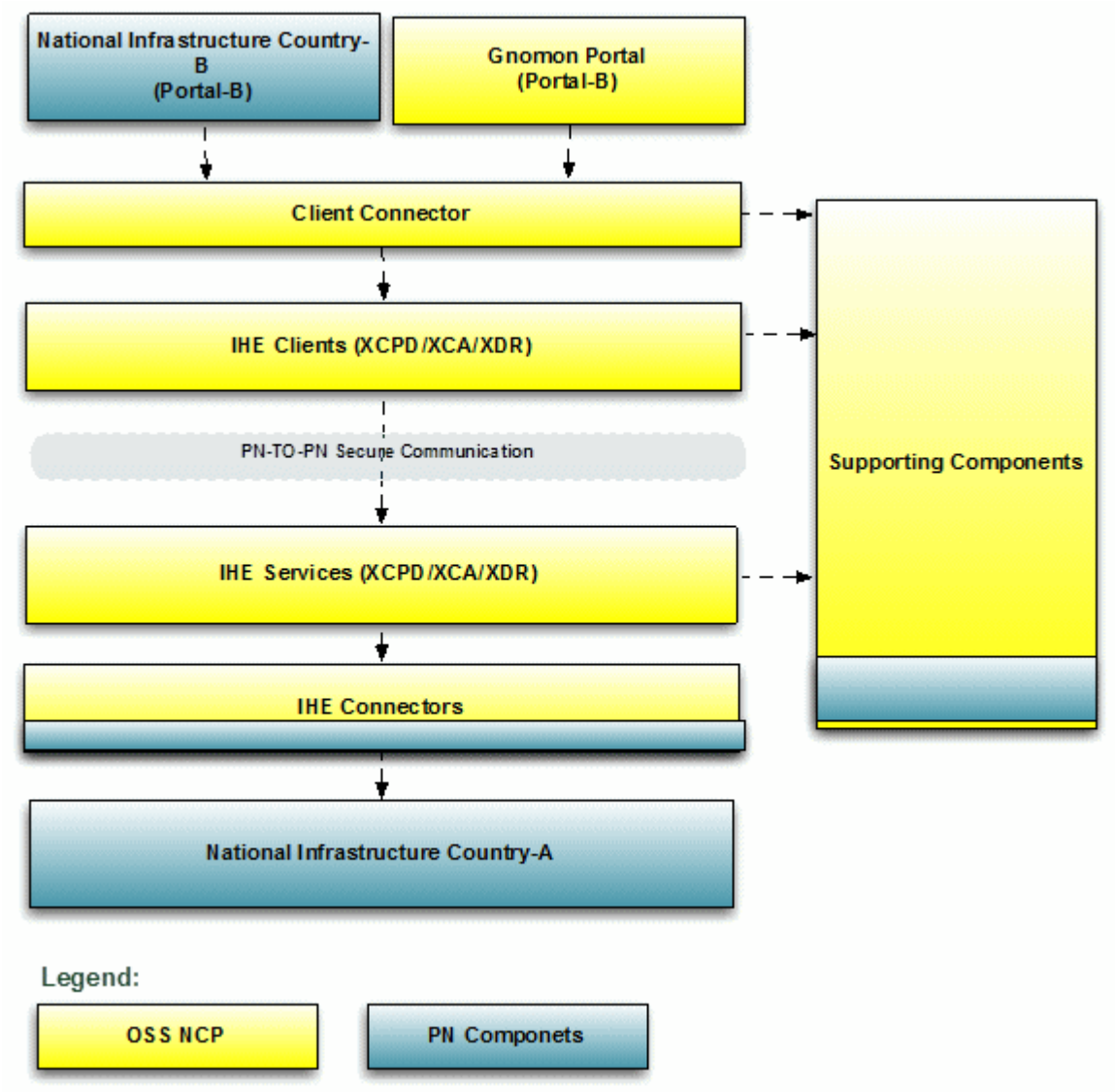

Figure 1 - NCP architecture, Logical High Level Model

3.2 OpenNCP release plan

All information about OpenNCP, including architectural and technical specification, release plans and notes, support documentation, can be retrieved from:

https://openncp.atlassian.net/wiki/display/ncp/OpenNCP+Community+Home

In the sequel, the history of releases is provided.

More details can be found on:

https://openncp.atlassian.net/wiki/display/ncp/OpenNCP+Release+Notes

3.2.1 OpenNCP 1.0 Working NCP (Pre-Pilot-Testing Ready)

The main goal from this first release was to deliver a working NCP that could comply with epSOS requirements, recommendations and specifications.

The main challenge surrounded the fact that it was needed to combine and harmonize several software components provided by different software teams with different rationale and software development practices and patterns.

In this context, significant resources were allocated to refactoring work as well understanding the foundations from the base components used to build the OpenNCP.

Many of the developers, who initiated the OpenNCP Community, were new to the code and to the project. Insignificant efforts were needed to train people and to organise the teams to achieve a common software delivery.

Finally, the epSOS project managed to release a working release that would allow a Participating Nation to deploy its own NCP. This release has been embraced by 1 (one) PN who submited it to a Pre-Pilot-Testing stage and the results where surprisingly positive.

That was the ignition point for aim the OpenNCP team to the next goal: provide an Operation Ready OpenNCP.

Three releases of OpenNCP 1.0 (OpenNCP1.0.0, OpenNCP1.0.1 and OpenNCP1.02 were provided to the Participating Nations from November 2012 to January 2013.

3.2.2 OpenNCP 1.1 Operation Ready

Aiming to excellence, the epSOS OpenNCP Community start digging the 1.0 version looking for mandatory features (for Operation), bug fixes, improvements or quality increments.

In that way the work flowed naturally but hard decisions have to be made, namely deciding what is mandatory (MUST be included) and what is optional (MAY be included) in the 1.1 Release.

There were a lot of discussions involving, not only development team but also requirements and security expert groups, in order to capture the essence and fundamental features that should be considered.

And comfortable agreement has been established between all groups and in the 24th of January 2013, the version 1.1 from the OpenNCP has been release and made publicly available at JoinUP.

Four releases of OpenNCP1.1 (from OpenNCP1.1.0 to OpenNCP1.1.3) were provided to the PNs until May 8th 2013. Each of them provided bug fixing and performance improvements, after OpenNCP team and PNs implementation teams indications.

3.2.3 OpenNCP 2.0 PAC and HCER

In application of the epSOS Project Steering Board decision, to give priority to PAC and HCER services, the OpenNCP Team concentrated on these two epSOS 2 services,

With the release from the OpenNCP 1.1.0 the path for the OpenNCP Community has become a two-path road:

- In one side it is needed to deal with support and bug fix requests from Participating Nations that start adopting the OpenNCP software components.
- In the other side there is the need to conquer and accomplish epSOS 2 goals. Those goals imply the development or adjustment of certain components in order to provide the technological platform to a new set of services of cross border information sharing.

Having this in mind, the OpenNCP Community started to organise itself in a different form. Keeping in mind the agile principles, the community focused on delivering working and stable software combining new features and bug fixing.

Once again, the involvement of requirements specification expert groups had a huge impact in the strategy that the development team chose to handle with the modifications required. In that way, the development team is now designing the changes and evolutions that need to be implemented.

In order to make OpenNCP easily maintainable, the two development tracks converged into the formal release 2.0.0, that includes:

- epSOS phase 2 services:
    - Patient Access (PAC): possibility for a patient to directly retrieve its Patient Summary and display/print into an epSOS language.
    - Health Care Encounter Report (HCER): report returned from the Country of treatment to the Country of affiliation.
- epSOS phase 1 services from OpenNCP 1.1.3 plus further fixings.

Four releases of OpenNCP2.0.x were provided between June and November 2013.

It has to be noted that OpenNCP 2.0.x were classified as Major Releases: this implied the related testing strategy had to be applied.

PNs who passed the PPT-Slot with NCP-in-a-Transparent-Box from FET or with OpenNCP1.x, had to (partially) repeat the PPT-Slot, to be allowed to go to Operation with OpenNCP 2.0.x.

3.2.4 OpenNCP 2.1 MRO and Continuous Integration Automated Testing Tools

OpenNCP2.1 is the final OpenNCP release from epSOS.

Medication Related Overview service was included in Version 2.1.0

Three further implementations alternatives were proposed to the TPM and to the NEPC:

1. Continuous Integration (CI) and Conformance Testing services, allowing the automated use of the IHE Gazelle Testing tools. The whole purpose of this tool is to aid PNs to assess the conformance of their NCP instances by automatically validating all the transaction, audit messages and the related CDA documents, avoiding manual interventions, prone to errors.
2. Implement the HL7 CTS2 compliant interface to the Terminology Server
3. Implement the function to export a PS generated by the PAC service in IHE XDM profile
4. Implement the Extended Security Safeguards

The CI Automated Testing was considered the most relevant for OpenNCP maintainability and sustainability by NEPCs and TPM.

It was recognised the adoption of the HL7 CTS2 was premature, not having identified any CTS2 compliant Open Source Terminology Server, providing the level of services for editing and validating the epSOS MVC/MTC.

The TPM and the OpenNCP Community considered the specifications of the profile to export on a media the PS generated by the PAC service not enough consolidated by the Technical Specification team (WP3.A) and by the Industry Team.

Already in the past the PSB assigned a low level of priority to the implementation of the Extended Security Safeguard.

In conclusion, it was unanimously approved by TPM and NEPC, and ratified by the PSB, the OpenNCP 2.1.0 would have included the Continuous Integration services for Test Automation.

Additional information can be found on:

https://openncp.atlassian.net/wiki/display/INT/Integration+of+CI+Environment+With+Gazelle+Services

and: **https://openncp.atlassian.net/wiki/display/INT/Automated+Testing+Tool+Usage**

The final OpenNCP2.1.0 Gold Release was distributed on December 17th, after validation tests of the OpenNCP2.1.o Release Candidate:

3.2.5 Obtain Artefacts

OpenNCP releases, after component testing and integrability validation, are formally released on JoinUp.

After OpenNCP 1.0.0, other 12 releases were made available, plus several intermediate patches and Candidate Releases.

The full list of the links to the correct components is provided in Appendix B, Section 2.

All releases and support material can be retrieved from:

https://openncp.atlassian.net/wiki/display/ncp/OpenNCP+Community+Home

Participating Nations or other entities can openly use the released components to build up the NCP, the User's Portal and the Connectors to the National Infrastructures.

3.2.6 Future possible extensions of OpenNCP after epSOS

In consideration of what was implemented, and what remained in the pipeline, in this short section we list the components that it is worth taking into consideration while deciding about what to do next.

Besides functional improvements regarding new services in the scope of epSOS 2 project, the OpenNCP roadmap should include interoperability and security enhancements.

HL7 CTS2

KT1.4.10, Semantic Services, provided functional and technical specification of new Terminology services, including the HL7 CTS2 standard interface.

It is also expected that, in order to provide the epSOS TSAM component the compliance with CTS-2 (Common Terminology Services 2), and revision and update MUST be made to the TSAM synchroniser component. This improvement is in line with the Semantic Sustainability policy of providing a standard CTS-2 interface to allow the adoption of any Open Source Terminology Server.

epSOS Documents export

None of the epSOS use cases foresees the possibility a patient or a Healthcare Professional may export an epSOS document (PS, eP, HCER, MRO) on a media in a secured way, to allow the

implementation of the “Patient Mediated Access”, as a further evolution of the eHealth cross-border interoperability, to overcome legal constraints and allow extra-European interoperability.

This Use Case is the most relevant when the cross-border eHealth happens between Countries not in the epSOS loop (e.g. EU-US Interoperability, PNs out of the Circle of Trust).

The team started analysing IHE XDM profile, Further investigations have to be performed, to exclude the risk of injecting virus while exchanging USB keys (e.g. Patient Mediated Access through a telecommunication provider: secured mail, secured cloud, …).

Extended Security Safeguards

Due to the fast evolution of European Community and European Countries policies and recommendations, the project epSOS MUST accommodate the technological improvements needed in order to be compliant with most of the emerging policies and regulations. Regarding this scope, the OpenNCP has planned a specific version for security extension features.

Sustainable NCP network building

The mechanism to establish the network of the NCPs and build the secured VPN is currently based on the retrieval from a Central Configuration Service of NCP endpoint IP addresses and certificate informations,

This mechanism implies the existence of a Central Configuration Service,

The Central Configuration Service is also used to share other configuration info, like the Patient Search mask parameters for each specific Country (i.e. which identifires each Country is requesting to allow its patient search),

When epSOS will be over, in order to allow the survival of the epSOS network, this service should be handed over to other Organizations,

A more sustainable solution would be to define a configuration mechanism by polling the NCPs, rather than pointing to a Central Service.

Another critical point in NCP network creation is the VPN set up.

Currently the Certificates are centrally stored. They are retrieved to set up the VPN. However the VPN has demonstrated to be a critical point not for security, but for constraints to be imposed to PNs, Just removing the VPN is a simplistic solution that cannot be taken without a careful risk analysis and without knowing the new EC requirements on Privacy and Security, However, less cumbersome and more robust VPN set up mechanisms have the be specified and implemented.

epSOS adopted SHA-2 certificates, in line with the EC security requirements.

At each transaction set up the validity of the certificate is checked looking up in the EU TSL List. This has been another “point of weakness”: non EC Countries are excluded by the EU TSL List and not all EC Member State laws already require/allow Certification Authorities to include SHA-2 certificates in TSL List.

New certificate validity check methods have to be adopted to overcome security relaxations imposed by these limitations.

All the aforementioned actions to improve epSOS NCP network sustainability MUST be, when specified and approved, implemented in the OpenNCP.

4 Support to PNs and OpenNCP Community

In line with the goals of KT3.B.3, support was provided to the PNs and to Vendors.

In the sequel, the main activities will be shortly described

4.1 Support to PNs to adopt OpenNCP

The FET NCP-in-a-Transparent-Box was adopted by all of the PNs entered in the first piloting wave and by most of the new PNs at the beginning of epSOS 2.

The PNs who installed the Closed Source NCP were (in bracket, those who entered in Operation):

- Austria (PPT and Operation)
- Czech Republic (PPT and Operation)
- Denmark (PPT and Operation)
- France (PPT and Operation)
- Greece (PPT and Operation)
- Malta (PPT and Operation)
- Italy (PPT and Operation)
- Spain (PPT and Operation)
- Switzerland (PPT and Operation)
- Germany (PPT)
- Slovakia (PPT)
- Slovenia (PPT)
- Sweden (PPT)

The OpenNCP Team provided relevant support to the PNs to adopt from scratch or to switch from FET NCP to OpenNCP,

The following table provides the most updated picture of the NCP solution adopted by PNs, regardless the fact they will be in Operation in 2014:

Patient Summary		
PN	PS A	PS B
Austria	FET	FET
Czech Republic	FET	FET
Estonia	OpenNCP	OpenNCP
France	FET	FET
Germany	-	FET
Hungary	-	OpenNCP
Italy	OpenNCP	OpenNCP
Luxembourg	-	OpenNCP
Malta	OpenNCP	OpenNCP
Portugal	OpenNCP	OpenNCP
Slovenia	OpenNCP	OpenNCP
Spain	(FET) OpenNCP	(FET) OpenNCP
Switzerlan	OpenNCP	
Slovakia	-	FET
Turkey	OpenNCP	OpenNCP

Figure 2 - NCP technology by the end of 2013 for Patient Summary service

ePrescription		
PN	eP A	eP B
Croatia	OpenNCP	OpenNCP
Denmark	FET	FET
Finland	OpenNCP	OpenNCP
Greece	-	(FET) OpenNCP
Hungary	OpenNCP	OpenNCP
Italy	OpenNCP	-
Spain	(FET) OpenNCP	(FET) OpenNCP
Sweden	OpenNCP	OpenNCP

Figure 3 - NCP technology by the end of 2013 for ePrescription service

Each release was documented: release notes configuration information, upgrades, bugs fixing and installation guides were provided, openly accessible from the OpenNCP home page

https://openncp.atlassian.net/wiki/display/ncp/OpenNCP+Community+Home

4.2 Technical support for continuous improvements

KT3.B.3 performed the technical management of the bug reporting and fixing process, co-operating with NEPC Technical Leaders, OpenNCP Team and Vendors.

In epSOS, incident reporting is very structured, layered and governed by configuration and change management procedures.

Bugs detected in the development phase are directly reported and managed on the OpenNCP Community JIRA service.

Incidents, Problems or Change Requests are reported during testing, PPT or Operations are reported and managed on the Central Support Service. And dispatched to the appropriate incident owner: OpenNCP Team, WP/KT, Vendors.

Bugs report are transferred to the OpenNCP JIRA and included in the incident management and bug fixing process of the OpenNCP Team. Solutions are released as patches, Release Candidates or formal minor/major releases.

Incidents impacting vendors are discussed with the specific owner and monitored in the Periodic Vendors Call Conferences.

Incidents related to testing tools are transferred to IHE Europe for analysis and fixings.

Issues detected during the NCP network creation or during end-to-end testing are dealt with the support of the specific Expert Groups.

As for semantic interoperability issues, root-cause-analysis is performed with the Clinical/Semantic expert group, suggesting solutions to the single PN or proposing improvements to the next releases of MVC / epSOS CDA specifications.

A specific quality improvement activity was performed in order to identify technical solution to the issue of instability of the NCPs VPN. A task force lead by Portugal was established, gathering Security experts from KT1.4.11 and National experts.

Several factors may induce the instability, from usage of different releases of the firewall software, not fully compatible, to configuration issues and procedural issues. Guidelines on how to overcome these issues have been provided to PNs.

4.3 Support on Central Services and technical relations with Vendors

KT3.B.3 also acted as technical support on the selection of Central Service Provider and on setting up and testing of the epSOS Central Service, both for NCP Configuration Service and Central Terminology Server.

CONET was selected after a technical negotiation. Strict co-operation between technical experts and CONET was established during the new Central Service set up and activation, contributing to the change management process to adopt it in PPT and Operation.

Technical support was provided to the identification and the adoption of the new Open Source environment, to migrate the Central Support Service to the same platform where the OpenNCP issue tracking system is running, to simplify the trouble ticket management process in the last part of epSOS and in view of a future sustainability.

Technical consultancy was provided to Project Co-ordinator to define contracts with suppliers. Periodic call conferences Industry Team members were organised both to analyse troubles and share joint actions toward OpenNCP improvement.

4.4 OpenNCP Community building and hints on roadmap toward its sustainability

The epSOS decision to develop an Open Source toolkit to implement NCPs and National Infrastructure connector, although a fully operational NCP-in-a-Transparent-Box was available, stimulated the creation of a community and helped the improvement and consolidation of cross-border eHealth knowledge in the PNs.

The OpenNCP Community can be defined as an open group of people orchestrated by an agile software development methodology conducting effort on designing, he coding, testing and delivering OpenNCP software.

More than 30 members from 12[9] Participating Nations worked together in a distributed environment spanning over three time zones.

The vision that led the Community was to design and develop a set of Open Source Components (OpenNCP) that can be adopted by Participating Nation, to build their local implementation of the NCP (*National Contact Point).*

The method was to develop components, unit tested, readily deployable, validated through the Continuous Integration environment,

Since June 2012, the Community organised more than 100 call conferences and meetings, carefully tracking progresses on the weekly basis (Sprint method was adopted for a stringent process control).

The success factors were: collaborative design, high technological knowledge, rigorous engineering, knowledge sharing, support and maintenance.

As any other Community, the risk is to loose the momentum when the project ends.

Actions to consolidate the Community itself and PN adoption of Open Source implementation strategy are basic conditions toward the Community survival.

In order to provide the time and space for the OpenNCP Community to completely fulfil its mission and vision, there are still some milestones that need to be accomplished.

In fact, the mission and vision from the OpenNCP Community go further beyond making available healthcare standard compliant technology (like software artefacts).

It is strongly believed that, as an Open Source based community, there is high value added for countries and vendors if they participate and contribute in the process of technology design and build, instead of just using the final artefacts.

Being part of the process creates the perfect opportunity for learning new skills and competences that endure in time much longer then technology as well as enhances the country resilience and expertise concerning technology changes.

Having that in mind, the OpenNCP Community has been looking for ways to engage countries and vendors that could sustain and expand the OpenNCP Community work.

1. As first step we believe that for being able to participate and contribute countries should have the opportunity for better understand - HOW THINGS WORK.
2. As second step - to allow new elements to interact and learn from more experienced team members - could be a hands on encounter, for immersive and intensive discussion on activities related to OpenNCP technology - HANDS ON.

It is proposed to organise webminars to disseminate the knowledge on OpenNCP and hand it over to new national and EC initiatives.

Indications on contents of the webminars can be found on:

https://openncp.atlassian.net/wiki/display/ncp/Road+to+Sustainability

[9] In alphabetic order: AT, CH, DK, EE, FI, GR, HU, IT, PT, SE, SK, TR

5 Achieved results

epSOS 1 defined three implementation strategies, leaving to PN the role of specifying and implementing, or leaving complete freedom to the market opportunities and open competition, or jointly develop the full proof of concept.

All the PNs opted to adopt the last one, minimizing the risk of non-interoperability and covering the lack of the National Infrastructure.

This solution, valid for epSOS 1, shows some limits as for medium long term sustainability.

WT3.B.1 identified that epSOS core responsibility is and remains to specify and support testing for compliance to the epSOS Interoperability Architecture.

The proposed implementation strategies for epSOS 2 offer opportunities to create/enforce the eHealth interoperability ecosystem (through the establishment of a Consortium or through the open competition) to assure market opportunities which might allow sustainability for PNs and Vendors.

PNs are free to choose either solution.

The first PN who chose to implement an Open Source solution was Turkey, combining the Open Source components from the Fraunhofer Elga Team (FET), released in ASL v2 licence, with internally developed components, in place of the TIANI-Spirit back-bone, released under GPS V3 license.

This platform, provided to the partner who requested it, triggered the creation of the first nucleus of the epSOS Open Source Community in which Beneficiaries and vendor co-operated, organised in Miniprojects, to create the basic components and demonstrating the integrability through joint testing.

A limited amount of central funding (JAB) was used to cover vendors' cost and to guarantee the maintenance and the extension of the epSOS 1 FET Open Source components.

The result was not a turn-key product, but a toolset of components that can be used by Participating Nations, Public / Private organisations and Vendors to implement their own solution, tailored to the national realities.

Turkey, Estonia, Finland, Portugal passed the pre-pilot testing with OpenNCP solution. The OpenNCP community, initially lead by Denmark, then by Sweden and since April 2013 by Portugal, grew up to 12 Countries participating to the design and development..

The major difficulty encountered was the various implementation alternatives left by the Functional Specifications (D1.4.3) and the on-going Architectural Specifications (WP3.A), Semantic (KT1.4.10) and Security (KT1.4.11), that introduced some delays.

The continuous co-operation with the aforementioned WPs and Key Tasks, combined with the tactical approach of maximising the re-use of existing components, and the adoption of the Sprint methodology applied to the step by step implementation have allowed to release the first version of the OpenNCP 1.0.0 on November 9th, 2012 and the first "Operation Ready" OpenNCP 1.1.0 on January 13th, 2013. OpenNCP1.x provided epSOS 1 PS and eP/eD services.

Starting from OpenNCP1.1.0, the "Ready for Operation" releases are made available on JoinUp for dissemination and re-use under ASL v2 and GPS v3 Open Source Licenses.

OpenNCP 2.0.0, including epSOS 2 services was released on June 20th, 2013.

The final version OpenNCP2.1.0 "Gold release" was released on December 17th, 2013. It includes services for Continuous Integration Automated Testing with IHE Gazelle tools, to make it more easily maintainable and sustainable.

In total 13 formal releases of OpenNCP have been made available.

Fourteen PNs already adopted OpenNCP solutions, while six PNs remained, in the epSOS project period, with the FET NCP-in-a-Transparent-Box solution.

We are currently observing FET NCPs interoperate with OpenNCP both for PS and eP/eD services.

We also acknowledge the advantages provided by the Open Source Community to the growing up of the eHealth Ecosystem in the Countries, with the creation of core development teams who fruitfully co-operated to the implementation of the Common Components at EU level and of the National Solutions.

Appendix A : Abbreviations / Definitions

Abbreviations

Terms and Definition used in this document are included in the epSOS. In order to ease the reading, most common abbreviation are reported in this appendic abbreviations.

CCD	(epSOS) Common Component Design
CDA	Clinical Document Architecture
eCRTS	epSOS Central Reference Terminology Server
eD	eDispensation
EDQM	European Department for the Quality of Medicines
eP	ePrescription
FET	Fraunhofer ISST / Elga and IT consortium
GUI	Graphical User Interface
HCP	Health Care Professional
HCPO	Health Care Provider Organization
HLDD	High Level Design Document
ID	Identifier
IHE	Integrating the Health Care Enterprise – Europe
IT	Industry Team
JDBC	Java Database Connectivity
JWG	Joint Working Group of Work Packages 3.8 and 3.9
LSP	Large Scale Pilot
MS	Member State
MTC	epSOS Master Translation/Transcoding Catalogue
MVC	epSOS Master Value Sets Catalogue
NC	NationalConnector
NCP	National Contact Point
NCP-A	National Contact Point of Country A
NCP-B	National Contact Point of Country B

NI	National Interface
OCSP	Online Certificate Status Protocol
OID	Object Identifier
PAP	Policy Administration Point
PD4	Project Domain 4
PDF	Portable Document Format
PDP	Policy Decision Point
PEB	Project Executive Board
PEP	Policy Enforcement Point
PID	Patient Identity
PMT	Project Management Team
PN	Participating Nation
PoC	Point of Care
POJO	Plain Old Java Object
PoU	Purpose of Use
PS	Patient Summary
PSB	Project Steering Board
SAML	Security Assertion Markup Language
SME	Subject Matter Expert
SOAP	Simple Object Access Protocol
SQL	Structured Query Language
SSL	Secure Socket Layer
STS	Security Token Service
TPM	Technical Project Manager
TRC	Treatment Relationship Confirmation
TSAM	Terminology Services Access Manager
TSL	Trusted Service List

URL	Uniform Resource Locator (world wide web address)
WSDL	Web Services Description Language
WP	Work Package
WS	Web Service
XFRM	Transformer
XCA	Cross Community Access
XDR	Cross-entreprise Document Reliable Interchange
XML	eXtensible Markup Language
XUR	Cross-Enterprise User Authentication

Definitions

Central Common Services	A set of central services jointly used by NCPs.
Circle of Trust	See epSOS Glossary.
Common Software Components	Software components of the NCP-in-a-Transparent-Box
Country A	See epSOS Glossary
Country B	See epSOS Glossary
eDispensing (eD)	See epSOS Glossary.
ePrescription (eP)	See epSOS Glossary.
epSOS Central Reference Terminology Server (eCRTS)	Web tool (based on the HealthTerm system developed and maintained by CareCom) to allow every MS to develop, validate, archive and download to the NCP the MVC and MTC.
epSOS Master Translation/Transcoding Catalogue (MTC)	This is the epSOS Master Value Sets Catalogue which contains, in addition to the original terms, their translation in different languages corresponding to the respective Member States and the possible cross-referencing (transcoding) with other code system that are used at the national level. The translation and the cross-referencing (transcoding) is a national responsibility. Providing the content of each country's contribution to the epSOS Member States is under epSOS' responsibility.
epSOS Master Value Sets Catalogue (MVC)	Collection of terms used within certain parts of the pivot documents (either parts describing the patient demographics or the clinical problems for example) based on known code systems such as ICD-10, SNOMED CT, ATC, EDQM, UCUM, etc.
High Level Design Document (HLDD)	Document describing the concept and high level architecture of NCP-in-a-Transparent-Box

Interoperability Architecture	epSOS Interoperability Architecture shall include not only the NCP-to-NCP interoperability specification, but also critical end-to-end requirements/policies and other elements such shared data distributed by shared services-e.g. MTC/MVC). The possible specification of components and of back interface has not to be considered as mandatory part of the epSOS Interoperability Architecture.
Nation-Specific NCP Components	The components of the NCP that will not be developed in common but are still part of the NCP
National infrastructure	It represents all entities where patient or HCP or Health Care records are managed in member states.
NationalConnector (NC)	Entity that encapsulates the Nation-Specific NCP Components. The NationalConnector is implemented as a black box having its subcomponents hidden from the NCP
NCP gateway	A gateway system under the control of the NCP that manages all epSOS transactions and which connects the National Infrastructure (NI) to the epSOS backbone. It is a point of entry/exit to/from the NCP, acting on behalf of a HCP (at a PoC) who requires access to a patient's medical data through epSOS, or acting as service broker of an epSOS data provider
NCP-in-a-Transparent-Box	A modular set of software components (Common Software Components) intended to facilitate a NCP implementation that can be used completely or partly by any MS to fulfil NCP obligations. This implementation is not mandatory.
OpenNCP	epSOS NCP software publicly available under Open Source licensing
OpenNCP Community	Open group of people orchestrated by an agile software development methodology conducting effort on designing, coding, testing and delivering OpenNCP software
Requirements	Definition of all relevant needs (business, functional, non-functional, technical and technological) for system specification and implementation
Software Component	Software that can be installed or replaced only as an entity to create a scalable implementation (e.g. component can provide directory services, data storage, provisioning, etc.)

Appendix B : Open Source NCP Design and Release Notes

For a complete reference on the NCP “core” components, together with their interfaces, that were centrally developed as Open Source and made available to all through the identified Open Source Community, please refer to the following autonomous document:

- Documentation: D3.B.2_App_B_OSS_NCPDesign_V1.1.pdf

For technical details on the epSOS Phase 2 services and tools, please check the following appendixes, included as Appendixes of V1.1 of the current document:

- Services
    - Patient Access (PAC):
        - Appendix C: Patient Access (PAC)
    - Health Care Encounter Report (HCER):
        - Appendix D: Health Care Encounter Report (HCER)
    - Medication Related Overview (MRO):
        - Appendix E: Medication Related Overview (MRO)
- Tools
    - Continuous Integration (CI) and Conformance Testing:
        - Appendix F: Continuous Integration (CI) and Conformance Testing

Appendix C : Patient Access (PAC)

Documentation: **D3.B.2_App_C_PAC_Design_V1.0.docx**

Online documentation:
https://openncp.atlassian.net/wiki/display/ODC/Patient+Access+to+Information+PAC

This information will be continuously updated online.

Appendix D : Health Care Encounter Report (HCER)

Documentation: D3.B.2_App_D_HCER_Design_V1.0.docx

Online Documentation:
https://openncp.atlassian.net/wiki/display/ODC/HCER+Service+for+Patient+Summary+Extension

This information will be continuously updated online.

Appendix E : Medication Related Overview (MRO)

Documentation: D3.B.2_App_E_MRO_Design_V1.0.docx

Online Documentation:
https://openncp.atlassian.net/wiki/display/ODC/Medication+Related+Overview

This information will be continuously updated online.

Appendix F : Continuous Integration (CI) and Conformance Testing

Documentation: D3.B.2_App_F_CI-ConformanceTest_Design_V1.0.docx

Online documentation:

- Continuous Integration Workflow:
  https://openncp.atlassian.net/wiki/display/INT/Continuous+Integration+Workflow
- Conformance Testing with Gazelle:

https://openncp.atlassian.net/wiki/display/INT/Integration+of+CI+Environment+With+Gazelle+Services

This information will be continuously updated online.

Appendix G : VPN problems tracking and resolutions

Documentation: D3.B.2_App_G_VPN_problems_V1.0.docx

Online documentation:
https://openncp.atlassian.net/wiki/display/ODC/VPN+problems+tracking+and+resolution

This information will be continuously updated online.

Appendix H : Assessment of the epSOS licensing policy (Christian Lovis)

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Genève, le 7 mars 2013

Assessment of the epSOS licensing policy

Licensing is a global hot topic and nothing that epSOS will solve. However, epSOS must ensure a) large adoption of the project and large scale pilots; b) sustainable process.

Statements A - Objectives

1. The objective of epSOS is to achieve cross-border exchange of clinical patient information.
2. The cross-border exchange of clinical information shall boost interoperability in the field in general.
3. Interoperability in health has proven to improve quality and efficiency of care.
4. Interoperability will only be achieved if access to all what is required, specifications, requirements, systems, semantics, etc. is not a limiting factor.

Statements B - Constraints

1 Sustainability of epSOS requires sustainability of all what is required torun epSOS.
2 Sustainability requires constant care and thus requires resources.
3 The epSOS licence model must support large access and reliable sustainability.
4 The intellectual property must be protected
5 The public funding of epSOS and the global objectives must be respected.

In order to meet the statements, a approach must be taken that has two components.

Foundations

The general epSOS foundation components have a very open licensing approach, strongly oriented to a Copy Left vision, with limited or not at all "heritance" of copyrights.
The general epSOS foundations cover all the minimal elements in each domain required to run an epSOS pilot. The non exhaustive list of domains are: specifications, requirements, overall context knowledge, system and software code, semantics and data models, evaluation frameworks, business model examples, etc.

Extensions

These foundations must allow the production of more complex requirements, specifications, projects, systems, etc on their top, with additional features while preserving the core of the function of epSOS on cross-border exchange of patient information.

Market vision

The foundations must be seen as strong enablers to leverage adoption and extension of the use of epSOS in a “facilitating licensing model”, while the extensions must be seen as market-driven differentiators to provide added value and direct for profit product lines with usual copyright licensing models.

Copyleft comments1

According to Free Definition Software2, there are 4 basic rules:
Freedom 0 the freedom to use the work,
Freedom 1 the freedom to study the work,
Freedom 2 the freedom to copy and share the work with others,
Freedom 3 the freedom to modify the work and the freedom to distribute modified and therefore derivative works.
Copyleft licenses are sometimes referred to as "viral licenses" because any works derived from a copyleft work must themselves be copyleft when distributed.
There is a wide range of interpretation on the “viral” aspect of copyleft licensing. GNU GPL applies a strong copyleft but copyleft licenses can have a clause allowing components to interact with non-copyleft components as long as the communication is abstract, such as executing a command-line tool with a set of switches or interacting with a Web server.

Pr Christian LOVIS
Médecin responsable
Service des Sciences de l’Information Médicale

1 http://en.wikipedia.org/wiki/Copyleft (01.03.2013)
2 http://en.wikipedia.org/wiki/Free_Software_Definition (01.03.2013)

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