PERSONAL HEALTHCARE RECORD

The urgency of returning to a development approach shared by all the actors

NOTE TO THE POLITICAL MANAGERS (BOTH PRESENT AND FUTURE)

(This document is available in French on demand)

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THE CO-SIGNATORIES

Created in late 2004, LESISS is a grouping of the main **businesses dedicated to health information systems, bringing together SMEs with experience in the field, medical software publishers and major industrial firms**. This trade association arose from the realisation that community medical practice and hospital practice were becoming increasingly interpenetrated, having hitherto operated separately from each other, with organisational structures whose segmentation reflected the separateness of issues and practices. Through its members' expertise, LESISS provides support and advice for the changes that are essential to enable the French health-service system to adapt. Properly-used information technology effectively contributes to the necessary coordination of health-care services, the improvement of medical practices and the reduced risk of lost opportunity for health-care beneficiaries, as well as contributing to more efficient allocation of public funds.

Created in 1987, SNITEM is a grouping representing the majority of the players in the **medical technology and devices industry**. As France's leading employers' association representing businesses in this activity sector, it is the prime channel of communication with, and the reference body for Government, being also represented on many French and European decision-making and/or consultative commissions and other fora. SNITEM has more than **200 member businesses**. Among its aims, it promotes to those industrial actors an involvement in groupings of direct relevance to their activity sectors: sector-based core facilities and groups, decision-making groups, cross-disciplinary panels. Lastly, it regularly publishes opinions and recommendations designed to foster the expertise of market decision-makers.

CRITICAL FOREWORD

In launching with great pomp, on 11 May 2004, France's Personal Healthcare Record (*Dossier Médical Personnel* – DMP), the then Health Minister, Philippe Douste-Blazy, probably did not foresee the difficulties with which this project was to become fraught. Presented at the time above all as a service focused on the benefits to the user of the health-service system, the DMP was also intended to foster improved practices and quality of health care, as well as – subordinately - being streamlined to rapidly optimise health-care expenditure.

Graven though it was in the marble of Republican law, in the outcome to an exceptionally rich Parliamentary debate illustrating the importance with which this essential topic was viewed by the Parliamentarians, this major national project has in the space of two years endured a switchback career, and will undoubtedly continue to do so. In addition, by confirming on 5 May the new step of anchoring the DMP around the State sickness-insurance data, the project's political promoters have taken the risk of seeing the project rapidly go the same way as the wasteful paper-based medical booklet, rejected by practitioners, and received with indifference by the health-service beneficiaries.

The industrial actors in general, and the members of LESISS and SNITEM in particular, obviously welcome the new team's determination and enthusiasm

As evidence of this switchback progress in framing the policy, the project ownership structure, formed as a "*DMP pilot development GIP* [public interest group]" has witnessed since its creation its senior officials rapidly succeed each other, pointing to the degree of tension within. In less than one year, this Grouping of some ten members has seen the back of a Chairman, a Director-General, a Deployment Director and a few subordinate officers. And further changes are probably in store.

In this context, for the new management team and in actual fact, the change announced on 5 May 2006 amounts to an abrupt and unconcerted wiping-out of a development process that, at the State's request, had been followed for close upon eighteen months, and was based on a pragmatic approach to preliminary design and development. Hospital and community health-care professionals, along with patients' associations and private industrial interests, had considerably invested themselves in the experimental work that consisted of developing pilot schemes prefiguring the future service, prior to its generalisation.

The advocates of this change in strategy are arguing the urgency of the political timetable: every health-care beneficiary is supposed to have access to his or her DMP Personal Healthcare Record by March 2007. Furthermore, it is supposed to be easy to use for both the beneficiaries and the health-care professionals. Lastly, noting the State's budgetary tightness, the advocates of this change are warning that the project will need to be conducted with limited resources, under conditions already described by a good many observers as a catchpenny sprinkling of public funds among the regions.

Numerous countries have planned projects of the same kind and scope, with budgets matching the scale of the undertaking (the unit generally used is one *billion* euros or dollars, see item 2.1 in the appendices), deployed over several years and with the project-development arm outsourced. At the very antipodes of these prerequisites, the

French DMP promises in theory to be simple, rapidly deployed, inexpensive and implemented by internal Government resources.

The industrial actors in general, and the members of LESISS and SNITEM in particular, obviously welcome the new team's determination and enthusiasm. However, the legitimacy conferred upon those industrial concerns by complex major projects with which they have again and again been involved, in the health sphere or in other areas, causes them to temper this enthusiasm. The industrialists recall in particular that, while the State has a role as a prudent manager of public funds and, pre-eminently in the field of health, a sovereign duty to supervise the use of the data relating to its subjects, the facts attest that it is not best placed to assure modern methods of management for very large-scale industrial projects such as the DMP. On the evidence, this analysis has long been shared in a great many countries, particularly among our partners in the concert of Europe.

Numerous examples illustrate this fact, and the *Comité National d'Ethique Médicale* [French National Medical-Ethics Committee] recalls, in a policy statement on health-service information systems published in April 2006, an example demonstrating the risks entailed in the State conducting large-scale projects: the SNCF (French Railways) *Socrate* reservation programme. Initially conducted by that public-sector undertaking's technostructure, the project foundered in a technical and financial disaster, impelling a call to be made to the market so as to get the project out of the mire, and get it up and running ; it became fully operational once this wise decision had been taken. In the end, this service was developed by a major private software house.

The new outline for the project is leading to some dire extremities, with a concomitant worsening of France's already worrying delay in modern medical information systems

LESISS and SNITEM are keen for history not to repeat itself, but those organisations view the new project outline as leading straight into dire extremities, with a concomitant lengthening of France's already worrying delay in acquiring modern medical information systems, and hence in ensuring a high standard of health care. Beyond this observation, and backed by their recognised expertise, those two bodies find it essential to formulate prudentially, for the present and future political leaders, recommendations for avoiding another failure, and they urgently call for objectives to be refocused around the main actor concerned: the health-service system user.

In this connection, public opinion is likely soon to make itself heard with calls for political managers to arbitrate on decisions without invariably using cost as the adjustment variable, with the emphasis instead a return-on-investment outlook. By taking this unbiased line, and relying on the actors in the competitive sector, they will ensure entire success for both the DMP and, beyond it, the deployment of all the groupworking tools for health-care actors. Otherwise, the lack of preparation and the allocation of under-evaluated resources would have ruinous consequences for our country. This guidance paper describes the existing situation, recalls the issues involved and, furthermore, proposes ways forward towards realistic solutions. This paper is contributed by the specialist industrial concerns in order to provide managers with a clearer vision of the complex implications of this project, and it earnestly recommends a genuine coordination with all the actors involved in the DMP project, without disregarding the lessons of experience: diversity and the right of inspection are the citizen's best guarantee.

TIMETABLE

DOCUMENT SUMMARY

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CONCLUSION

APPENDICES

HIGHLIGHTS

- In the concert of developed nations, France is already lagging far behind in the acquisition of modern health-service information systems, and cannot take the risk of deviating from the objectives of the Personal Healthcare Record [DMP], laid down by law and *focusing on patient benefit*

- The industrial specialists are perplexed at the arrival of a new project-ownership structure, doubtless determined, but driven by a *centralising agenda, manifestly no longer focused on the interests of the health-care professionals and users*

- This abrupt change of strategy, announced without any consultation, gravely jeopardises the efforts deployed for close upon 18 months, *at the request of the State,* by these actors working alongside the industrial specialists to provide a phased and concerted implementation of the DMP

- As the health-care professionals have already recalled time and again with reference to the costly failure of the paper-based medical booklet, the DMP's success – and it is only one of the groupworking tools necessary to making our health-care system evolve – entails fully involving those professionals in the scheme, and this the new strategy does little to guarantee.

- As analysed by numerous experts in the realms of politics and civil society, *the objectives pursued by this new strategy are more concerned with the determination to score very short-term gains* than with seeking the bases for a genuine, generalised sharing of health information in the interests of our citizens

- Apart from the fact that the new strategy of internal implementation by the State fails to satisfy the users and health-care professionals, who have been excluded from its development process, and unless it is sought to make the DMP an empty shell, it has to be said that *its timetabling is unrealistic and the costs announced have been extensively under-evaluated.*

- Acknowledging nevertheless the wish to implement a health-care portal hosted by the State, the private operators are ready to demonstrate that this highly-controverted public project, *provided it is backed by a complementary scheme built around a preliminary development process involving private operators,* can lead to success

- They propose that both projects should be conducted in parallel, beginning to analyse the results in the first half-year 2007 by measuring their respective performance on a fair basis of comparison, then adjusting the scenario for deploying a DMP for the benefit of the health-service beneficiaries and health-care professionals which, as in other countries, will take several years

- At the same time, and without awaiting the generalisation scenario, those industrial operators feel it indispensable to consider ways of *financing these new tools on a scale in keeping with the project, using innovative financing packages*

DOCUMENT SUMMARY

The purpose of this paper is to set out a solution for deploying the DMP Personal Healthcare Record, in the spirit of the Act of 13 August 2004 and complementing the scenario set out on 5 May 2006 by the new project ownership, without breaking the pattern of continuity in the statutory texts, communications and the experiments conducted to date. This contribution takes a commonsense line in clarifying the roles of the various actors, and hinges around 4 main points:

- a carefully thought-out apportioning of the roles between the public and private sectors
- added value for health-service users and the health-care professionals
- compatibility with the public procurement contract awarding procedures and the proper exercise of competition
- a realistic economic scenario meeting the expectations of health-care professionals and patients

Equilibrium between the role of regulator and the position as competitor

The enactments and the steps taken until recently succeeded in eliciting a highly responsible attitude among the private operators (health-care data hosts) involved in deploying and managing the DMP: end-to-end responsibility for software, the collection of information at source, data retrieval, the guarantee of the data not being used for unauthorised purposes, user support (hotline), administrative processes of file opening and access rights management. A particular benefit of this model is that it embodies a clear commitment.

In this context, a complementary Universal Public Service can be envisaged, providing a package of services (access, identification, elementary case file, health-expense refund information, disease prevention campaigns, etc.) and ensuring connection towards DMP operators freely chosen by patients wishing to consult it or add information to it.

Obviously, however, it is the balance between an offering of public services and the recourse to private operators that will secure achievement of the objectives set forth in the Act, focused as they are on the health-service user. In this regard, only a combination of strict public best-practice rules, information sharing and security in synergy with the involvement of private operators can guarantee a phased upgrading of the information systems, and in step with this, the corresponding raising of practice standards in the health-care sector.

Accordingly, if we are not to allow the DMP project to drift towards assured failure, it is absolutely essential for the announcements made by the new project-ownership structure to be tempered so as to bring the project into this virtuous circle.

Such a temperate stance is all the more vital since the Act of March 2002 defines the notion of medical-data hosting by referring to a set of user rights and duties, so that the user can then entrust his or her case file to a medical-data host, provided he or she is free to choose which host. This freedom of choice laid down by the Act assumes that the medical-data host in question is empowered and able not only to guarantee a sustainable service, but also, above all, to act responsibly towards the contracting user. What this amounts to is that the medical-data host must be capable of providing *end-to-end* service including the assumption of all the responsibilities that entails, particularly in the legal sphere, towards the patient. Unfortunately, the stance recently taken by the GIP DMP project owner of imposing a "Universal Service" results in there being a single public operator, with the hosts thus becoming mere sub-contractors to that single operator, and reduced to the function of executors entirely stripped of any initiative and responsibility. In these circumstances, there is conflict between the Act, which confers on the user the possibility of choice, and the new strategy which imposes a single operator; this is at variance with the often-expressed wishes of patients' associations among others.

Short and medium-term horizons

In the short term, the following are essential for the coming 14 months (from May 2006 to July 2007):

- **organising the implementation of the Universal Health Service (national platform);** to be available, this will require at best 9 to 12 months' work starting from the implementation decision, provided no technical, legal or administrative obstacles arise. The objective will be to construct from scratch a central platform made available to all health-service beneficiaries through an Internet portal which will be operational in the Spring of 2007

- **extending the pilot experimentation phase** until October 2006, in order to compensate for the implementation delays due to administrative aspects and the summer break, so as to draw instructive conclusions on the technical and applications scope of the target solutions

- **providing a pre-generalisation stage, hinging around an appropriately-tailored tender procedure:** For the DMP, this phase should be undertaken on 4 to 6 geographical zones that may or may not be exhaustively nationwide in scope, and concerning 1 to 2 million patient files per zone. This phase will last 12 months, renewable for two half-years, and will feature a geographical monopoly of 3 to 6 private operators selected as the outcome of an invitation to tender launched this spring, for notification in autumn 2006

This new invitation to tender will be based, in coordination with the project owner structure, on the proposals of the operators selected, and will take into account the support from the geographical areas concerned. It will be clearly distinguished from the experimental pilot phase by a distinctly different object: large-scale change-management testing, organising a genuine industrial-scale deployment, incorporating high-value-added services and practices, planning for its integration into the Universal Health Service and the national portal. Moreover, this fresh competitive bidding stage will enable some actors in the experimental phase to leave the field, as well as enabling new entrants to position themselves, and the experimentation zones to refine their strategies in the light of the results published.

In the medium term, this model will give way to a Universal Health Service scheme (with a national portal and access to centralised databases hosting various types of "central" data, such as those for the Compulsory Sickness Insurance scheme. In keeping with the State's declared aim for over two years, this service will go hand in hand with nationwide competition among 4 to 6 private operators, which will foster emulation and creativity around new services validated and controlled by Government (medical information, telemedicine, ASP-mode practitioners' management software, patient home care, pathology files, best-practices protocols and reference bases, etc…). In addition, private operators may also see their autorisation withdrawn at any time in the event of non-fulfilment of the undertakings they have made.

To prepare this stage, consultation focused around the collective objectives, with the health-care professionals and health-service users, will be essential for the stepwise ordering of expectations and needs, and for repositioning the DMP among the other groupworking tools necessary to make the French health service evolve. This stage will consist of drafting a master plan for the shared health information system. Its drafting will take several months, and its implementation will be phased over several years, given the need to migrate the present mixed-platform information systems towards a natively intercommunicating system.

Where interoperability is concerned, and in opposition to some occasionally-voiced allegations, international standards are currently available and are simply waiting to be used. From this standpoint, the State must fully play its role in ensuring, in its master plan, that these standards apply to all (DMP, but also information systems for community medical practice, hospitals, networks, etc.), including the Universal Health Service platform.

To sum up, no firm or final breakdown can currently be made between the activities performed by the national portal (Universal Health Service) and those performed by the private operators. For when the national platform and the services provided by the private operators are brought to full working

strength, the role and responsibilities of each of the actors will be more clearly identified. This bringing to full working strength must, unless the scheme is to suffer massive rejection, take on board the findings from a *genuine* consultation with all the actors.

Clarifying the implementation and operating costs

In the final analysis, it is unreasonable and counter-productive to contrast the private and public sectors, since they evolve according to different logical patterns. The facts show the supposed excess cost of resorting to private enterprise is a legend, since, out of a basic concern for transparency, private businesses strive to calculate their costs from a global standpoint, including a high standard of quality of service corresponding to the issues involved in the project they support. Public-sector solutions sometime show costs that are *apparently* not as high, since Government does not as a rule evaluate all the expenditure items and regularly omitting certain works – sometimes cutting things very fine – or reducing the standard of quality expected. In the end, the allocation of public resources (call centres, IT and hosting centres, machines, etc.), even if they are hidden in accounting terms, will nevertheless inevitably swell public-sector deficits.

Regarding the economic aspects, it will be found that:

- the costs of initial deployment and recurrent management of the DMP are composed of cost items already shared transparently by the different actors with the DMP managers
- these cost items are factual and are based on assumptions whose validity can be monitored over time, so as to fine-tune the cost of the DMPs as and when necessary (e.g. call centre traffic volumes)
- all the actors agree that the costs regulated by the Public Authority will evolve over time, although it will not be possible to detail beforehand the proportions in which they will do so

Naturally, cost comparison and pooling must be sought (e.g. by taking advantage of sickness-insurance postal items to convey passwords to patients when opening their individual patient file).

However, on the basis of the management cost of some 8 euros per patient file per year (13 € including file initialisation) for an activity volume of some 10 million patients, a substantial reduction is illusory unless – as seems the case with the new strategy announcement by the project ownership structure – a reduction is to be made in the quality or scope of the services provided to patients and health-care professionals.

Thus, to limit the DMP for a – long – time to sharing the Compulsory Sickness Insurance bases would not be compliant with the Act, and would miss the target of providing a medical service designed to improve the health-service quality and efficiency (no protocols, no help with continuity of care, no avoidance of redundancy in the absence of medical content, no real decrease in interactions between medicines, …).

It is therefore urgent to conduct a detailed analysis, broken down between the private operators and the GIP DMP as outlined in Appendix 2 of this note, of the cost components and quality levels associated with them, keeping in mind that they will undoubtedly evolve in the light of the results of the pre-generalisation phase set forth in this document, conducted during the next two years.

It will be also indispensable begin a study exercise in parallel, to find innovative financing mechanisms appropriate to the enormous investments to be made for funding a genuine sharing of health-care information, of which the DMP is but one of the components. The study involved will, on its completion, remedy the Government Authorities' persistent absence of budgetary margins, and ensure the matching of funding requirements with public-health objectives in keeping with the Act and with the legitimate expectations of health-care professionals and patients. The study exercise, in which LESISS and SNITEM are providing their expertise alongside other proactive actors, is already in progress.

FOR A DEVELOPMENT APPROACH SHARED WITH ALL

1 - A scenario balanced between public and private actors

Since the passing of the Act of 13 August 2004 on the Personal Healthcare Record, several important stages have been crossed in preparing for its implementation: clarification of the Personal Healthcare Record's content and operation, institution of a project-ownership structure (GIP for preliminary development of the DMP, which became the GIP DMP), mobilisation of the actors concerned (health-service users, health-care professionals, private industrial operators), announcement of the launching of full-scale experimentation.

While the situation has appreciably progressed, strong doubts nevertheless remain, particularly regarding the return on investment for the operation, the long-term cost to the community of the DMP, and the practicalities of operation using the multiple hosting of health-care data.

This note was drafted collegially by the members of LESISS and SNITEM, and seeks to propose a deployment scenario responding to the legitimate preoccupations of Government with these various aspects, by capitalising on the development approach which has been undertaken for several years between the public authorities and the private operators.

The government can at this stage embark on three possible scenarios:

1.1 Predominantly private

This scheme of work has been providing background guidance to the work by the Authorities for 3 years. It consists of phasing in private operators with the responsibility, in accordance with the Act, of operating and distributing the DMP. This ambitious project has the advantage of fostering a responsible attitude among industrial operators as well as turning to best advantage their know-how and investment capacity, but it assumes a high degree of maturity on the part of the Authorities in terms of management and interoperability. This scenario also raises a financial issue by highlighting in a very transparent fashion (the impact of outsourcing) the overall cost of the DMP

1.2 Predominantly public

In this scenario a central public portal would become the sole reference and a system shared for all citizens. This scenario, which has an *apparent* appeal, has the additional benefit of guaranteeing, in theory, intrinsic interoperability and, on a wider canvas, fair and uniform access by the citizen and health-care professionals. Its effect is to significantly reduce the private partners' role by confining them to the role of service providers, whether in helping to construct and acting as sub-contractors for the central platform, or for assisting local actors in deploying the system (call centre, connection works, local change management support …). On the other hand, this scenario would operate according to a financial logic confined to a certain opacity[1].

[1] In addition to the visible costs involved in the GIP DMP operating budget (of which the dozen or so members should in theory increase to 75), it is worth pointing out that, under the new financial reasoning, the decrease in "public" DMP expenditure will be based on a notion of "marginal costs", bound up with the use of available resources that are wholly or partly already allocated for budgetary purposes (sickness-insurance telephone staff, available public and parastatal IT teams and hardware). However, it is clear that these costs, which in actual fact are *hidden*, cannot long remain so on account of the new impetus from the current reform of the Finance Acts (LOLF) which will bring them to light sooner or later. This revelation will occur either willingly, in the light of the financial statement associated with a comparative audit, or through the investigations by the State's inspecting bodies (Cour des Comptes [Court of Audit], IGAS [General Welfare Inspectorate], IGF [General Inspectorate of Finance]) and/or of the Parliamentary evaluation and inspection missions of both chambers (MECSS [Parliamentary mission for the evaluation and inspection of Social-Security legislation]which has just published a first report presenting the State in a very damaging light). Naturally, this transparency will become all the more unavoidable since the European authorities, already much exercised by the budgetary orthodoxy of Union countries, will sooner or later call to account those members whose public-sector deficits move worryingly out of alignment

Evidently, neither model is exempt from difficulty. While the private model can be seen to be difficult to generalise as it stands (the issues mentioned earlier are far from resolved), the public model marks an abrupt, unconcerted shift which, besides putting the private operators into difficulty (loss of investments unilaterally imposed by the Authorities), would inevitably lead to wasted time (corresponding to the bringing to full working strength of the public structures concerned). It would also considerably reduce the contribution by private suppliers to the industrialisation and to quality of service, as well as leading irrevocably to a functional impoverishment of the DMP, with its probable subsequent rejection by users and health-care professionals.

Moreover, the public model would arouse misunderstanding at a time when the government, under the impulse of the European Commission is seeking (in clearly identified areas when they can naturally develop: Defence, Justice, Health) to promote, in a recurrently tight budgetary context, financing schemes negotiated in innovative contractual frameworks.

In addition, this public model raises questions among actors in the field who are involved in the preliminary-development phase, as to its usefulness at the onset of a drastic change of model and of the rules to the game.

Lastly – and chiefly – the acceptability of a centralised, national model to the community health professionals or patients (and particularly to the associations representing them) remains to be validated politically[2]. In this regard, the strong reservations uttered in response to announcement of the recent change, by health-care professionals and users' associations alike, should not be underestimated. Were their utterances to be so, however, then the spectre of the paper "carnet de santé" health booklet, a memorable, regularly-mentioned squandering of public money, would soon loom into view.

1.3 Combined public/private scenario

Manifestly, it is in the government's interest to consider introducing as soon as possible a scenario combining a public approach with an approach having recourse to private operators. Beyond July 2007, this scenario will consist of the following:

- **providing an access portal and a public-service base** comprising the following services:
  - Health-service public portal,
  - Doctor and patient identification and secured-access services (a unique, compulsory identifier needs to be instituted),
  - Universal Health Service DMP (a citizen or health-care professional can log on to this central platform so as to connect to the DMP hosting platform freely chosen by him or her, and so perform all the operations of relevance to him or her: opening, updating or viewing the file…),
  - Elementary file based on information already available and centralised by the Compulsory Sickness Insurance scheme (subject to validation of such use by CNIL[3] and the actors concerned[4]).

- **hosting within this public portal private operators** providing the DMP content service and differentiated services (after approval by the Authorities) such as:
  - the collection, retrieval and hosting of data and information output by field health-care actors (community health-care professionals, radiology practitioners, biology laboratories, public and private institutions) indispensably supplementing the bare centralised information of the Sickness Insurance scheme; in compliance with the regulations and in keeping with the spirit

[2] In this connection, the announcement of the recent change in strategy has elicited very sharp reactions, as evidenced by communiqués from these actors and their representatives among others

[3] French data-protection agency (Commission nationale de l'Informatique et des Libertés)

[4] As concerns this, there is nothing to indicate that the data host used to provide the "Centralised Universal Service" may be exempted from compliance with the authorisation procedures provided in Decree 2006-4 published in the French Republic Official Journal on 4 January 2006

of the DMP, only information judged by the health-care professionals to be "of subsequent use in handling the patient's case" (whether of value for community assumption of responsibility for an acute or chronic condition, or useful in logging the patient's health episodes throughout his or her life) will be recorded in the DMP;
- Local or hospital network connection services based on specifications for and a review/audit of the source-systems quality,
- Call centre for consulting these operational health-care data,
- Host's responsibility for the integrity, availability, storage and use of the data and documents entrusted to it by health-care professionals in agreement with the patient
- Managing on the patient's behalf the authorisations for accessing such information,
- Complementary value-added services (validated by the Authorities before commissioning); purely by way of illustration: retrieval of epidemiological data for provision to the Institut des Données de Santé[5], telemedicine services[6], home care including hospital services at home, ASP-mode private-practice management software, patient medical information and admission to preventive-care routines, help for the patient in locating a neighbourhood health-care professional or institution, updating of qualifying medical knowledge for purposes of professional-practice assessment, etc…

To sum up, in the spirit of Act 2002-303 of 4 March 2002, patients will be able to choose their individual-data host freely from among the various private operators available and authorised; the cost of the DMP will be standardised and laid down by the Authorities, and competition among operators will foster creativity in the supply of differentiated, value-added services.

***Important note**: The interoperability indispensable to communication among the different actors in the health field cannot be provided without a more determined policy stance by the State, which must impose international market standards in the specifications for generalisation – among others[7] of the DMP – in consultation with the industry. Naturally, these standards, already defined for the most part (HL7 / CDA Release 2, IHE / XDS …) must be made mandatory for the Universal Health Service central platform.[8]*

These standards are already enabling private operators to enrich their DMP files with medical data (discharge letter, surgical operation report, laboratory test result, radiology report, relevant images …) using health-care data outputting software. Similarly, they enable a complete patient file to be transmitted from one operator to another in the event of a patient wishing to change host.

The HL7 France[9] "CDA Group" has even established, consensually with the main medical-practice management software publishers, a single exchange model (Common Medical Component) based on the 'CDA Release 2' international standard. The work involved was submitted to the GIP DMP on 13 November 2005 by the HL7 France association.

The work was conducted nationally and internationally by industrial specialists working in this country under the auspices of HL7 France on defining messages, and in the IHE Europe organisation on implementation specification and operational testing. As proof of French dynamism in the area of

[5] Health Data Institute; provided under the Act of 13 August 2004, in Article L. 161-36-5 of the Social Security Code; today, the terms and procedures for implementation of this Institute are under study

[6] Provided in Articles 31 to 34 of the Act of 13 August 2004, and in the 'SROS III' (third-generation Shémas Régionaux d'Organisation Sanitaire – Regional Health-Organisation Schemas – launched by the Hospital Care and Health-Care Organisation Division attached to the Health Ministry)

[7] It will be also essential, in order for France to catch up rapidly, for the Authorities to use their sovereign powers to make those standards mandatory in all invitations to tender concerning the introduction of groupworking IT tools (hospital information systems, home hospital care, tele-health-care systems)

[8] The members of LESISS and SNITEM, and the industrial actors aware of its importance naturally support this interoperability goal (on this subject see the "*Note on the interoperability of the DMP components*" published (in French) in October 2004 - www.lesiss.org/publications); naturally, they wish to assure the relevant State departments of their full support for a coordinated approach designed to help the State promote these standards – or better still, make them mandatory.

[9] Hprim – HL7 France is that country's representative of the HL7 international standardisation association, which has 24 daughter organisations world-wide

interoperability, it is worth nothing that the IHE Connect-a-thon IHE in Barcelona[10] was attended by members of four out of the six consortia selected for the preliminary development phase of the French DMP, as well as by the main specialist software publishers.

On the evidence, the allegation seeking to deny the interoperability-orientedness of industrial actors concerned to comply with international standards is manifestly unfounded. Furthermore, it is the task of the State, as owner of the project for generalised health-care data sharing in this country, to ensure that these international standards, which have now become operational, are rendered mandatory for all service providers and industrial actors involved in tender procedures, *including public-sector service providers*.

The precise breakdown of roles between what must be performed by the Universal Health Service platform and what is to be assigned to private operators (integrated service providers) remains to be defined. However, whichever the role breakdown finally opted-for, obviously, the objective sought will be achieved thanks to a mix of public services and recourse to private operators: to generalise a groupwork tools infrastructure to serve the patient and health-care professionals, of which the DMP will be one of the major components.

For, like countries elsewhere in the world, it is the combination of strict public best-practice rules, information sharing and security combined with the involvement of private operators which will allow a phased upgrading of health-sector information systems, and the corresponding raising of that sector's practice standards.

2 – Stepwise tackling of obstacles, distinguishing two management horizons

In view of the extreme complexity of the matter, it would be to the Authorities' benefit to prefer this methodology. Only by following it will essential issues be clarified: the cost to the community of the DMP, the return on capital invested, multiple-host deployment strategies.

To suspend the work which has been in progress for 18 months would inevitably lead to forecasts being made on the basis of mere assumptions, whereas deploying the DMP on a realistic scale and over a significant length of time (well above 5000 files over 6 months) will provide guarantees as to the relevance of the measures to be taken for the project's operational, technical and financial components.

Accordingly, it is worth distinguishing two management horizons:

2.1 A short-term horizon, corresponding to the next fourteen months (from May 2006) until the on-full-load date decided by the project ownership structure

This is because, while it is difficult to define in detail today the final operating method for the multiple-host DMP, it is essential to rapidly implement actions with the following aims:

- responding to the demands of the project owners by showing tangible results in keeping with their expectations, if possible by July 2007:
    - making available a medical-file "central" component for each citizen, incorporating the CNAM (national sickness-insurance fund) data
    - the possibility, in the ensuing months, of opening up a DMP to authorised and selected private operators, who will join themselves on in complementary fashion to the central component in order to gather medical data from the field: hospital discharge letters, results of biological tests, radiology reports and relevant images, community practitioners' clinical observations,

[10] On this subject see (www.lesiss.org/publications/documentation/2006connectathon) the video report filmed at the May 2006 session in Barcelona

- effectively demonstrating, on a significant population, the value contributed, including value added, by the use of the medical file:

  - by introducing, for a geographically-targeted population, a "field" DMP reporting medical information so as to enhance collaboration among health-care professionals around patient information, and foster genuine exchange between professionals and patients on disease-prevention or watch information, enriched by medical value added functions such as the detection of interactions, contra-indications, intolerance or redundancy…)
  - by assessing in a first approximation the DMP's actual impacts (in terms of costs and operational-support requirements), and hence, its return on investment,

- developing a target-DMP operating model, clarifying the roles of the different (public and private) actors and the overall economic equilibrium of the programme, while avoiding crystallising thereupon choices with structural implications, and at the same time turning to best account the work already begun.

2.2 A medium-term horizon (a few years) with the twofold aims of:

- affording the possibility for every citizen to open a "field" DMP file for gathering together his or her health-care information produced by the different hospital and community health-care professionals.
- effectively generalising the DMP to all data sources (interconnection of institutions and community health-care professionals, which assumes upgrading their information systems, including training and change management), to achieve in the long run the systematic enrichment of the DMP with a content "rich" because of all the field operators involved.

This approach is essential, in allowing a stepwise approach to problems, with concrete progress in overcoming the obstacles entailed in the DMP project while continuing to deepen examination of key topics. This approach is a practice of long standing in the private sector for complex major projects, and marks a break with practices still often resorted-to in the public sector, even though the State is imparting a positive impulse for obvious reasons:

- it is not always possible to define everything beforehand,
- it is as they progress that project teams gradually clarify the precise vision of target operating methods,
- in the case of the DMP, speed of implementation is an important parameter for success, which will remedy the risk of health-service professionals and users losing interest.

Remarks on the DMP deployment timetable

Observation of projects for sharing health information in other countries gives us an idea of the lead times required. Two examples could be cited, that are roughly similar in scope to the French project: thus the British and North American programmes (having been funded to the tune of several *billion* euros – and for the US project, by as much as several *tens of billions* of dollars) will be deployed over some ten years.

The French DMP project owners are announcing for their part that this project will be operational as early as July 2007, with a 3-years to come up to full working strength. The industrial actors of the LESISS trade association consider that 5 to 8 years will be necessary before final commissioning of the tools contributing to groupworking among health-service actors[11]. Without underestimating France's know-how or the project-ownership team's determination, private industrial actors have the duty, with their proven experience of major projects, of stating their view that the timetable announced is, at best, highly ambitious when measured against the resources available, and even dangerously unrealistic.

11 It is doubtful whether the project's political managers have clearly grasped the extent to which the timetabling constraints admit of no short cuts. At a public sitting on 11 May 2005, the special Rapporteur for the Senate Finance Commission asked the Minister of Health: "*Will France be able to achieve in so little time* [scarcely more than a year] *what Britain did in twelve years with ten times the budget resources*?". The reply was clear: "*Yes!*"

3 – Objectives achieved in an equilibrium between the private and public sectors

Short-term actions must be rapidly initiated to strengthen the pattern of progress under way for 18 months, while preserving the public/private balance of the programme, in order to achieve the objectives set by the Act, in conformity with the clearly-expressed aspirations of health-service professionals and users. Three types of action must be considered:

3.1 Universal Health Service "DMP – central component" available for all citizens in July 2007

The objective will be to construct a central platform made available to all French people who wish it via a web portal opening in the spring of 2007. This project will allow the attainment of two objectives of limited scope, but available in the short term:

- providing a formal response to the aims of the Act by proposing a scheme enabling each and every citizen wishing it to have a DMP file containing the central information component (patient identification and data already centralised by the Compulsory Sickness Insurance agencies)
- providing branching to private health-care data operators, who are freely chosen by the beneficiaries, and who collect field medical data (hospital discharge letters, biological test results, radiology reports and relevant images, community practitioners' clinical observations) and supply the DMP's "rich content".

The existence of this central system will guarantee the nominal attainment of these objectives, but these files will have limited operational reality: only a few major national bases (such as the CNAM national sickness insurance bases, if that body agrees, and if the CNIL data protection agency gives its agreement) will be used to provide the DMP's central component.

However, this minimum central component should rapidly have added to it:

- scope for opening a "field component DMP" to private operators, for gathering information produced by health-care actors (whether by direct inputting on the Internet or, especially, by transmitting information from health-care information systems used in compliance with international health-sector standards or national standards widely deployed and used in France, ideally rendered mandatory by the State)
- the effective enrichment of "field component DMPs" by bringing data sources on-line (private-practice health-care institutions and professionals whose systems have been technically connected and who have received training in the system including its practical use)

3.2 Lengthening the design pilot phases by a few weeks (via the existing contractual framework)

The existing pilot-phase contract (focusing on the technical and applications operation of the platform) can be extended within the constraints set by the French Public-Procurement Code. This extension will enable the existing design to be tested to completion; a majority of observers shares the view that the time allowed is far too short (allowing for the delays to date – due among others to the authorisations, and attributed to divergences of opinion between the CNIL data protection agency and the Authorisation Committee – and bearing in mind that the summer months do not lend themselves well to any experimentation).

Note that this extension assumes the signing of an addendum with the private operators selected for preliminary development for an amount of not more than some 15% of the initial contract amount. An amount of this order cannot reasonably be expected to extend experimentation by more than two months, bringing its ending to October 2006.

Appropriately endowed, this extension will enable work to be continued up to the pre-generalisation contract, when the full findings have been produced for the pilot demonstrator, which should provide input to the design of the central development platform (Universal Health Service).

3 .3 launching a pre-generalisation contract, with a regional breakdown

The objective of this phase, in keeping with the new aim declared by the project ownership team, will be to:

- evaluate the workload involved in connecting and technically deploying the DMP in a region,
- define the most appropriate deployment resources and organisational methods, and prepare their setting up (training local trainers, setting up steering committees, …),
- identify the industrial technical resources for connection,
- perform a life-sized demonstration of the DMP's use so as to support nationwide promotion of that tool among citizens and their associations, and among health-care professionals,
- evaluate the return on investment, and hence, the economic model for the DMP[12],

This phase will be implemented through the launching of a new public-procurement tender call with the object of deploying several hundred thousand DMPs outsourced to private operators positioned in limited geographical areas:

- The tender call will be launched in May, with 3 to 6 operators selected in October,
- the principal will take the necessary steps to avoid any conflict regarding fairness of procedures (making the demonstrator-phase documents available to all candidates, eligibility of any new entrant wishing to bid, hosting authorisation application to be made by each candidate, …)
- Candidate operators will present themselves in partnership with field actors (institutional actors: ARH [regional hospital admissions board], URML [regional private community practice union], URCAM [regional union of sickness insurance funds]… and/or operational health-care providers: networks, doctors and other health-care professionals, institutions… and/or patients: associations, collectives…) to drive a joint groupworking and interconnection project.
- The operators will need to provide for their connection to the central portal/target universal health service for the term of the contract, as well as providing for the transfer /copying of data on completion of the contract if they are not selected for generalisation,
- The pilot generalisation phase shall be set at 1 year + 2 conditional segments of 6 months each, bringing the maximum total term of the contract to 2 years

The benefit of this phase will be to introduce into field practice the Medical File initialised by the Central Universal Health Service.

The Universal Health Service will rely on central data (mainly from the CNAM national sickness insurance fund) and will be supplemented by the territorial DMP of the preliminary development operators, which will support:

- the reporting, storage and retrieval of field information (discharge summaries, biological test results, clinical notes, radiology reports and relevant images)
- the use by operational health-care providers of the information from the Universal Health Service and from the territorial DMP.

This phase will turn to account both types of useful information and accustom users to day-to-day practices. This pre-generalisation phase will get round the issue of private operators competing with each other by creating temporary territorial monopolies (the territories having supported the respective candidate hosts they had chosen).

4 - Parallel actions for preparing and clarifying the target system

[12] In this connection, the project ownership team indicates that an invitation to tender has been launched for specifying the project's economic model. As recalled earlier, this worthwhile initiative, for lack of related experience since a project on the scale of the DMP has never been deployed, will unfortunately serve only to frame recommendations based on abstract assumptions. On the other hand, a preliminary development phase conducted to completion will provide genuine experience for developing credible financial scenarios

Alongside the short-term work described above, three concrete actions must be launched so as to prepare the target functioning:

4.1 Consultation on the overall DMP/Health Service target system

The objective is to launch a general consultation with the health-care professionals to:

- clarify their expectations of the health-service systems in the broad sense and not just as regards the DMP which will undoubtedly "crystallise" and accelerate expectations for the modernisation of clinical information systems,
- reposition the DMP as part of the whole array of health-care information systems (community medical practice software, hospital information systems, CNAM…) by more precisely identifying the long-run organisational system for managing the medical file, which is a basic building block of future health-service systems. A particular benefit of this analysis is that it will serve to define a target system in which the DMP may or may not be distributed within the different health-service management systems.

This work (joint-exercise master plan for health-service information systems) will inevitably take several months (in terms of design) and several years (to migrate the information systems to the target system). This stage may appear long, but even so, will enable risky choices to be circumvented, both those that would be liable to deviate from the objectives, and those that would turn out to be ruinous for public funds. It must be implemented promptly, since any delay would inevitably impact the general timetabling of the project.

4.2 Clarifying the breakdown of roles between the national portal and private operators

No hard-and-fast breakdown can be at present be established between the activities performed by the national portal (Universal Health Service) and the private operators (one way or the other).

Rather, the bringing to full working strength of both the national platform and the services provided by the private operators will lead to a clearer identification of the respective roles and responsibilities.

Obviously, economic analysis constitutes an important parameter (comparing the cost of the service provided by a private operator with the cost of the service provided by public facilities). Naturally, it is not the only parameter. Quality of service, consistency in the positioning of each of the actors (scope for providing end-to-end service as opposed to providing a part of a service), the availability of local or national resources providing closely similar services that could be used, the organisation's ability to generate new value-added services driving modernisation… all these are factors to be taken into consideration in a discussion which must be rooted in the reality of the field implementation of the projects.

4.3 Clarifying the implementation and operating costs

Economically, transparent exchanges must determine the scope of responsibility and of the service provided.

The private actors are obviously aware of the opportunities for cost optimisation of the DMP through the pooling of resources (as an example, writing to patients using the CNAM health-expense refund letters) or for shifting cost allocation (using the CNAM[13] call centre instead of entering the associated cost in the DMP budget); those actors are convinced of their competitiveness in an arena where the rules of the game are clearly defined and regularly audited by independent bodies.

The private operators are capable of providing, as a complement to the Universal Health Service, a competitive and innovative service within the bounds set by the Authorities and based on a high

[13] In this respect, it would be worth checking whether, on an identical basis (required quality of service, availability, volumetrics ..), care provision by a public or parapublic service genuinely generates cost savings, something an independent audit will verify where the occasion arises

standard of quality. Appendix 2 to this paper sets out in this connection a detailed scenario for the costs of implementation and management of the files.

The private operators can naturally be relieved of some of these costs, if they are borne by the Authorities. Thus, if those Authorities intend to provide the call centre, the opening and particularly the communication of passwords or other confidentiality safeguards to the patient by registered letter, time-stamping using their own system without recourse to a market time-stamping system, etc., then this relieves the private operators of all these cost elements.

The economic dialogue with the Authorities to determine the scope of the service expected of the DMP operators will reconcile as far as possible:

- end-to-end responsibility, enabling industrial operators to commit themselves and perform the work of integrating the different components of the service[14],
- the maximum pooling and use of public resources available for the relevant cost items.

4.4 A sustainable DMP operating method paving the way to nationwide competition

At the conclusion of the pre-generalisation phase, the target schema will consist of re-assessing the private operators' territorial assignments:

- competition will become nationwide (with competition controlled by the Authorities according to terms and procedures to be defined, particularly as regards promotional means authorised),
- the patient may opt for the operator he or she chooses according to the criteria of basic-service quality or of differentiated service, which will obviously be subject to approval by the Authorities prior to being opened to competition),
- the private operators of the generalisation pilot phase will made to re-submit bids, new entrants will be able to position themselves and candidates whose rate of deployment and/or service level are not satisfactory may have their authorisation reviewed.

The manner of implementing this schema remains to be defined in detail, in consultation with the health-care professionals and users' associations[15], as regards both tendering for contracts (with a procedure guaranteeing fairness) and planning (phased or immediate generalisation). Similarly the practicalities of organising nationwide competition among private operators will need to be defined (permitted promotional activities, frequency with which an authorised host can be changed, and financing for the carrying costs, term of the autorisation given to a host and the terms and procedures for controlling/monitoring its level of service…).

Also in this study, the cross-functional operating methods can be investigated in greater depth (interoperability among hosts based on international standards imposed by the State). Here again, there is much work to be done, possibly taking several months, and drawing to a large extent on the findings from the generalisation pilot phase.

5 - Difficulties and risks

In response to the cost stated – but in keeping with reality – of the DMP, to the lack of clarity in the target methods of operation and the lack of visibility over value added services that could be provided

[14] In the new imagined scenario, the industrial operators are relegated to the role of sub-contractors in a complex patchwork of which only the project owner is supposed to have an overall view. While it does not raise difficulties of principle to the businesses concerned, this scenario nevertheless appears to them to be highly risky

[15] On this point, the mission of the COR (guidance committee) of the GIP DMP will undoubtedly need to be specified and reinforced. *Specified,* since the running of this Committee requires prior publication of the list of its members. *Reinforced,* since most of its members perceive its operation as a mere recording body with no real power to influence policy. This strengthening must not, as seems to have been proposed, taken the form of increasing the number of members (to 70) , since the present number (50) already suffices to ensure the absence of any genuinely concerted decision making, and it would be better instead to streamline this committee. On the other hand, including elected officials among the membership of this body (at least one specialist Parliamentarian from each chamber), will manifestly guarantee greater credibility

by private operators, there may be a strong temptation to overturn radically and irreversibly the initial policy approaches.

It is essential, in the choices that will be made, for the following risks to be clearly identified:

5.1 The risk of an operating time lag in the implementation of the central portal and the Universal Health Service

While the value of a national platform can be admitted, as regards both the portal and the turning to account of certain existing national information bases, it is important to gauge carefully the scale of the work to be carried out, and correspondingly, the lead times to allow for such an operation.

Although the implementation of the DMP may appear simple, this is far from the case in reality: the operating clauses that control the use of the DMP (governing access, security, legal liability…), the volumetrics involved and the performances requirements render this project very demanding technically. To this issue is added that of supplying data to the DMP, which supposes that the source databases provide the necessary items (which is far from the case at present) and that they interconnect with the central database.

It is clear that the combination of the times involved in setting up the teams on the government side, the institution of public-procurement procedures for certain components of the platform and the technical construction of the platform will take as a minimum between nine and twelve months from the date of inception of such a decision, assuming there are no obstacles. It should be also recalled that, like the platforms managed by the DGI General Tax Directorate (VAT and income tele-returns), these initially simple projects were revealed in practice, and given the volumetrics, to be highly complex as well as internally and externally resource-consuming[16].

That does not mean that this approach should be abandoned, quite the reverse. It appears worthwhile and will effectively complement the scheme initially planned. Even so, it would be illusory, and even dangerous to expect a significant tangible result from this change of direction, within the coming fourteen months, except as part of political communication drive.

5.2 The risk of disintegration in a beguiling approach of calling for projects

In view of the considerable effort and the time required to standardise and connect health-care professionals to the national platform to allow it to be supplied with data, it would be tempting to resort to a call for projects in which the health-care professionals would commit themselves to standardising and connecting their systems using a budget allocated to them[17] (seeking help from the private operators if they wish).

This approach is beguilingly attractive, since *in appearance*, it enables 3 objectives to be satisfied:

- Satisfying the health-care professionals seeking to make up their own systems and concerned not to be forced to a choice that does not suit them,
- Making health-care professionals at least share responsibility for connection and preventing the central service from being positioned as the natural scapegoat for future malfunctions,

[16] The new Director of the GIP DMP will have difficulty in disagreeing with this, since in his previous capacity as Director of the GIP MDS [modernisation of declarations to welfare agencies] then of the ADAE [development of electronic data handling in government], he will naturally not be unaware of these constraints. In this respect he will without doubt provide his proven expertise with regard to the prudence needed in predicting lead times when dealing with major national projects, the more so when they are carried out in a tight budgetary context

[17] The Belgian government has instituted an original scheme for sustainable financial support, requiring the health-care professionals to acquire and maintain authorised medical software, one of the requirements for which is interoperability. Those professionals fully appropriated the scheme on account of the guaranteed interoperability and the sustainable financial support they obtain as the counterpart to their guided choice. The quality requirement arising from this initiative has also contributed to the structuring of a market on which a few high-performing businesses are now developing. For the record, the French medical-software market is still shared among more than 150 suppliers

- Limiting the cost of connection by allocating small budgets which, given the inexperience of the health-care platforms' local IT specialist, will be perceived as high.

This interest in the "projects call" approach, which is not new, is understandable, but exhibits severe drawbacks:

- First, a high, persistent risk of non-quality. Clearly, health-care professionals are not equipped to set up projects such as the DMP. Information technology is not their business, and there are insufficient skills available locally to at least call in, if not actually involve professionals. There is no small risk of seeing the proliferation, as is already the case, of poor-quality platforms which will rapidly raise issues of sustainability and open-endedness with which the local structures will be unable to cope.
- Moreover, the fragmentation of costs among a multitude of local platforms will inevitably involve severe deviations. At a time when both public and private structures are tending to revert to highly-centralised IT architectures making central applications available on thin-client workstations, the atomisation of resources is perplexing. From the community's viewpoint, it would be regrettable for the health-care sector to evolve in a different direction from the major trends in modern information technology.
- Lastly, while a small percentage of professionals is familiar with IT developments or maintenance and are capable of showing a degree of self-reliance, the majority of them wishes to rely on true professionals in the field who are able to supply them services comparable with those they can find in other sectors.

To sum up, in our view, the logic of calling for projects should be examined with great caution (moreover, the use of public subsidies was criticised on several occasions – and will no doubt be so again – by the State supervisory bodies). Stringent safeguards are therefore desirable for this approach.

First, the object itself of the call for projects should be targeted and detailed to a degree sufficient to enable the declared objective of creating nationwide interoperability to be effectively attained. The actors in the field who have a clear view of the nature of expectations and of the specifications will be better placed to assign missions to private operators with the assurance that their work will be consistent with the work carried out in other interconnection projects. Thus, the call-for-projects specifications will need to specify the following in particular:

- quality of expected information flows (document type, standards / inter-application communication technology / data-exchange protocols to be used, structuring level and reference thesaurus, one-way or two-way flows),
- the processes / functions required for purposes of exchanges (formats control, presence of information, coded value checking, signature of dispatches, routing of information, transfer monitoring, processing results, …),
- the technical architectures recommended (different connection modes planned by the GMSIH, secure messaging / web service applications),
- the required security processes and levels[18],
- the commitments required of the operator (availability, data integrity, …),
- the terms and procedures for validation / acceptance of the interconnections (particularly while awaiting the generalisation DMP).

The call for projects should also provide a strong incentive for field operators to federate in order to avoid fragmentation of the collegiate control structures which have sprung up in the various experimentation sites. Today, these structures are hosting consensual projects, with individual variants embodying the expectations of the different actors, while avoiding the development of competing solutions pursuing individual strategies that are not aligned with the common interest. The call for projects should also specify the operating method for governance of projects on the model of

[18] The Act of 13 August reiterates Article L-1110-4 already set out in the Act of 4 March 2002, which provides for the publication of a Decree on health-data confidentiality. It is regrettable that this Decree, which is essential to the robustness of the chain of trust since it specifies the policy directions taken by the Authorities, and of which the text is now ready, is not in any way scheduled for publication

the project alignment proposed by the GIP DMP for the experimentations. The presence of institutional actors in these structures (ARH, URCAM, URML, …) will give the project owner greater control for conducting operations within the specified lead times.

Discussing next the recourse to private operators to supervise the interconnection projects, the call for projects should lay down the terms and procedures for selection and specify among others the criteria for candidate eligibility[19]. The setting of criteria drawn from the experience with the experimentation work will capitalise both on the credibility of the experienced industrial operators and on the between-businesses collaboration networks (publishers, integration service providers, …) that are now operational.

On the other hand, leaving too much latitude to the field actors in selecting their service providers will inevitably lead to a weakening of the emerging industrial business disciplines (that have been long sought by the Authorities in the health-care sector), with each entity hoping that the diversity of points of view and levels of competence will lead to a more favourable dealing of the cards. In practical terms, a nationwide process of calls for candidature or of prior authorisation of industrial operators will avoid the dispersion of efforts to convince and the interference between the utterances of actors at various levels of competence, or even the "buddy system". The field actors will then be invited to choose an operator / industrial discipline, from a pre-defined list which will guarantee consistency of competence and behaviour fostering the development of a serene climate for bringing the DMP to full working strength.

Lastly, in evaluating projects, attention should be paid to projects' cost structure and the promoters' commitment to allocating resources, particularly in adhering to the breakdown of funding between the project developers and the project ownership. The initial evaluation of the project's credibility and balance will thus better secure its due completion.

5.3 Risks pertaining to local connection

Local connection of professionals to the regional or local DMPs nonetheless remains a real difficulty. The number of actors involved, their diversity, geographical distribution and dispersion constitute a true obstacle to the deployment of the DMP, and this could lead to considerable delay in implementing it (the Sesame-Vitale syndrome).

It is therefore very important to circumscribe the risks inherent in this diversity by favouring industrialisation of the process. It is also in this area that the private operators can contribute genuine value added by conducting a change-management and technical-concentration exercise of which they already have proven experience in other sectors of activity.
Lastly, a nationwide initiative supported by well-thought-out political communication and incentive measures will help local operators accelerate the deployment process.

There is probably no single solution to this problem. Rather, the combination of different roles will ensure that the objectives sought are attained.

It is important to point out that the same type of reasoning applies to the other components of the generalised sharing of health-care information, as in the case – among others – of telemedicine, for which the Act of 13 August 2004 also provides.

5.4 Interpretation risk in analysing the DMP's cost

The evaluations put forward by the private operators probably lie behind the current questionings as to the DMP's feasibility in the present configuration. While it is healthy for the political authorities to have

[19] This point is important, since it will provide a solution to a difficulty experienced by the Authorisations committee: a heavy influx of candidatures (more than 40 applications in early May) that the committee's configuration and the divergences with the CNIL make it very difficult to absorb. On this subject, Decree 2006-6 states that every candidate health-care host must obtain authorisation; however, it does not specify the pre-requisites to which the candidate must subscribe, and it will no doubt be advisable to place the level of stringency (e.g. as regards the applicant's creditworthiness or financial guarantees) sufficiently high to prevent the procedure becoming glutted with candidatures that are bound to be rejected.

doubts about the financial impacts of the decisions they are taking, there are several reasons for viewing such misgivings in a relative light:

- First, because the operators have made evaluations of the DMP unit cost for a project of which the parameters are far from stabilised. It is somewhat incongruous to show such large figures (especially multiplied by sixty million inhabitants) for a patient file with an as yet limited maturity (there are not yet one thousand patient files throughout France).

- Next, because it is true that private-enterprise thinking works out an overall external cost whereas government logic (while we await the budgetary and accounting stringency imposed by the LOLF organic financial reforms Act) traditionally has difficulty in identifying the complete cost of its own structures.

- Lastly, because these evaluations provide the basis for assumptions that must be reviewed and, above all, need to be contrasted with the actual conditions in the field. Thus, the works of connection and change management have been integrated, whereas an equally relevant schema could view them as being the responsibility of local structures.

- All in all, it is unwise to contrast a private sector showing high costs (because it has made the effort of calculating them according to a total-cost logic) with a government solution that is apparently less costly because it does not evaluate all the costs or (sometimes rightly so) because it bypasses certain tasks.

While the economic analysis is naturally a very important element, it would be regrettable – and even dangerous – to condemn certain approaches at this stage of the project. On the contrary, the economic analysis must be continued and conducted in greater detail. As an example, the work on ENT (digital working environments) demonstrated that the economies of scale flatten out above regional level (in other works, a nationwide ENT platform is not less costly than *n* regional platforms). In this spirit, the juxtaposition of a public nationwide platform and private regional platforms should not necessarily be considered more costly than a national solution.

At the risk of seeming insistent, the economic analysis of the project is only in its very early stages, and the coming months will (thanks to the pre-generalisation pilot exercises) enable costs to be more closely identified and, above all, point to schemes for optimising them.

CONCLUSION

The new senior-management teams of the DMP project-ownership structure have undeniably made a contribution to maturing a scenario for bringing the Personal Healthcare Record to full working strength, and some initiatives (such as the national portal and the Universal Health Service) will undoubtedly provide material for study.

However, to match the clearly-announced political vision – the primordial importance of the DMP and its availability in 2007 – with the expected operational objectives necessarily involves the scenario expounded in this guidance paper, which alone will guarantee the long-term development of such a tool.

Provided the exercise takes place in a consultative approach involving all the actors, these different contributions can be harmoniously reconciled, thereby appreciably increasing the programme's chances of success. This paper follows precisely that line of seeking a concerted solution in the common interest.

APPENDICES

1 – Analysis of the pre-generalisation public-procurement contract

The table below sets out the main elements that exhaustively differentiate the current experimentation agreement, and the pre-generalisation procurement contract that can judiciously be implemented to manage the intermediate period of setting up the DMP.

This new contract, open to the consortiums currently involved in the experimentation exercises, which may come together again, will also be open to any new candidate wishing to bid.

The objective of this contract is to:

- evaluate the workload involved in connection and the technical deployment of the DMP in a region,
- defining the most appropriate organisations and resources for deployment, and making them ready (training local trainers, setting up steering committees,…)
- identifying the industrial technical resources for connection,
- performing a life-sized demonstration of the DMP's use so as to support nationwide promotion of that tool among citizens and health-care professionals,
- evaluating the return on investment, and hence, the economic model for the DMP.

Theme	**Experimentation agreement**	**Pre-generalistion public-procurement contract**
Length	5 months, non-renewable, included in the DMP specification alignment phase	1 to 2 years, included in the generalisation approach for the DMP and the Universal Health Service
Object	*"To design and produce a DMP demonstrator* *Deployed at one or more pilot sites*" *"Experimentation feedback to be made available to the GIP-DMP project owner"* "*Enable a schedule of specifications to be developed – as the common benchmark for all future operators*"	Implement locally-deployed target solutions: - following the target-system definition described by the GIP-DMP - having particular regard to the findings from experimentation and from the implementation of the Universal Health Service - including an essential component for the definition and implementation of deployment and change management actions, with quantified evaluation of requirements
Scope	Validation of a demonstrator (whose specifications can be reviewed in the light of the experimentation results) Experimentation of 30 000 test patient files – non-permanent, on sites and with actors of limited scope and number	Implementing a target solution, taking account of the new specifications (Universal Health Service, security, …) and catering for the issues involved in large-scale deployment. Between 3 and 5 million operational and permanent files on regional bases that can cover the whole territory …/…

(*Table continued*)

Theme	**Experimentation agreement**	**Pre-generalistion public-procurement contract**
Permanency	The demonstrators implemented are proposed by the consortia, but are not necessarily permanent	The special technical clauses lay down the functional and technical terms and procedures to adhere to; The solutions are sustainable
Organisational environment	Not defined in this demonstrator phase	Inclusion of the Universal Health Service and the new methods of organisation defined by the GIP-DMP
Elements of the special technical clauses made available to candidates	- General description of the experimentation phase objectives - The demonstrators are proposed by the candidates	- Findings from the pilot experimentation contract - Description of an organisational, technical and functional target expected by the GIP-DMP
Authorisation by the hosting committee	Authorisation confined to the demonstrator implementation phase	Authorisation to be applied-for by all candidates, for the pre-generalisation phase
Economic and deployment scenarios	Not planned and not feasible owing to the very limited number of files (5000)	To be integrated in the contract objectives, and relevant to the pre-generalisation target Effective implementation of an approach combining target deployment and measurement of the inhibiting factors /key success factors Genuine quantification of the actions to be carried out

2 – Analysis of the DMP costs

2.1 A few figures from foreign projects

While it is naturally difficult to predict the exact cost of the French DMP (whose definition and scope have yet to be specified), it can already be deduced on the other hand, that they will in any event be appreciably on the same scale as similar programmes planned or in progress among our partners in the concert of nations.

Numerous projects in the field of health-service information systems have indeed been initiated, of varied functional scope but with a range of costs showing not inconsiderable amounts:

- bIT4Health (Germany) - €1.4 billion over 4 years, covering the whole population
- Quebec – $537 million over 4 years, 7 million inhabitants
- Diraya (Spain, Andalusia Province) € 60 million over 2 years for 7 million inhabitants

(m€ = Million d'euros; M€ = Milliard d'euro)

In addition, numerous other national projects are in progress, as very succinctly summarised in the table below:

Country	Population (Million)	Programme	Budget	Cost/inhab.
Australia	20	EMR Infrastructure	€ 80 million / 7 years € 1.2 billion	€ 4-7 / year € 60
Canada	31	EMR Infrastructure	€ 5.6 billion € 700 million	€ 32 € 18
United States	295	EMR and Infrastructure	€ 160 billion / 10 years	€ 542 / 10 years
Kaiser (HMO)	8.4	EMR	€ 2.4 billion	€ 286
United Kingdom	60	NPfIT	€ 24 – 45 billion / 10 years	€ 400 – 750 / 10 years
Sweden	8.9	Computerisation	€ 800 million / year	€ 89 / year
France	*60*	*DMP*	€ 600 million / year	*€ 10 / year*

Source: Denise Silber / Basil Stratégies in Sève – Winter 2005 (published by Editions de santé)

In the light of this table, it seems that the French project, of which the per-capita DMP cost is lowered by some sources to around 1 (one) euro[20], is widely under-scaled compared with initiatives in other countries.

However that may be, in echo to the issue of the investment required to finance a project of the scale of the DMP – and beyond that, of health-care groupworking tools – another issue arises as regards *return* on investment (ROI). Numerous works have been commissioned on the subject, and two tables bring into striking prominence the potential areas for savings – financial and human – that can reasonably be expected.

[20] This curiously low figure, mentioned on several occasions in the press in April and May 2006, was repeated by the Senator, Jean-Jacques Jégou, Special Rapporteur of the Finance Commission when evidence was heard from the Minister of Health on 11 May 2006; it has not been denied

Drawn from a report published in September 2005 by the Rand Institute, an American think tank, the table below plots savings expected in both the hospital sector and community medical practice.

	$ billion
Outpatient consultations	
Transcription	0.4
Search for file	0.4
Laboratory tests	0.5
Consumption of medicines	3.0
Radiology	0.8
Total (*outpatient care*)	**5.2**
In-patient hospital care	
Nursing time	1.4
Laboratory tests	0.8
Consumption of medicines	1.0
Length of stay	10
Archives	0.7
Total (*in-patient care*)	**16 .1**

Source: Denise Silber / Basil Stratégies in Sève – winter 2005 (published by Editions de santé)

The second table, below, forecasts the overall improvement in sickness prevention through better patient identification, embodying – according to a classic rule in public health – the combination of financial results and the number of deaths prevented. The Rand report points out that, in the management of chronic pathologies, the savings achievable by optimising medical practices, thanks to the information system among others, could reach $40 billion per year.

Indicator	**Flu vaccine**	**Pneumonia vaccine**	**Breast cancer screening**	**Cervical cancer screening**	**Colo-rectal cancer screening**
Target group	aged 65 and over	aged 65 and over	F 40 years +	F 18 – 64 years	aged 51 and over
Frequency	1 /year	1 / life	0.5 /year	0.33 – 1 / year	01 to 0.2 / year
Annual cost	$134 / 327 million	$90 million	$1 – 3 million	$152 – 456 million	$1.7 – 7.2 billion
Gains / year	$32 / 72 million	$500 – 1000 million	$0 – 643 million	$52 – 160 million	$1.16 – 1.77 billion
Deaths prevented / year	5200 - 11700	15000 - 27000	2200 - 6600	533	17000 - 18000

Source: Denise Silber / Basil Stratégies in Sève –Winter 2005 (published by Editions de santé)

These few indicators tend to demonstrate that two approaches exist to the funding of generalised health-care information sharing tools: a cost-based approach, designed to reduce costs as far as possible (this seems to be the new option taken by the DMP project ownership team); and an ROI-based approach, in which the amount of investment is commensurate with the return expected. This second option seems to be the one preferred by our partners on the world stage.

2.2 Determinants of the economic approach

The DMP is a service of a legislative nature whose initially-proclaimed objective is to benefit patients and health-care professionals. At this stage, the different actors have only a piecemeal understanding of its object and of the way in which it will become an ordinary part of their lives, and progressively influence day-to-day practice.

Since the speed of adoption of the DMP by the actors is in any case as unpredictable as its target use profile, this makes it necessary to adopt a flexible approach, adapting to needs as they become apparent.

In this spirit, a scheme should be devised for rapidly and easily re-scaling the solutions implemented by:

- introducing variables as far as possible into the cost structure so as to limit boundary effects and investment anticipation, while using cost units that are consistent with the unit of service produced,
- de-correlating the resources used for the various service domains so as to give them the flexibility required to evolve in differentiated mode according to the way each is worked on by users, while preserving the functional coherence of the whole.

Another key issue is arriving as soon as possible at a unit cost that is competitive (in comparison with unit costs for equivalent services proposed in other sectors) and that points to the expected cost in ordinary operation. With this objective in view, it is appropriate to rely on operational environments that can be pooled under the conditions defined for the DMP, that limit the setting-up costs, lower the threshold of access to economies of scale and give the benefit, from the outset of the bringing to full working strength, of a marginal-cost approach.

Moreover, the launching of the DMP service among patients is only conceivable if it is at the same time rooted in the reality of conditions for health-care actors, institutions and private practitioners who jointly determine its operation. For the health-care actors to acquire a technical and functional grasp of the DMP supposes a sizeable initial effort, before the DMPs are launched into existence, and this effort will appreciably affect patient demand.

In these circumstances, we feel it worthwhile, in order to allow for dynamic adjustment of the economic model, to break down the overall final cost of a DMP into three major cost types, that can be de-correlated so as to better reflect the reality of the bringing to full working strength.

These three major cost types are the following:

- the contractualisation and initialisation of a DMP
- the annual management of a DMP
- the territorial deployment

Information concerning the scope of the responsibility and of the service delivered, as well as the associated cost, must be exchanged in a transparent manner. At this stage, and on the basis of the assumptions given below, the estimated cost of the DMP is some 13 euros for 10 million patients.

Allowing for the need to have significant feedback so as to scale each item as accurately as possible, it will probably be appropriate to re-evaluate them in a year's time, under a procedure representing all parties so as to determine a realistic price for the service.

The private actors are obviously aware of the opportunities for cost optimisation of the DMP through the pooling of resources (as an example, writing to patients using the CNAM health-expense refund letters) or for shifting cost allocation (using the CNAM call centre instead of entering the associated cost in the DMP budget); those actors are convinced of their competitiveness in an arena where the rules of the game are clearly defined. They are capable of providing a competitive and innovative service within the bounds set by the Authorities (i.e. to complement the Universal Health Service).

Thus, if the Authorities intend to provide the call centre, the opening and particularly the communication of passwords to the patient by post, time-stamping using their own system without recourse to a market time-stamping system, etc., then this relieves the hosting organisations of all these cost elements.

The economic dialogue with the Authorities to determine the scope of the service expected of the DMP operators will reconcile as far as possible:

- end-to-end responsibility enabling industrial operators to make a commitment and adopt a responsible attitude to performing the work of integrating the different components of the service,
- the maximum pooling and use of public resources available for the relevant cost items.

2.3 Cost structure of a DMP (for 10 million files)

	Cost per DMP and per year
Contractualisation and initialisation of a DMP	9.80
File opening kit Telephone support Processing the request Storing the contract Confirmation of opening and transmission of access keys	
Annual cost per DMP	8.54
Annual management of a DMP Application licence Application maintenance Technical infrastructure Operation Time-stamping by a trusted third party Structure Insurance Storage of contract Health-care professionals telephone advice service Patient telephone advice service	
Territorial deployment (assuming an annual 120 institutions and 10,000 community private-practice professionals) Change-management support for community private practice professionals Technical connection of community private-practice professionals Change-management support in health-care institutions Technical connection of health-care institutions	1.09
Complete cost, with contractualisation costs written down over two years	**13.44**

A zoom is given below onto a few cost items set out in the table above, explaining:

- the calculation principles and methods
- the underlying quality levels

The components of the cost of contractualisation and initialisation of a DMP are described as follows:

The opening kit comprises all the documents, both contractual (Registration forms, general conditions, prepaid return envelope) and informational (presentation brochure) of the DMP service as defined by the GIP DMP for experimentation.

Telephone support is provided by a call centre located in Mainland France (France Métropolitaine), which has AFNOR certification, and guarantees an answering rate, in fewer than 15 seconds, higher than 95%, and also exhibits the skills appropriate to supporting the DMP service. The number of calls is assumed to be one call per patient. Average call time is an estimated 4 minutes.

Processing the DMP request includes receiving letters, digitising them to put them on line within 48 hrs., and interpreting the information shown on the registration forms (optical character recognition and automatic generation of the digital order to create the file, including configuration of the file operating rules, its access rights and individualised responses to the check questions protecting access to the DMP).

The contract is stored with certified professional services.

File opening is confirmed and access keys are transmitted to the patient by two individualised ordinary-post letters. The identifier and the password are delivered separately, thereby enhancing security.

The DMP annual management cost components are characterised as follows:

Technical costs for a redundant main pre-production and production site providing high service availability, and a standby site providing continuity of service in case of disaster, includes the following:

- the hardware, software, applications and network infrastructure costs;
- the costs entailed in secure hosting and components administration.

The technical architecture of the software base and the application structure of the proposed DMP solution were designed to:

- provide tested capability for sustaining a workload of millions of files;
- implement an end-to-end chain of trust, capable of demonstrating the preservation of the integrity of the data entrusted and the (traced) observance of confidentiality configured by each patient;
- incorporate detection, reaction and action capability in the area of logical security;
- generally, enable the DMP service to be carried on in accordance with the requirements of the professional-liability insurers having examined the scheme.

Time stamping is performed by a trusted third party using an electronic time stamper to mark the imprints of the documents calculated and submitted at the time when the document is filed in the DMP and to mark significant application actions, such as changes in powers and delegations. Some twenty stamps are planned per DMP and per year. (The number of contacts with health-care professionals is 7 per year and per patient; statistically, a given patient is admitted to hospital every 6 years).

The telephone advice service is provided by a call centre located in Mainland France (France Métropolitaine), which has AFNOR certification, and guarantees an answering rate, in fewer than 15 seconds, higher than 95% and exhibiting the skills appropriate to supporting the DMP service.
For patients, the assumptions for use of the telephone advice service are extrapolated from the call statistics for the State Sickness Insurance “Allo Sécu” service (increased by 50%). Average call time is an estimated 4 minutes. For health-care professionals, the assumptions used are one call per month and per health-care professional, for an average call duration of 5 minutes. One health-care professional out of five uses the call centre of a given host.