EUROPEAN COMMISSION
DG HEALTH AND CONSUMERS
DG COMMUNICATIONS NETWORKS, CONTENT AND TECHNOLOGY

eHealth-units

5TH EHEALTH NETWORK 13 MAY 2014
COVER NOTE BY SECRETARIAT

Topic 3: Connecting Europe Facility (CEF) – *for adoption*

Issue at stake
The CEF is designed to support projects of common interest for the deployment of digital service infrastructures. Ultimately, its role is to support the development of a Digital Single Market. These infrastructures should create European added value and meet proven needs. They should be sufficiently mature for deployment, technically and operationally. The eHN sub-group set up in November 2013 and the eHealth Governance Initiative (eHGI) seek the endorsement on a list of 4 digital services infrastructure (DSI) to be included in the 2015 work plan (WP) of the CEF. The ultimate decision on inclusion in the WP lies with the CEF governance board (2nd half 2014). The proposed eHealth infrastructures are: (1) exchange of patients' summary data, (2) ePrescription, (3) European Reference Networks and (4) patients registries.

Summary of document
The first document ("discussion paper") was prepared by the eHGI to summarise the 4 DSIs and facilitate the discussion within the eHN. The second document ("draft position paper on the 2015 work programme for the CEF") was prepared by the eHN secretariat, building upon the reports made by the rapporteurs on each DSI of the eHN sub-group. It is for endorsement by the eHN as it will be presented to the CEF governance board for prioritisation in the 2015 work programme, by mid May 2014. It might be revised by the dedicated eHN CEF sub-group by mid June 2014. A budget of 38,3 million € is sought for 2015/2020 period. The third document ("information paper") was commissioned by DG SANCO and prepared by the consultant Diane Whitehouse to provide information about the CEF and the preparation of sound proposal(s) for funding of DSI in the area of health.

Format of procedure in the eHN
The Co-Chairs will introduce the topic. The eHealth Network members are invited to: – Contribute to the debate and answer the questions raised by the eHGI – Endorse the draft position paper on the 2015 work programme for the CEF – Express their commitment on a future liaison with the existing eHN sub-group on CEF, which will prepare a list of Member States seeking CEF funding.

1. DISCUSSION PAPER

ON THE FUNDING OF EHEALTH SERVICES BY THE CONNECTING EUROPE FACILITY

Proposed by the eHealth Governance Initiative

Date: 13 May 2014

At its third and fourth meetings, the eHealth Network discussed options for fostering the cross-border interoperability of eHealth services by utilising funds from the Connecting Europe Facility (CEF).

In particular, the Network agreed to set up a subgroup to investigate the funding mechanisms further. The subgroup met on 10 February 2014. Additional input was provided by the eHGI and an information paper commissioned by DG SANCO for a workshop on 1 April 2014 (Appendix 1).

Based on this investigation, it was concluded that CEF funds may be used to fund technically mature and sustainable eHealth services. The standing coordination group discussed at the last meeting of the Network would however not be eligible for CEF funds.

Four potential eHealth services eligible for CEF funding were identified:

1) Cross-border ePrescription and eDispensation service[1]
ePrescription and eDispensation as piloted by epSOS extended by additional core services such as eSignature and eIdentification

2) Cross-border patient summary service[2]

[1] Denmark, Finland, Greece, Italy, Spain and Sweden are currently piloting the ePrescription service in epSOS. Croatia and Hungary will join shortly.

[2] Austria, Estonia, France, Italy, Luxembourg, Malta, Portugal, Slovenia, Spain and Switzerland are currently piloting the patient summary service in epSOS. Hungary will join shortly.

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Patient Summary as described in the guidelines of the Network extended by additional core services such as eIdentification and eAuthentication

3) eHealth services for European Reference Networks

Virtual communication tools and telemedicine services for low-prevalence, rare and complex diseases including telemonitoring, virtual clinical boards, shared patient and knowledge databases and virtual training

4) Infrastructure services for interoperable Patient Registries

Registry of registries, registry assessment tools, repository of common data and process models for building patient registries, open source software components for building interoperable patient registries and to support data exchange between registries

Members of the eHealth Network are invited to express their interest and to comment on the proposal based on the following questions:

1) Does your Member State have an interest in sharing eHealth services for cross-border exchange of health data with other Member States at the European level?
2) Does your Member State agree with the preliminary choice of the four candidate eHealth services for CEF funding?
3) Does your Member State plan to deploy the national components of these eHealth services from 2015-2020 (funding period of CEF)?
4) Would your Member State be prepared to finance the national infrastructure necessary for these eHealth services and to work towards their long-term sustainability?

Core services (cross border infrastructures) are likely to be given priority in terms of the CEF funding, meaning that the funding of generic services (connection between the national and international infrastructures) is not guaranteed.

Next steps

Based on the expression of interest of Member States in the eHealth Network, the Commission may issue a call for CEF funding of eHealth services in 2015. A first contribution from the eHN to the CEF governance in DG CONNECT is provided here after ("the draft position paper"), for endorsement.

Final contributions from the eHN should be sent out in May/June 2014 for the preparation of the 2015 work programme and mapping out of the management provisions of the DSI deployment. In this respect, interested Member States may form a consortium to apply for funding in 2015.

Finally, services may benefit from funding from the end of 2015 till 2020.

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2. DRAFT POSITION PAPER OF THE EHEALTH NETWORK TO THE CEF GOVERNANCE BOARD, ON PRIORITISATION OF 4 DIGITAL SERVICES INFRASTRUCTURE ON EHEALTH

First contribution to the preparation of the 2015 work programme

1. INTRODUCTION

The eHealth Network (eHN) set up by Directive 2011/24, article 14 endorsed this position paper on 13 May 2014.

Voting provisions? Prioritisation among the 4 DSI? Individual MS positions? To be filled in after 13 May 2014

This position paper was prepared by the eHN secretariat on the basis of the conclusions of an eHN sub-group workshop (10th February 2014) and the eHealth Governance Initiative meetings (eHGI, 1st and 9th April 2014), which is the operational arm of the eHN. Rapporteurs were appointed for each of the 4 DSI, namely:

- Appointed Spanish expert for the DSI on exchange of patients summary (PS) data
- eHGI subgroup for ePrescription (eP)
- SANCO for European Reference Networks (ERN)
- Appointed Slovenian expert for the patients registries (PR)

Seeking the financial support under the CEF is necessary to reach the overall objective of article 14 of Directive 2011/14, namely to "facilitate the cooperation and the exchange of information among Member States (…), to work towards delivering sustainable economic and social benefits of European eHealth systems and services and interoperable applications (…)". It is also needed to implement the specific objective of the same article, namely "to support Member States in developing common identification and authentication measures to facilitate transferability of data in cross-border healthcare".

Seeking the financial support under the CEF is necessary as well for the implementation of the guidelines on eP, as foreseen in article 11.2.b, and deployment of ERN, as foreseen in article 12 of Directive 2011/24.

Seeking the funding of infrastructures of the DSI is not eligible under the scope of the Regulation 282/2014 setting up a third EU health programme for the period 2014/2020.

The individual contributions from the 4 rapporteurs are available and summarised in part 2 of the position paper.

2. INFRASTRUCTURE INVESTMENTS NEEDED FOR THE HEALTH DSI'S

2.1. Preamble

When adopting this position paper, the eHN is fully aware of the eligibility criteria for CEF funding, ie:

- Technical maturity of the services to be deployed
- The operationality of the services to be deployed (24/24h, 7/7d)
- The sustainability of the services, when CEF funding ends

In addition, the eHN is supportive of the need to avoid duplication of funding, notably by making proper reuse of some core DSIs to be deployed (eID, eDelivery, eInvoicing) and of other specific DSIs such as the multilingual platform and the social security platform for exchange of information on reimbursement of cross border care services, provided that health specific considerations are taken on board, notably to secure the security of transactions and the protection of the patients data.

The operationality and the post CEF sustainability of the services is a major challenge to be addressed by Member States and the Commission, in order to identify relays of and complementary funding, notably for the costs to be incurred at national/ regional levels. The business model of some DSIs such as PS and eP can evolve very rapidly, from a limited deployment today to full deployment within a couple of years (*eP in Belgium, Croatia, Denmark, Estonia, Finland, Greece, Sweden etc).*

Banning the CEF funding today would clearly discourage those Member States willing to deploy and to take over, despite understandable uncertainties.

The technical maturity of the DSI is evidenced by the deliverables of the EPSOS large scale pilot (PS and eP), the two existing ERN and the PARENT Joint Action on Patient Registries.

The eHN should also be properly consulted and incorporated in the governance structure of the CEF, as mentioned in its multiannual work programme 2015/2018.

The overall budget estimated in §3, 38,3 millions €, aims at covering 100% of the cross border infrastructures and national connections to it ("core and generic services"). In fine, when clearly identified, the generic services part should be covered at max 75%, hence leaving 25% to national co-funding.

Costs of deployment at national and regional levels are not included.

For PS and eP, assumptions were made on the number of MS using the services, the number of patients and health professionals, the multi lingual combinations, and the assets supported.

The overall budget highlighted in §3 corresponds to 4 DSI only, for which budgetary commitment is expected in the 2015 work programme of the CEF, with payment appropriations being scattered over the period 2015/2020. Should other services be identified in the upcoming years, such as deployment of telemedicine ones, a new call for funding will be made by the eHN.

2.2. Patients summary data

2.2.1. Description of the service

When a citizen makes an unplanned cross-border healthcare visit to a health provider in the European Union, both patient and health professional will have access to the person's Patient Summary and other relevant Electronic Health Record documents.

In addition to ensuring improved and enhanced healthcare in Europe, the service will be supported by effective technology and more meaningful and efficient data exchange, thus enhancing a European digital health space.

For being able to render this service, there is a need for a European eHealth infrastructure which can transform ("transport, transcode and translate") information products that are in different languages and use different coding systems, in response to requests and actions occurring between healthcare systems of different Member States.

<u>Specific objectives:</u>

Deploy and operate a common and shared infrastructure for digital services regarding eHealth-based on mature ICT solutions and sustainable business models.

Set up the necessary assets to enable Member States to exchange interoperable extracts based on electronic health record (EHR) systems that are already in place or may be adopted in the future.

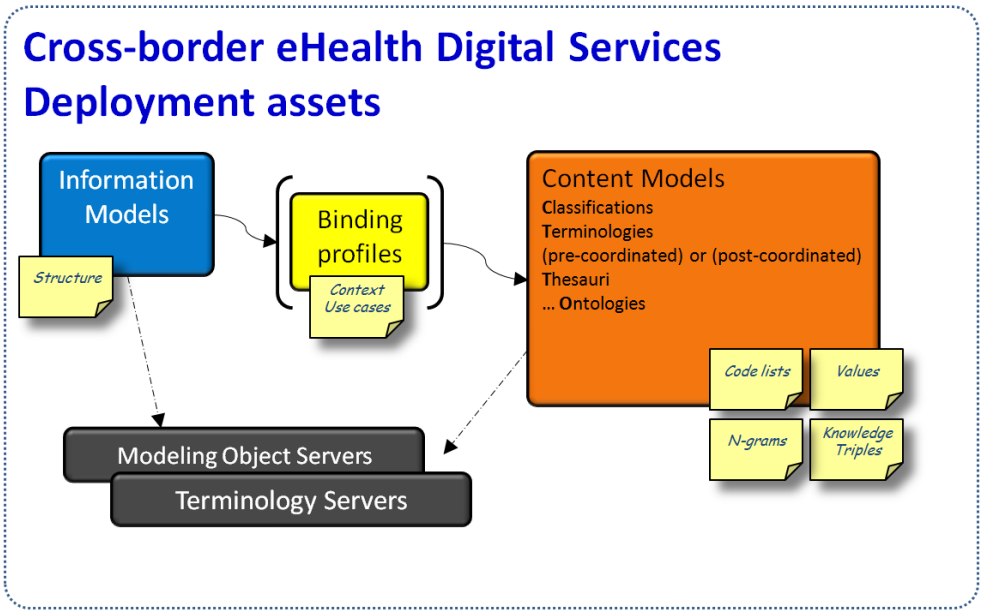
Coordinate and support real-time cross-border exchange of patient data for healthcare episodes on the basis of a set of real-world services.

Provide transcoding, translation, mapping, analysis, and validation service modalities for services such as the exchange of a Patient Summary, which can also be applicable to ePrescription & eDispensing documents, Reference Networks data sharing, Patient Registries database coordination, and later other types of services such as Request and results sharing workflow for radiology, Requests and Results sharing workflow for laboratory, Remote monitoring and care of people at home or on the move using sensor devices.

Provide guidelines, instructions, practical advice, frameworks, synergies identification, and practical support on how to improve the model of meaning

(matching the meaning of the document labels with the meaning of the associated value(s), in order to facilitate cross-language interpretation of document data) of existing patient information products.

2.2.2. Infrastructure needed



The information models

A repository of information models for different data exchange situations is a valuable asset for the EU; cross-border agreements on structure are established beforehand, and citizens can receive optimum healthcare with adequate information represented in a meaningful structure.

Rules of the exchange are clear for both MS involved. Individual instances (information components, full documents, complete folders) can be validated and potential errors marked for alerting the receptors. Translation of labels can be performed in real time, according to pre-existing rules. Context for each data item can be fully understood by healthcare providers and patients alike.

Administration of modeling objects can be done using a repository controlled via application(s). The modeling servers allow search, retrieval classification, tagging, versioning, maintenance, specialization, etc. Improving the models can be shared as well.

The content models

When clinical content is elaborated, free text is still very important. Capability to have exchange of interoperable medical data strongly depends on structured and encoded data capture. Since different encoding standards are used in different countries, having the encoding resources accessible and cross-referenced in a shared platform and accessible to Member States.

2.2.3. Budget estimates

2015: 1,4 million €

2016/2020: 19 million €

Total: 20,4 million €

2.3. ePrescription

2.3.1. Description of the service

Guided by the principles of continuity of care and patient safety, ePrescriptions and eDispensations support the concept that a patient being abroad can receive the equivalent same medical treatment that he would receive in his home country.

The objectives are to:

- Allow dispensation of ePrescriptions across all Europe
- Support the documentation of dispensed drugs.
- Cross-border ePrescription and eDispensations services in Europe will become even more essential with a move of additional countries to electronic prescriptions particularly since their counterpart cross-border paper prescriptions - have as already been achieved.
- Patient safety while staying abroad will be increased since an electronic prescription can much more easily been translated, e.g. using multi-lingual classifications and nomenclatures.
- Using Dispensation data from the dispensing pharmacy in the country of temporary stay, the health services in the home country can update the medication record of the patient, making health care and prescriptions for him safer.
- Although Reimbursement services are out of scope of the epSOS eDispensation service, any characterisitics of the service that will assist patients claim reimbursement would also be a significant element of the service. Defining European wide interoperability measures will also support to establish the ePrescription and eDispensation services in countries that have not yet implemented them. Any synergy with the EESSI infrastructure should be sought.

2.3.2. Infrastructure needed

- Solving interoperability issues inherent to ePrescriptions, particularly in the semantic domain (identification of drugs, information for patients, drug use instructions) and for issues of substitution.
- Analyse different scenarios of gradual adoption, e.g. paper-like prescriptions transmitted in PDF format.

- Seek collaboration with regulatory bodies with respect to semantic interoperability (generic and brand-name consistency, similarities of dosage), prepare use of a EU common database on medicinal products.

- Deploy and validate a European-wide reference for drug nomenclature provided by EMA in the context of cross-border prescribing - linking it to the requirements and current practice in Member States.

- Develop processes to involve National Contact Points (NCPs) in confirming the validity of a prescription - cross-checking with the concept of end-to-end encryption.

- Processes to routinely access professional registration databases for validating ePrescriptions.

- Link the identification of health professionals with their authority to prescribe verify existence of doctor/patient relationship.

- Define assurance levels for eID for cross border ePrescription services

- Build on common identification and authentication measures for eHealth to foster their use within ePrescription services across Europe.

- Establish access to authorisation datasets of Member States' competent authorities including linkages to professional bodies

- Implement ePrescription Guidelines (to be adopted by the eHN in November 2014)

- Semantic adaptation of epSOS achievements

- Maintenance, evolution and deployment of technical and semantic interoperability assets based on the ePrescription guidelines and common NCP assets

2.3.3. Budget estimates

The budget estimates provided are for EU contribution to building the key elements for the Digital Service Infrastructure dedicated for cross-border ePrescriptions. They do not include any national or regional implementation costs nor any licensing fees that may be needed to enable service operation.

2015: 1,4 million €

2016/ 2020: 6, 8 million €

Total: 8,2 million €

2.4. European Reference networks ERN

2.4.1. Description of the service

Directive 2011/24/EU provides for cooperation in the specific areas where the economies of scale of coordinated action between all Member States can bring significant added value to national health systems. This is the case for European Reference Networks, as the objectives of the Networks set in Article 12 of the Directive – e.g. European co-operation on highly specialised healthcare, pooling of knowledge, improvement of diagnosis and care in medical domains where expertise is rare, helping Member States with insufficient number of patients to provide highly specialised care - cannot be sufficiently achieved by the Member States by themselves and can be better achieved at Union level.

Establishing European Reference Networks will help to provide affordable, high-quality and cost-effective healthcare and to improve these patients' access to the best possible expertise and care available in the EU for their condition.

The service will provide all the healthcare providers, members of a European Reference Network, with the capacity to communicate and exchange medical information in a similar manner as if the professionals were working in the same physical environment by means of virtual tools and eHealth solutions. The networking dimension and in particular the IT tools and eHealth solutions are the key elements for the success of the European Reference Networks.

The service aims to improve the exchange of expertise and clinical data through the network and across the EU; allow the swift and smooth contact between providers and between patients and providers at a distance and to maintain and support collaborative/cooperative actions and systems

The service will allow healthcare professionals to:

- Strongly interact and cooperate on clinical cases by:
- Multi-disciplinary virtual boards (e.g. tumour boards) (multilateral connection)
- Bilateral consultation between two centres
- Transmission of and consultation on clinical images (XRay, scans, patology etc..)
- Tele-consultation involving patients
- Interactive production of guidelines, technical documents etc
- Diagnosis support tools: Shared decision trees/other diagnostic tools
- libraries of technical documents
- Training and at distance learning activities

- Research activities: shared protocols for clinical trials, shared databases

- Patient registries for secondary use of information

2.4.2. Infrastructure investments needed

The initial amount for 2015 represents mainly initial investment costs and is an estimate for the establishment of 2 Medium Size ERN (25 centres & 100 users). Running costs (annually) would represent an estimate of 20% the initial costs). More detailed cost estimation is needed. Estimated budget for 2016-2017 includes the investment costs of 2 new ERN per year and the running costs of the previous ones.

- Initial costs includes costs for Hardware, SW-Licenses and activities for set-up, configuration and Integration
- Running costs include operations, maintenance and support (2nd level helpdesk)
- Cost included: Includes central costs and raw average costs at individual centres(e.g. PACS integration, rough estimate here: 5-10k€/Center)
- Implementation costs only, costs for related design of organisation aspects not included and assumed to be completed at the start of infrastructure set-up
- Standard Internet based communication - costs for high reliable or high security network services are not included
- Some of the services/tools/components may be shared by more than one RN in the future
- Training costs are not included

2.4.3. Budget estimates

2015: 1,4 million €

2016-2017: 3,7 million €

Total: 5,1 million €

2.5. Patients registries

2.5.1. Description of the service

Cross-border services for support of interoperable patient registries‘ will be comprised of a set of interoperability assets and services aimed at (1) supporting establishment of patient registries that contain interoperable data; (2) improvement of interoperability of existing patient registries; (3) facilitating exchange (including but not limited to cross-border exchange) of registry data.

Specific components will be:

(1) tool to provide online access to Patient Registries Guidelines and

Recommendations

(2) Registry of Registries (parent-ror.eu)

(3) Registry (self) assessment tool

(4) Repository of registry related common data and process models for building patient registries

(5) Repository of best practices

*(6) SW components for interoperable patient registries and for support of data exchange across registries

**(7) Registry-as-a-service for micro-registries

And additionally

(7) consulting services to registry holders

(8) Supporting services: asset support services, further improvement of the assets, overall management and governance

2.5.2. Infrastructure needed

See specific components above

2.5.3. Budget estimates

2015: 0,9 million €

2016-2020: 3,6 million €

Total: 4,5 million €

3. OVERALL BUDGET ESTIMATES

The eHN asks the secretariat to make a bid for the CEF WP 2015 of ***38.3 million €***

DSI, in m€ at 100%	2015	2016-2020	Total to be claimed WP 2015
Patient summary	1,43	19,00	20,43
ePrescription	1,43	6,79	8,21
EU REF Network	1,43	3,71	5,14
Patients registries	0,86	3,64	4,50
Total	5,14	33,14	38,29

Should other services be identified in the upcoming years, such as deployment of telemedicine services, a new call for funding will be made by the eHN.

Information Paper

This paper is intended to provide the eHealth domain with information about the Connecting Europe Facility (CEF) and the preparation of sound proposal(s) for funding of eServices in the area of health. The information paper should be read in conjunction with the accompanying template.

Information paper drafted by:
Diane WHITEHOUSE, The Castlegate Consultancy

Document versions

Date	Version	Content
19 December 2013	0.0	Initial notes.
22 January 2014	0.1	Template and overview.
31 January 2014	0.2	Further content added.
2 February 2014	0.3	Further content added.
3 February 2014	1.0	Submission of draft document to European Commission.
4 February 2014	1.1	Revised following comments from project officer.
5 February 2014	1.2	Revised by project officer.
5/6 March 2014	1.3	Modifications made to take on board commentary made in 10 February 2014 meeting and through specific technical observations made by A. Romero (sub-group member).
17 March 2014	1.4	Modifications made following comments by members of European Commission staff, particularly with regard to reference to a stand-alone template; details pertinent to Table 2; details pertaining to specific business model methodologies; and the need to refer to concrete (business/financial) figures; Annex 2 was also removed (it is now a stand-alone template). Occasional grammatical or stylistic improvements made.
19 March 2014	1.5	Revised following comments from project officer, and with final proof reading.

Table of contents

1. Introduction

This information paper concerns the funding of the electronic exchange of medical data (i.e., patient summaries) across borders. To deploy this activity as a digital eHealth service, there is a need for funding under the Connecting Europe Facility (CEF), which is the principal funding instrument for trans-European networks in the field of telecommunications.

This information paper is intended to serve as an input for the sub-group of the eHealth Network on the CEF. The purpose of this sub-group is to start the work on writing proposals – in the form of (a) business plan(s) – for funding through the CEF for eHealth services. Further work on such business plans will be carried out by the eHealth Governance Initiative (eHGI) and others, and will ultimately lead to a set of proposals being created that are to be endorsed by the eHealth Network.

The sub-group has been requested to:

- Identify the eServices, and deployment of assets, to be funded by the CEF.
- Start preparations, in the form of a business plan, in order to have CEF funds allocated.

Therefore, this document is intended to make it clear to both the sub-group participants (and, ultimately, the eHGI and eHealth Network) what issues should be addressed in terms of the documentation to be provided so as to obtain potential CEF funding. The document's overall purpose is to enable the sub-group to know what its members might expect of the CEF, and to encourage them to consider the types of services, and assets needed to run these services, that might be submitted to the CEF.

The information paper should be read in close conjunction with the accompanying template. This information paper and the accompanying template place their main focus on the year 2015.

Contents of this information paper

This information paper contains the following elements:

- Background information.
- Objectives, services and assets.
- Content of the business plan.
- Information about next steps.

Note: Sources of materials used to draft the content of this information paper
A number of sources have been used to draft this information paper. The majority of these sources are publicly identifiable. A small number are either confidential or have not yet been released for publication. Wherever it has been possible to identify these sources, this has been done in the *6. References* section of this document.

2. Background information

This section of the information paper overviews the background, EU dimension, and added value of the service.[1]

Background to the CEF

The CEF is designed to stimulate and support projects of common interest for the deployment and operation of digital service infrastructures (European Commission, 2013a). Ultimately, its role is to support the development of a Digital Single Market. Initiatives that it supports are intended to **improve the competitiveness of the European economy, promote interconnectivity and interoperability** of national, regional and local networks, and **access** to such networks (*all this, and subsequent, emphasis added*). These infrastructures will **enable the provision of essential services** for businesses and **citizens** in areas **such as "interoperable health services"** (Op. Cit, p.2).

According to the CEF guidelines, these infrastructures should **create European added value** and **meet proven needs** (Op. Cit, p.4). They should be sufficiently **mature for deployment**, **technically** as well as **operationally**. Further details should be offered with regard to the **sustainability** of the services and the **reduction in their funding** over time (see *Section 4. Content of the business plan*).

EU dimension

There will be positive and constructive effects achieved by the large-scale deployment of eHealth services on various current challenges: patient safety, the quality and continuity of care, reduction in the costs of health systems, and improved quality of life for both older people and patients with chronic diseases. For a clear statement on these impacts, see e.g., the *eHealth Action Plan 2012-2020 - Innovative healthcare for the 21st century* (European Commission, 2012a).

Despite the articulation of the positive impacts of eHealth on several aspects of European healthcare, today there is no generally valuable business case for national authorities to deploy cross-border health services. There are also a number of reasons why the private sector finds such investment potentially challenging: these include the cost of the infrastructure involved; the complexity of the legal framework (which is currently being revised, particularly in the data protection and security fields); and the lack until recently of an agreed eHealth interoperability framework.

Therefore, concentration on cross-border eHealth services at the level of the European Union, in close conjunction with the Member States, is an appropriate approach to follow. The intention would be for public authorities to initiate cross-border eHealth service deployment themselves. Ultimately, as appropriate, they might progressively transfer the operation and further deployment of these services to the private sector.

[1] The texts that follow in Section 2 of this document could possibly be tailored to fit more specifically the argumentation needed to support a proposal for e.g., *Cross-border service(s) to exchange medical data*.

Added value of the proposed service

As identified in European Commission documentation, the CEF is a funding instrument designed to support the deployment of Digital Services Infrastructure in Europe. It does so, for example through investment in high-speed broadband investments. The relevant outcomes should permit job creation, productivity, the modernisation of public administration, and improvements in the quality of life (among others, "**by enabling new applications in eHealth**") (*emphasis added*) (European Commission, 2012b, p.17).

As also described by the European Commission: "*In today's internal market, digital services stop at borders. ...* ***Doctors treating individuals who fall sick[2] while travelling or living in another member-state have trouble retrieving their patient's medical records****. ... The fragmentation of systems is a major obstacle to the emergence of a Digital Single Market, hampering the growth of cross-border services and imposing needless transaction costs on pan-European companies as well as mobile Europeans*." (*emphasis added*) (European Commission, 2012b, p.15).

The added value of a support for eHealth service(s) would therefore generally be to:

- **Add to the quality of life of European citizens** by ensuring easier online access to their health data by the health practitioners treating them (in whatever European Member State they find themselves as mobile citizens of Europe).[3]
- **Ensure greater effectiveness and efficiency of European health systems** through the access to data facilitated by the cross-border exchange of medical data.
- **Respond to the need to overcome barriers to the deployment of eHealth** services. These include the lack of interoperability between eHealth solutions; the relative weakness of governance of health systems at the national level (when the systems are themselves all facing common, shared challenges); and the current relative lack of a business case for national authorities or the private sector to deploy and maintain cross-border eHealth services.
- **Facilitate growth in appropriate health solutions**, and eHealth solutions. Some possibilities to facilitate growth may lie in the opportunities for access to this medical data by people/patients themselves, and also by public health authorities, research bodies, and other institutions, as appropriate.

[2] Statistics to support these claims would be useful.

[3] The care required or given could include the identification of potential care, scheduled or non-scheduled care, and continuous or intermittent care.

3. Objectives, services and assets

This section of the information paper describes the specific objectives and services to be proposed, the assets needed, and the necessary actions in 2015 and onwards. It can be read usefully in conjunction with the accompanying template.

The information provided in this section is based on the assumption that a proposal for funding will be put together by the Member States in order to obtain an "award of financial support in the form of grants" ... "done by the Commission via a competitive process" ... whether relevant to an "annual" or a "multi-annual work programme(s)" (European Commission, 2012b, p.9).

eHealth services are among those services which – as per November 2013 – were not included in the CEF's 2014 programme since they were "not deemed to be mature yet"; hence, it is likely that "they will be re-assessed in a year's time." (cf. European Commission, 2013a, p.1). That re-assessment is anticipated to take place in November 2014. Hence, it is particularly important for any relevant eHealth services to demonstrate their maturity and on-going viability.

Two different forms of calls will be used (both calls for tenders and calls for proposals). As stipulated by the European Commission (2013a, p.5): "Calls for tenders will be used by and large for work related to *core service platforms* (e.g. physical infrastructure, software and data, operational management and user support) and for horizontal actions (e.g. studies, events, awareness raising). Calls for proposals will be used for *generic services*, which connect national infrastructures and communities to the relevant core platform(s)." At this stage of preparation of the CEF, it is not precisely evident for which types of calls eHealth services would be able to make submissions: information on this matter should therefore be crosschecked with the Commission services. It is especially important to determine for which parts of services funding would come directly from the European Commission, and which would come from the Member States themselves.

The business plans for the individual specific services (see, the example four specific services listed below in the sub-section on *Potential Services*) will need to clarify these choices.

Objectives

Taking the domain of *Cross-border service(s) to exchange medical data* as an example, the objectives laid out will relate specifically to 2015 as well as longer-term. The essential focus of these objectives will need to be on the ultimate goal and scope of the initiative (i.e., in relation to **cross-border; patients; and interoperability**). It might include the particular features and tasks to be undertaken, and the numbers of Calls (e.g., Calls for Tender or Calls for Proposals) to be launched during a first year of action. Technically, it might need to make statements about particular services. It should outline the number of Member States to be involved in the initiative.

These different elements are listed below, purely illustratively:

- Fit with the goal and scope.
- Features and tasks to be undertaken.
- Specific services (or server networks).
- Calls (e.g., Calls for Tender or Call for Proposals) to be launched.
- Numbers of Member States involved.

Potential Services

The initial service(s) to be considered should be those which have received previous endorsement by the European Commission and Member States together, through either policy documentation or through predecessor programmes to the CEF (such as the Competitiveness and Innovation Programme).

Although up to four separate services are listed below (see A-D), it is highly unlikely that four services would be supported by the CEF within any particular year. It is much more likely, as a general approach, that only a single service would be supported per year (and perhaps exceptionally two services within the initial launch year). It is anticipated that work on initial business plans might concentrate on the initial elements required for a first business plan on *cross-border service(s) to exchange medical data* and a second on plans for *ePrescription*.

It is therefore expected that some prioritisation of the maturity of these various services (A-D), in terms of their likely fit with the scope of the CEF, needs to take place. Undertaking such a procedure may help to identify the future years in which these services might be supported, and the sequential order in which they could be put forward for support.

Despite the mentioning (below) of only four services, possible additional services could be identified, in the future, based on currently-operating large-scale pilots e.g., integrated care or telemedicine services. The cross-border element of this integrated care work, undertaken e.g., by the SmartCare large-scale pilot,[4] is at an early stage of investigation. Equally, other options to be specified might be based on evidence of actual operation in Europe e.g., reimbursement mechanisms. No assumptions can be made yet at this stage of the CEF about the feasibility of the success of any approach for support for these shared services.

[4] http://pilotsmartcare.eu/home/ Accessed 17 March 2014.

A. Cross-border service(s) to exchange medical data.[5]

Specifically this service takes into account the exchange of the patient summary data-set as specified in the guidelines as adopted by the eHealth Network in November 2013.

B. Cross-border ePrescription services.

The eHealth Network will adopt guidelines on ePrescription in 2014. The specifications included in these guidelines should act as the basis for the funding under the CEF.

C. eHealth services for European Reference Networks.

Two European Reference Networks were established in 2014. These Network exchange highly specialised medical information and plan to make use of different types of telemedicine services.

D. Infrastructure services for interoperable Patient Registries.

The Joint Action on cross-border Patient registries is working on several assets to improve the filing, exchange and use of patient registries within the EU. These assets are ready for support from the CEF as from 2015.

Assets and funding

Coverage is given in this section of the document to aspects of budgets that are to be covered in the business plan, the categories of items that need resourcing, scenarios for alternative funding of services, and various methods of funding.

Current potential components of services identified as needing funding

After a selection of the eHealth services which are mature enough to apply for funding under the CEF, it should be specified which components of these services (i.e. assets) should be maintained by the CEF. During a first discussion inside the eHealth Governance Initiative, a range of components were proposed. These included:

- Cross-border eHealth digital services/deployment assets.
- Connector ring.
- Nodes/contact nodes.
- Servers.
- Terminology, thesauri, models and bridges.
- Classifications and ontologies.

[5] Feasibility for both the exchange of medical data and cross-border ePrescription services exists in the application of the work undertaken by the epSOS large-scale pilot (http://www.epsos.eu). A bridging process to maintain the assets of the epSOS large scale pilot has also commenced, in February 2014, under the umbrella of the EXPAND thematic network (http://www.expandproject.eu). The network aims to achieve sustainability of "eHealth assets" on interoperability already developed. Thus, it should ensure that any pilots are to move towards the maturity of actual deployment.

Once it is made clear which specific services will be requested for support by the CEF, a list of potential components of services will need to be prepared. These components, and the financial resources needed to maintain them, need to be specified in any finalised business plan.[6] (See the accompanying template document.)

Types of categories of service and items needing resourcing

The precise items that require CEF funding resourcing may cover such issues as those listed in Table 1 (below). They should, ultimately, be classified into two categories that can be termed: Set-up and launch; Operation and Deployment. They can be considered as basic investments and operational costs. The basic business plan, for the purposes of possible CEF funding, will need to specify these elements.

Table 1: Possible aspects of resourcing to be considered in the eHealth domain (in alphabetic order) [7]

Awareness-raising (including, for example, co-operation and trust-building).
Access to existing infrastructures and services.
Basic language resources.
Core service platform.
Evolution of the service.
Governance (items could include, for example, dissemination costs, liaison, management costs, professional services, travel and subsistence, vendor management).
Infrastructure.
Liability.
Maintenance.
Operation (items could include, for example, compliance testing, infrastructure, operation of the central service, security features).
Portal (for example, hosting and maintenance of any portal).
Support service(s) (for example, support for platform providers and users, support for partner data providers, and other user support).
Training.

[6] See two related items exist: a) a outcomes of the first brainstorming exercise by the eHealth Governance Initiative involved a presentation prepared by Arturo Romero Gutiérrez, Director del Proyecto HCDSNS, Madrid; b) the minutes of the sub-group to the eHealth Governance Initiative meeting which took place on 10 February 2014.

[7] The items listed in this table are purely illustrative. They are not limited to all the elements for prospective resourcing that might be named. They have not been classified into basic investments and operational (annual) costs. They are to be read alongside complementary materials/minutes produced in the sub-group to the eHealth Governance Initiative meeting on 10 February 2014.

Scenarios for alternative funding of services

As a challenge to the sub-group, consideration should be given in any finalised business plan to a range of approaches or scenarios (up to three in number) that identify the manner in which services might be paid for alternatively and/or operational costs be defrayed.[8]

Methods of funding over the 2014-2020 period might include a combination of:

- The CEF programme itself.
- Participation in "generic services" and other shared cost activities.
- Financial support provided by other Digital Services Infrastructures.
- Other EU sources.[9]
- Member States (e.g., administrations and competence centres).[10]
- Industry and third parties (e.g., including named institutions, donations, royalties and fees).[11]

Typical budgets

As background information, example budgets to be requested by those mature services which were being put forward for operation under the 2014 Work Programme of the European Commission ranged from 6-9 million euros (for the year 2014), and exceptionally up to 18 million euros.

Funding from the CEF programme should be steadily reduced, in particular during the 2017-2018 time-period, and beyond.[12] The potential proposals submitted identified steady reductions in the funding of support by the CEF over a seven-year period (until 2020): these reductions in support ranged considerably depending on the service proposed. In the most ambitious cases, the proposals reached 0% public funding by 2020 and, in less ambitious cases, remained at 80% public funding.

Necessary actions from 2015 onwards

Year on year, it is likely that the following information will need to be provided by the Member States collectively in their proposal to the CEF. See also (*Section 4. Content of the business plan*). Clearly, the feasibility of providing very detailed information out into the 2018-2020 timeline, and beyond, may be currently limited.

[8] In the eHealth field, these might be considered in combination with, purely as examples, data collection and analysis, the involvement of a variety of health service providers and healthcare payers such as insurers, and various industry players including pharmaceutical companies.

[9] Several services in other eGovernment-related fields have identified the CEF's encouragement of partnerships between Member States and regions. Hence, they are exploring possible support through the structural funds. Some services have identified appropriate good practices on the part of specific regions of Europe which have been the recipients of such structural funds for health purposes. Given the regional organisation of some Member States' health systems, this might be a distinct possibility to be explored in the eHealth domain.

[10] This possibility could be explored.

[11] Options to be considered include the role that could be played by the various industry and standardisation associations involved in the eHealth field. The character of associations to which health professionals belong, as members, also needs some consideration.

[12] Given the potential start-date for potential CEF funding in the eHealth field, for example in the 2015-2017 time-period, some consideration will need to be given to the staging of reduced funding post-2020.

Nevertheless, it should be an ambition for the eHealth service(s) proposed to cover at least the three-year timelines, 2015-2017.

- The specific **objectives** for the year in question in terms of the services to be offered.
- More specifically, a description of the **prior work** on which the services are built, and its technical and organisational maturity.
- The expected **long-term viability** (e.g., impact, take-up, and deployment of the results).
- The anticipated **business model**.
- The **actual (or eventual) financial sustainability**.
- Those **elements of the service which are re-usable** by design by other Digital Service Infrastructures.[13]

Table 2: 2015-2020 timelines – Actions needed by those entities requesting eServices to be supported by the CEF

2015-2017 timelines	Actions needed by those entities requesting eServices to be supported by the CEF
2015	Submission of information with regard to e.g., objectives; description of prior work; long-term expected viability; anticipated business model; actual (or eventual) financial sustainability; elements of the service that are re-usable by other services.
2016	Submission of the same data for 2016.
2017	Submission of the same data for 2017.
2018	Submission of the same data for 2018.
2019	Submission of the same data for 2019.
2020	Submission of the same data for 2020. Anticipation of those services that will continue to request support over the 2020-2025 timeline is needed here.

[13] In the case of eHealth, it is evident that this includes elements which might draw on building blocks provided by other Digital Service Infrastructure elements (such as eIdentity or eProcurement mechanisms). In terms of the building blocks which are emerging out of the eHealth domain itself, these might eventually be shared with/by e.g., social care or social services.

4. Content of the business plan

This section contains an overview of the information needed for a proper business plan to be filed under the CEF. (See the accompanying template document.)

More specific sub-sections describe the:

- Outline of a potential business plan.
- Method to be used to draft and complete the business plan.
- Filing process under the CEF.

Outline of a potential business plan

This sub-section outlines what is a business plan, and what might be the anticipated elements of such a plan that need to be provided to the CEF to satisfy funding requirements.

- **Definition of a business plan**. A business plan is a formal statement of a set of business goals, the reasons they are believed attainable, and the plan for reaching those goals. It generally has a 3-5 year duration (Wikipedia, 2013). Often business plans have some 10-12 different elements that are covered specifically. Standard business plans in a business environment often include the undertaking of strengths, weaknesses, opportunities and threats (SWOT) analyses. Business plans may also be targeted towards external parties (which appears to be the case in terms of the CEF).
- **Comments on this business plan**. In the case of this specific business plan, it is to be used for the purpose of submission to receive funding from the European CEF programme during the five-year time-period, 2015-2020 (and potentially beyond). It should therefore comply with the precise format for such a business plan, as expected by the CEF administration. (Again, see the accompanying template.) [14]
- **Title of the business plan**. In the case of eHealth, in terms of the early versions of such a business plan, with specific reference to e.g., electronic health records, an anticipated title for such a plan might be e.g., *Access to a subset of electronic health records across borders* or *Cross-border service(s) to exchange medical data*.
- **Rationale for the service(s)**. Careful consideration needs to be paid to the proposal for support for service(s) that match (i) the requirements of the CEF, (ii) are closely associated with the *Directive on patients' rights in cross-border healthcare* and (iii) the work previously achieved by the epSOS large-scale pilot (http://www.epsos.eu), among other initiatives.
- **Framework and sections of the business plan**: A potential framework for such a business plan document might include such titles as (see *Section 3* (above) on *Objectives, services and assets* as well as the accompanying template):

[14] This sub-section of the information paper makes an attempt to foresee such a format or template. Indeed, an example template has been created (see accompanying template). The preciseness of its titles and proposed contents will need to be confirmed with the European Commission services/CEF.

- 1. Objectives.
  2. Description of prior work.[15]
  3. Long-term expected viability.
  4. Anticipated business model.
  5. Actual (or eventual) financial sustainability.
  6. Elements of the service that are re-usable by other services.[16]
- Among elements to be identified in the description should include:
  1. Why **access** to cross-border services is needed.
  2. **How** cross-border services might be expanded steadily in the way identified in the sub-section entitled *Potential Services* (see *Section 3* (above) on *Objectives, services and assets*)).
  3. The **issues at stake** when making a use case that involves particular elements (stakeholders) of the eHealth community.
  4. The **rationale for investment**.
  5. The extent to which **public-private partnerships** can be included in the initiative.
  6. Which peripheral technologies can make use of the **central technology** (i.e., the patient summary/medical data).
  7. The relationship of the requested services with appropriate **standardisation and regulation**.
- **Resourcing**: This business plan is expected to outline what are anticipated to be, on a multi-annual basis (i.e., from 2014 onwards (i) the necessary investments and ii) what might be the needed (annual) running costs. Expected investments are likely to be classified into such categories as (a) set-up and (b) launch. Running costs are likely to be categorised into such fields as (c) operation and (d) deployment. It is highly likely that such details will need to be provided in a tabular format with columns that refer to each year. (See the accompanying template.)
- **Core and generic services**. Careful consideration needs to be paid to those services which can be considered as "core" to eHealth, and those which can be considered as "generic" (and thus have implications for other digital services in the wider eGovernment field, including e.g., social care and social services). (See ANNEX 1 of this document for official definitions of core and general services.)
- **Supporting documentation**. This business plan will need to provide both direct and indirect evidence of the need for support by the CEF. While this evidence might include return on investment, it could also include reference to social return on investment.[17][18]

[15] There is a distinct need for any proposal to be associated with the prior work undertaken in this field e.g., the electronic health record (patient summary), and on interoperability more generally, that emerged from the work of the epSOS large-scale pilot (http://www.epsos.eu).

[16] This degree of re-usability may – in the case of eHealth service(s) – be related to the bringing together of both health and (social) care services or it could pertain to the re-use of patient summary data for other services such as ePrescription and/or public health or research uses.

[17] In particular, this is so since it is anticipated that the use of the service(s) will lead to improved quality of life on the part of European citizens. Overall, for example, the European Union currently has the ambition of expecting an enhancement of two healthy life years on average for European citizens throughout Europe. Some early appropriate findings relating to eHealth impact might therefore be

- **Figures**. The need for concrete evidence and figures in the business plan cannot be over-emphasised. Provision of such evidence will be especially important in a service area which, until now, has not been considered as sufficiently mature, and which will need to demonstrate its maturity and its business case.[19] In some cases, it may be possible for proxy figures to be stipulated.

As stated by the European Commission (European Commission, 2013a, p.4), in particular, attention needs to be paid in this business plan/description of services to a **strategy and sustainability plan** that ensures the **medium- to long-term operation** of **the core service platform** beyond the CEF. As feasible, the financial assistance provided by the CEF should be **phased out over time**. **Funding from sources other than the CEF should be mobilised** where appropriate. This should be outlined in that section of the business plan related to *long-term expected viability*.

The precise categories of information required in the submission documentation will need to be clarified formally with the European Commission.

Method to be used to draft and complete the business plan

No specific method is promoted here to investigate the handling of eHealth-related business for the purpose of seeking CEF funding. Various examples exist. Methods can be found that have been used by eHealth-related initiatives over the 2012-2014 timeline to formulate business plans.[20] Working sessions of e.g., a June 2012 workshop identified such domains of activity as:

available through documentation emerging from the European Innovation Partnership on Active and Healthy Ageing, especially where it has been collected in relation to e.g., shared exchange of records. A number of European Commission co-financed projects in the mid- to late-part of the last decade examined financial and economic returns on eHealth initiatives, including projects on general eHealth developments and on electronic health records, more specifically.

[18] Note how, purely as an example, the Clean Air Act (2013), published by the European Commission, identifies strongly in its impact assessment the degree of enhancement anticipated on quality of life of European citizens.

[19] For sources of relevant documentation, it will be important to investigate i) a wide range of relevant studies, including several co-financed by the European Commission; possible research undertaken by e.g., the World Health Organization or the OECD; as well as ii) considering the kinds of volumes of funding that have historically been contributed to appropriate fields by the Member States themselves.

[20] At a June 2012 workshop on *Shaping the Future Through Business Model Innovation* run by the FP7 project, SemanticHealthNet an interesting presentation was run by Danielle Dupont of Data Mining International SA (Switzerland). The presentation, which shaped the ensuing working sessions, was entitled "The Business Case for Interoperability: Towards Enabling Cross-Border and Cross-Organizational Information Flows" (ePractice http://www.epractice.eu, last accessed on 4 February 2014). Its outcomes are reported in a short document identifying "Meeting Highlights".

- Perceived key drivers to interoperability (e.g., a set of necessary elements for achieving and sustaining interoperability in Europe).[21]
- Perceived influential factors.[22]
- Perceived benefits and added value.[23]
- Perceived success criteria.[24]

Similar exercises undertaken in the context of appropriate workshops might provide structured information for possible inclusion in eHealth-related business plans.[25]

Certainly, appropriate materials should be extracted from a range of European co-financed projects to provide support documentation. It is anticipated that the recently launched EXPAND thematic network[26] may have specific insights to offer in this regard as will the eSENS project.[27]

Filing process under the CEF

As of the date of preparation of this document on 19 March 2014, additional information needs to be sought from the European Commission with regard to the precise perceived filing process and its timing over the 2014-2015 timeline. A tentative draft timeline for this process is outlined in *Section 5. Next Steps*.

[21] These included tools, assets, and services; stakeholders; organisational structures; processes; and funding sources.
[22] These included cross-border/cross-organisational scenarios; market forces; emerging trends; industry developments; and macro-economic forces.
[23] These included cross-border/cross-organisational scenarios; key stakeholders; perceived benefits; and the types of evidence needed to demonstrate interoperability overall added value.
[24] In cross-border/cross-organisational scenarios, these related specifically to defining the achievement of sustainable interoperable assets and their priority levels (low, medium and high).
[25] One such possibility is the Interoperability workshop run by a combination of European co-financed projects on 18/19 February, 2014, entitled MACSI.
[26] http://www.expandproject.eu/ Accessed 17 March 2014.
[27] http://www.esens.eu/home/ Accessed 17 March 2014.

5. Next steps, 2014-2015

This section of the paper outlines the immediate next steps to be completed.

Timelines during 2014

The eHealth Network will seek to approve the proposals to be submitted in May 2014. These proposals will then be submitted to the CEF Telecom Expert Group, which will evaluate the proposals on behalf of both DG Connect and the Member States. By the end of the year 2014, more fine-tuned decision-making will be handled either by e.g. DG DIGIT and/or an agency. It is highly likely that, at that stage, the materials will consist of a more technical Tender document, and the decision-making on that Tender (and other documentation submitted with regard to other technical services) will be handled by a technical group.

It should be noted that a period of around one year elapses between the approval of the planned proposals, by the CEF Telecom Expert Group, and the eventual publication of the relevant Call for Tender/Call for Proposals in mid-April 2015 (TBC). The process of acceptance of the proposed submissions (if they prove to be satisfactory) is however brief: i.e., it is currently described as taking place over a duration of around three months. It could therefore be expected that any accepted eHealth-related proposal, submitted in 2014, could become an action to be launched in July 2015.

Table 2: 2014 timelines – Actions needed by the sub-group and/or eHealth Network

2014 timelines	Actions needed by the sub-group and/or eHealth Network
April/May 2014	Sub-group to develop work relating to a proposal for financing by the CEF to be submitted for approval by eHealth Network. Concentration by the sub-group is likely to be needed on the accompanying template, with reference to and support of *Section 4* of this information paper entitled *Content of the business plan*.
May 2014	Approval of the proposal documentation (prepared by the sub-group) by the eHealth Network.
18th June 2014	Draft proposal to be submitted by the eHealth Network to the CEF Telecom Expert Group.
Summer/autumn 2014	European Commission internal treatment of the draft documentation in its possession.
December 2014 (TBC)	Acceptance of draft (eHealth) documentation by the CEF Secretariat (i.e. Steering Committee), if the documentation is considered to be satisfactory. Detailed planning for the 2015 timelines should be evident at this stage. European Commission internal orientations, and approval of 2015 Work Programme.

Timelines during 2015

The following timelines for 2015 are based purely on an extrapolation of the estimated development of the CEF Work Programme for 2014 (European Commission, 2013a).

Table 3: 2015 timelines – Prospective timelines for actions to be undertaken between the European Commission and Member States

2015 timelines	Prospective timelines for actions to be undertaken between the European Commission and Member States
Mid-January 2015	Informal meeting of European Commission officials with shadow CEF expert group. Feedback by written comments within one week.
End January 2015	Draft Work Programme subject to internal approval cycle. Discussions with inter-service group.
Mid-February 2015	Draft Work Programme. Second meeting with shadow expert group. Feedback
End March 2015	Meeting of the CEF Coordination Committee to provide an opinion on the Draft Work Programme.
Early April 2015	Commission adoption of the Work Programme, including a financing decision.
Mid-April 2015	Launch of the calls for tenders/proposals.
Mid-July 2015	Launch of the first series of actions.

6. References

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European Commission (2013b) (unpublished) *CONNECTING EUROPE FACILITY. Telecommunications. Orientations for the 2014 Work Programme ANNEX.* Multi-annual Sustainability Plans (early projections). 25.11.2013.

European Union (2013) Amended proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on guidelines for trans-European telecommunications networks and repealing Decision No 1336/97/EC /* COM/2013/0329 final - 2011/0299 (COD) */ http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2013:0329:FIN:EN:HTML. Last accessed 4 February 2014.

Wikipedia (2014) *Business plan*. http://en.wikipedia.org/wiki/Business_plan. Last accessed 4 February 2014.

7. Annex 1: Terminology relating to services which can be specifically funded by the CEF

- "*Digital service infrastructures*" enable networked services to be delivered electronically providing trans-European interoperable services of common interest for citizens, businesses and/or governments. Digital service infrastructures are composed of core service platforms and generic services.
- "*Building blocks*" means basic digital service infrastructures, which are key enablers to be reused in more complex digital services infrastructures.
- "*Core service platforms*" means central hubs of digital service infrastructures aiming to ensure trans-European **connectivity**, **access** and **interoperability**. Core service platforms shall be open to Member States and may be open to other entities. [*Emphasis added*]
- "*Generic services*" means **gateway services linking one or more national infrastructure(s)** to core service platform(s). [*Emphasis added*] (European Commission, 2013a, p.3.)