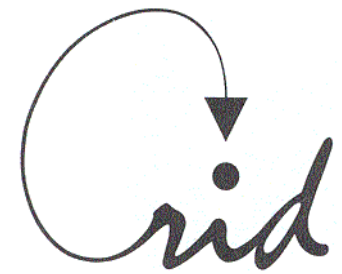


**2e HEALTHGRID CONFERENCE**  
**Clermont-Ferrand - 29 & 30 January 2004**



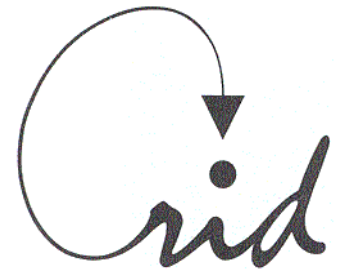
**Introduction to the European legal framework  
regarding privacy and contractual aspects of the  
provision of services based on grid-technologies  
for medical purposes.**

This work is supported by the EC under Research Contract IST-2001-37153 GEMSS  
(GRID-enabled Medical Simulation Services) (<http://www.gemss.de>)

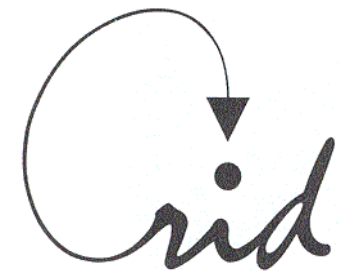
Jean HERVEG

Chercheur au Centre de Recherches Informatique & Droit (CRID) - Faculté de Droit de Namur - FUNDP  
Avocat au barreau de Bruxelles

**2e HEALTHGRID CONFERENCE**  
**Clermont-Ferrand - 29 & 30 January 2004**



**Presentation of the CRID**  
**Preliminary considerations**  
**Objective of the speech**  
**Privacy approach**  
**Contractual approach**  
**Conclusions**



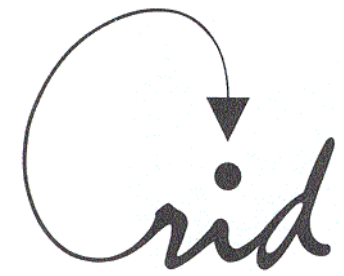
## Presentation of the CRID

**The CRID** was created in 1979 by Yves POULLET.

It gathers more than 30 researchers (lawyers, computer scientists & economists).

The CRID aims to study the consequences of the use of the new IC technologies on legal concepts (applied research and fundamental research).

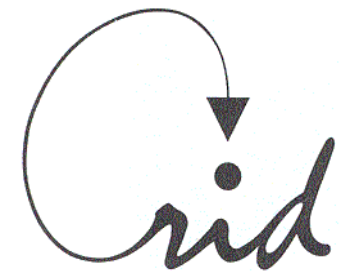
It also organizes 3d cycle formation.



## Presentation of the CRID

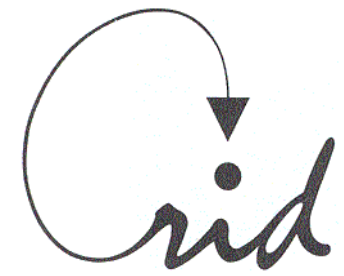
The CRID is divided into 5 departments :

- Liberties and Information Society
- Intellectual property rights
- Electronic communications
- Convergence of TIC and Law
- Electronic commerce



## Presentation of the CRID

The *Liberties and Society Information* Department focuses mainly on the protection of individuals with regard to the processing of their personal data (part of the Privacy issues).

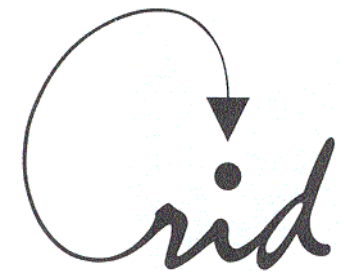


## Presentation of the CRID

This Department is involved in several projects related to the processing of medical data :

- **Serveur S3 (serveur soins de santé) :**

Creation of a telecommunication network binding hospitals and General Practitioners, at regional (?) level (founded by the Belgian Ministry of Public Health) (1999 - now).



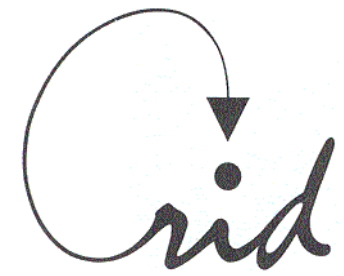
## Presentation of the CRID

- **Legal conditions for using medical data for scientific research :**

Study founded by the Belgian Prime Ministry Services.

- **Arthur :**

Analysis of the conditions for the use of IC technologies to support the activities of emergency units (founded by the Region wallonne).

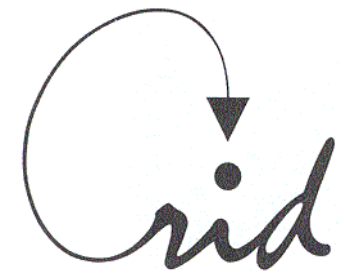


## Presentation of the CRID

- **GEMSS :**

Acting as legal expert of the GEMSS consortium ([www.gemss.de](http://www.gemss.de)) the CRID analyses the legal aspects of the provision of the GEMSS services. The legal analysis is limited to the European regulations (founded by the EU).

- **Nouveau concept hospitalier** (funded by the Belgian Ministry of Public Health)



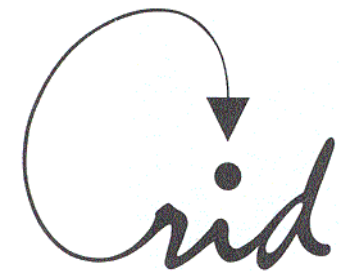
## Presentation of the CRID

- **DMMG :**

Analysis of the legal aspects of a medical record exclusively shared for medical emergencies.

- **HEMACARD :**

Analysis of the conditions of the use of a medical smart card (founded by the EU).



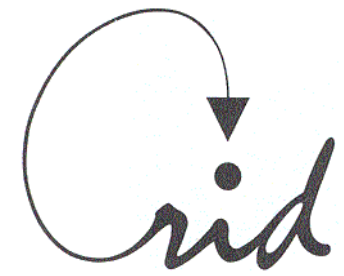
## Presentation of the CRID

- **HEMACARD :**

Analysis of the conditions of the use of a medical smart card (founded by the EU).

- **Use of medical data for preventive medicine** (breast cancer) (funded by the Belgian Scientific Institut of Public Health)

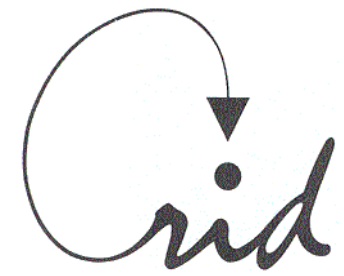
**Etc.**



## Preliminary considerations

The results of a legal analysis depend on the viewpoint adopted by its author.

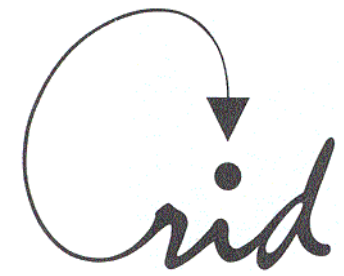
This is a consequence of the *normative plurality* characterising legal systems (a same situation is ruled by several norms pursuant different objectives).



## Preliminary considerations

In the GEMSS project the CRID has proposed (and is now in charge of) to analyse the European regulations concerning three aspects of the provision of the GEMSS services :

- Privacy,
- Contractual aspects,
- Liability issues.



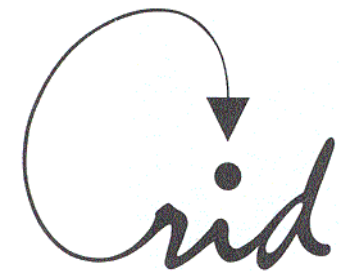
## Preliminary considerations

**Two aspects have been already analysed :**

- Privacy,
- Contractual aspects.

**Next step :**

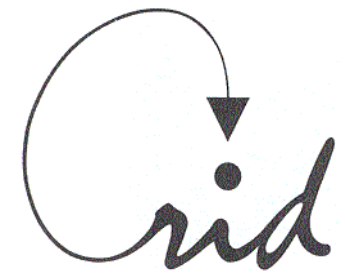
Analysis of the liability issues.



## Objective of the presentation

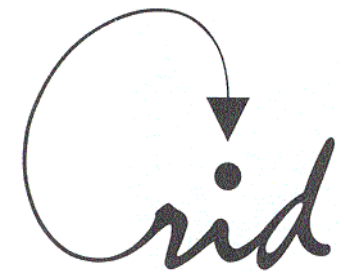
The current presentation aims to introduce the Privacy and Contractual analysis.

This introduction is relevant for all the HealthGrid Projects.



## Privacy analysis

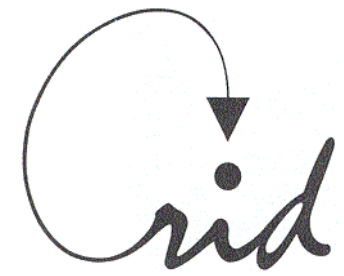
With respect to the major characteristics of the GEMSS services (mainly imaging services) the Privacy approach in the GEMSS project concerns the processing of the patient's personal data for medical purpose and scientific research.



## Privacy analysis

Indeed the use of the GEMSS applications starts with the collection of the patient's data in view of generating the needed medical images (e.g. by way of a scanner).

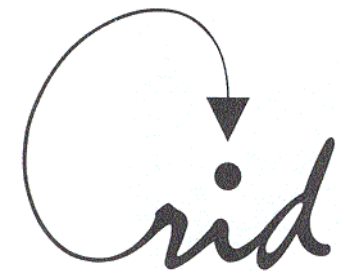
The medical practitioner is in charge of this collection. He sends the data through the Internet to the GEMSS provider. This last one might be chosen via a special electronic register.



## Privacy analysis

The GEMSS provider participates in the generation of the medical image by using software and computational resources both in his possession.

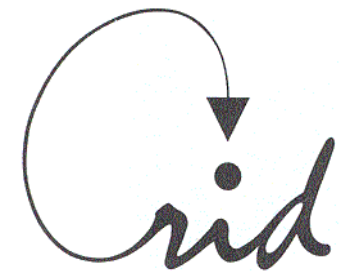
In some circumstances, another provider might allow the use of a software needed to generate the medical image.



## Privacy analysis

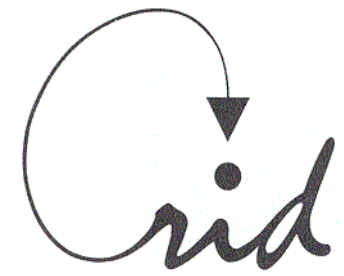
At the European level several normative sources (*sensu lato*) related to Privacy can be highlighted for the GEMSS project :

- Art. 8 of the European convention on human rights (cf. cases *Z. v Finland* & *M.S. v Sweden*),
- Convention of the Council of Europe for the protection of individuals with regard to automatic processing of personal data (28 January 1981) (Treaty n° 108),



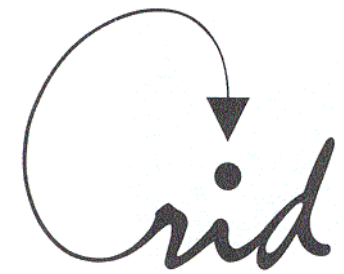
## Privacy analysis

- Recommendation (83) 10 of the Committee of Ministers on the protection of personal data used for scientific research and statistics, adopted on 23 September 1983,
- Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data,



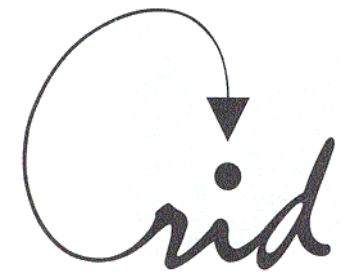
## Privacy analysis

- Title I, Common Provisions, art. F of the treaty on the European Union,
- Recommendation (97) 5 of the Committee of Ministers to Member States on the protection of medical data, adopted on 13 Feb. 1997,
- Art. 7 of the European charter of fundamental rights,



## Privacy analysis

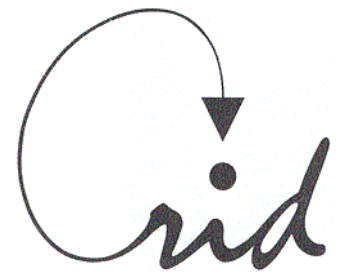
- Recommendation (99) 5 of the Committee of Members to Member States for the protection of privacy on the Internet – Guidelines for the protection of individuals with regard to the collection and processing of personal data on information highways, adopted on 23 Feb. 1999,



## Privacy analysis

- Directive 2002/58/EC of the European Parliament and of the Council of 12 July 2002 concerning the processing of personal data and the protection of privacy in the electronic communications sector (Directive on privacy and electronic communications),
- European Group on Ethics (opinion n° 13),
- World Medical Association's Declarations,
- Etc.

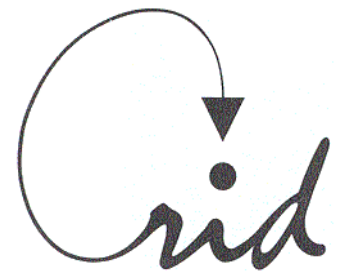
# Summary of the Privacy analysis regarding Directive 95/46



The collected patient's data, sent through the Internet and processed by the GEMSS provider, are personal data as they are related to a well-identified natural person.

If the data sent through the Internet is not directly nominative, it is nevertheless related to an identifiable natural person, by mean of any code in order to permit their imputation to an identified patient.

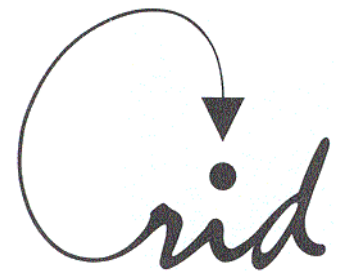
# Summary of the Privacy analysis regarding Directive 95/46



Besides the collection of the patient's personal data, its transmission through the Internet and its processing by the GEMSS provider constitute sets of operations performed upon personal data by automated means.

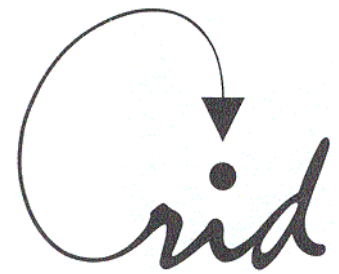
However, these sets of operations are only one part of all the sets of operations performed upon the patient's data to support the healthcare provided to him by his medical practitioner.

# Summary of the Privacy analysis regarding Directive 95/46



All the sets of operations performed upon the patient's personal data are integral parts of the same and unique data processing defined by its therapeutic purpose, and to which they are linked.

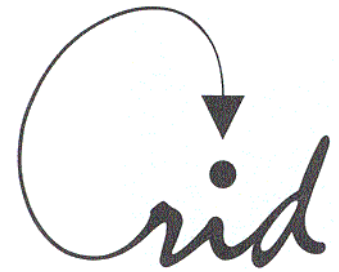
# Summary of the Privacy analysis regarding Directive 95/46



This implies that the use of the GEMSS applications does not create a new processing of personal data.

Their use is only a new part of a pre-existing processing of personal data for therapeutic purpose or for scientific research. If necessary, the controller of the personal data processing will have to adapt his procedures to the use of such new tools, according to the applicable national rules transposing Directive 95/46.

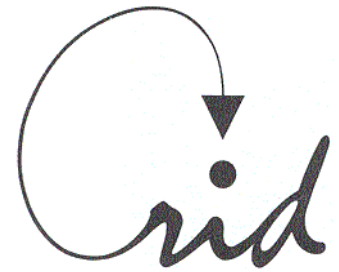
# Summary of the Privacy analysis regarding Directive 95/46



When processing personal data on behalf of the controller, the GEMSS provider acts as a processor defined in article 2, e, of Directive 95/46.

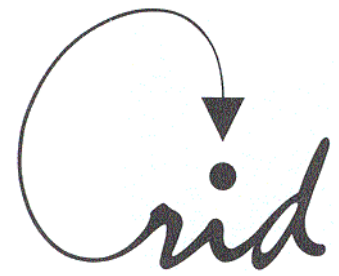
Providing software to help the imaging processing does not constitute in itself an operation performed upon personal data.

# Summary of the Privacy analysis regarding Directive 95/46



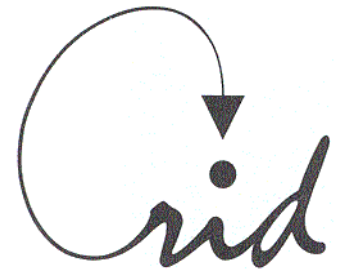
Using the GEMSS applications, the controller has to choose a processor providing sufficient guarantees in respect of the technical and organizational measures governing the processing to be carried out, and must ensure compliance with those measures, according to article 17, § 2, of Directive 95/46.

# Summary of the Privacy analysis regarding Directive 95/46



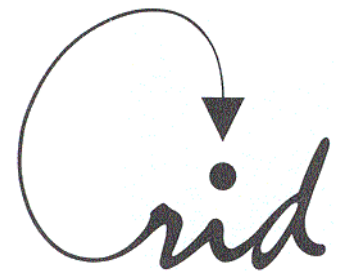
Carrying out the processing by way of a processor must be governed by a contract or legal act binding the processor to the controller and stipulating in particular that the processor shall act only on instruction from the controller and that the appropriate technical and organizational measures, as defined by the law of the Member State in which the processor is established, shall also incumbent on the processor, according to article 17, § 3, of Directive 95/46.

# Summary of the Privacy analysis regarding Directive 95/46



The measures used by the GEMSS provider have to protect personal data against accidental or unlawful destruction or accidental loss, alteration, unauthorized disclosure or access, in particular when the processing involves the transmission of data over a network, and against all other unlawful forms of processing.

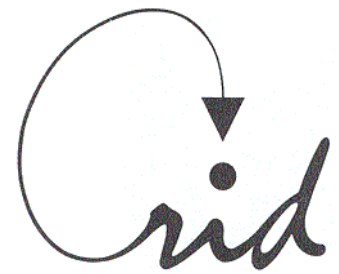
# Summary of the Privacy analysis regarding Directive 95/46



With regard to the state of the art and the cost of their implementation, such measures have to ensure a level of security appropriate to the risks represented by the processing and the nature of the data to be protected.

**Consequently, the more sensitive the data is the more risky the processing will be.**

# Summary of the Privacy analysis regarding Directive 95/46

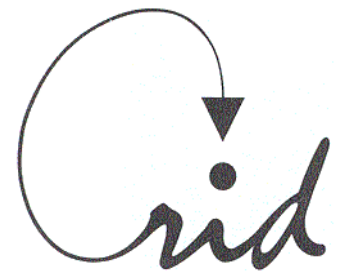


**As personal data related to health are very sensitive, the security level of the data processing has to be at maximum.**

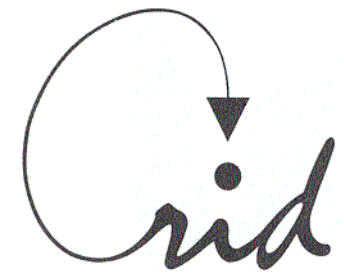
For examples of security measures, it is useful to refer to the measures recommended e.g. by Rec. 1997(5) of 13 Feb. 1997 of the Council of Europe on the protection of medical data, article 9.

**The CRID suggests the service providers to have a “security” label.**

# Summary of the Privacy analysis regarding Directive 95/46

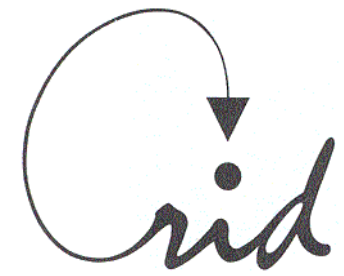


For the purpose of keeping proof, the parts of the contract or the legal act relating to the data protection and the requirements relating to these measures, shall be in written form or in another equivalent form, according to article 17, § 4, of Directive 95/46.



## Contractual analysis

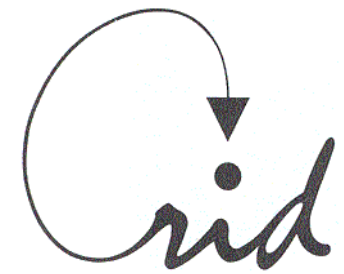
The contractual analysis aims to study the European regulations concerning the terms of the provision of medical services through the Internet and using GRID technologies.



## Contractual analysis

Prior it is useful to remind that no one may transfer more rights than he owns.

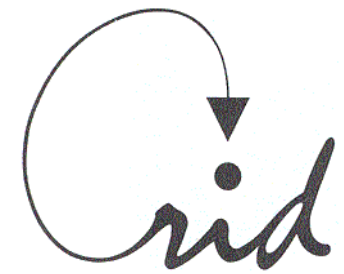
Hence the service provider has to be sure he is entitled to fully negotiate with the end-users. IPR are mainly concerned by this approach.



## Contractual analysis

### Several directives focus on IPR aspects :

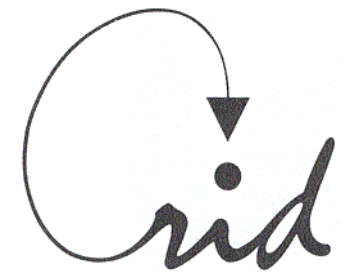
- Directive 91/250/EEC on the legal protection of computer programs,
- Directive 93/98/EEC harmonizing the term of protection of copyright and certain related rights,
- Directive 96/9/EC on the legal protection of databases,
- Directive 2001/29/EC on the harmonisation of certain aspects of copyright and related rights in the information society.



## Contractual analysis

### **European rules regarding the contractual aspects in the provision of the GEMSS services are :**

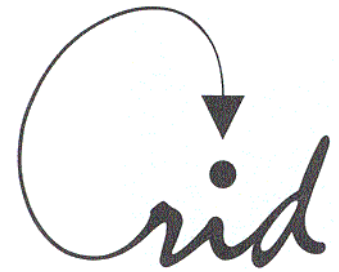
- Convention on the law applicable to contractual obligations (Rome, 19 June 1980),
- Directive 1999/93/EC on a Community framework for electronic signatures,
- Directive 2000/31/EC on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market (Directive on electronic commerce);



## Contractual analysis

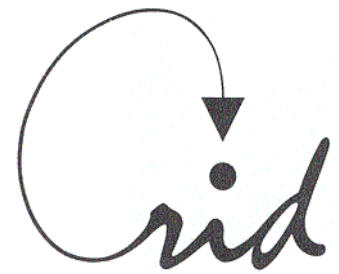
- Directive 2000/35/EC on combating late payment in commercial transactions.

# Draft of a contractual framework for the provision of the GEMSS services



- I. Identification of the contracting parties**
- II. Preamble**
  - 1. Presentation of the contracting parties**
    - Core business of the service provider
    - Core business of the end-user
  - 2. Identification of the end-user's needs with respect to the trade of the service provider**
  - 3. Identification of the services offered by the service provider with respect to the end-user's needs**

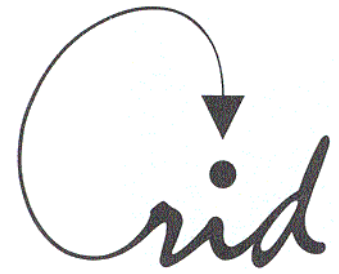
# Draft of a contractual framework for the provision of the GEMSS services



## 4. Context of the conclusion of the current contract

- Object of the contract
- Qualification of the services with regard to D 2000/31 (services of the society information)
- Qualification of the services with regard to D 95/46 (sub-processing of the patient's personal data on behalf of the data controller)
- Duties of the controller
- Commitment of the service provider in terms of security

# Draft of a contractual framework for the provision of the GEMSS services



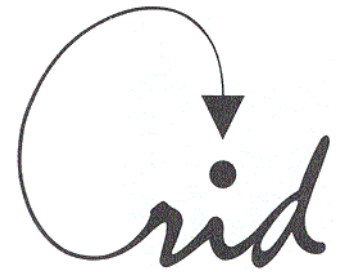
## **III. Object of the contract**

The contract aims to provide medical imaging services according to the contractual stipulations adopted hereafter by the parties considering the preamble.

## **IV. Quality of services**

## **V. Prices of the services provided to the end-user and conditions of the payment**

# Draft of a contractual framework for the provision of the GEMSS services



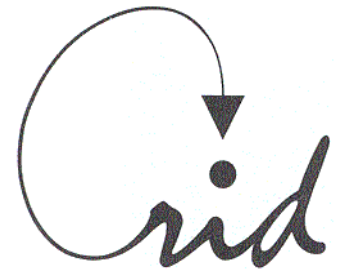
## **VI. Procedure for the submission of a work**

The contract aims to provide medical imaging services according to the contractual stipulations adopted hereafter by the parties considering the preamble.

## **VII. Technical and organizational measures ensuring the security and the confidentiality of the patient's data**

## **VIII. Crossborder data transfers (cf. model of contractual terms by the European commission)**

# Draft of a contractual framework for the provision of the GEMSS services

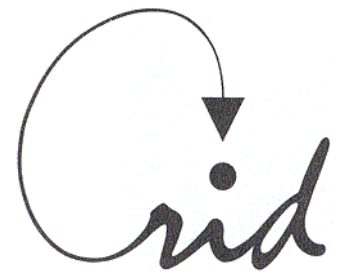


## **IX. Guarantees provided by the service provider to the end-user**

The service provider guarantees that he owns all the rights involved in any way in the provision of the medical imaging services which are the object of the present contract.

With respect to this the service provider guarantees the end-user against all type of action or claim.

# Draft of a contractual framework for the provision of the GEMSS services

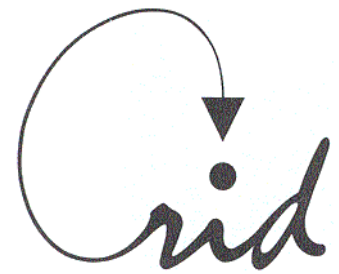


## **X. Applicable law**

### **1. Applicable law to the personal data sub-processing**

The law of the Member State where the data controller is established rules the sub-processing of the patient's data for medical purpose or for scientific research and performed by the service provider on behalf of the data controller.

# Draft of a contractual framework for the provision of the GEMSS services

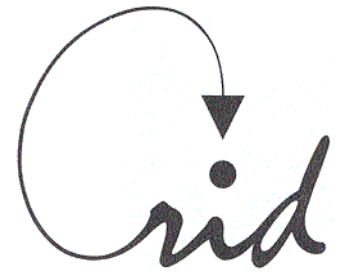


## 2. Applicable law to contractual aspects

According to the Convention of Rome and excepted for the contractual aspects subject to any European uniform material rules the contracting parties choose as applicable law the law of *INDICATION OF THE COUNTRY*.

This choice is without prejudice of the application of imperative rules or concerning the public order.

# Draft of a contractual framework for the provision of the GEMSS services



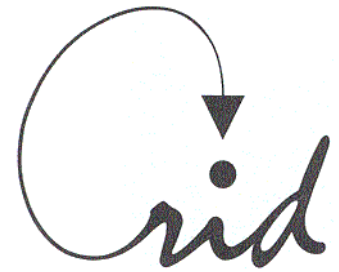
**XI. General information to be provided**

**XII. Special information to be provided in case of contract concluded by electronic means**

**XIII. Placing of the order**

**XIV. Duration of the contract and conditions of the unilateral termination of the contract**

# Draft of a contractual framework for the provision of the GEMSS services

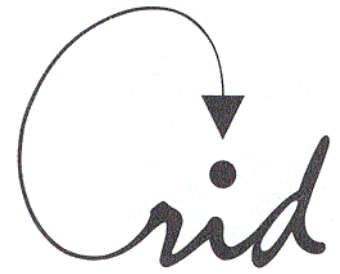


## **XV. Jurisdiction / Arbitration**

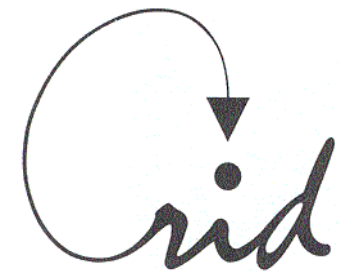
## **XVI. Penalties**

- For the non payment of the price : cf. conditions imposed by Directive 2000/35 on combating the late payment in commercial transactions,
- For the non provision of the ordered services : cf. next and last report on the liability issues.

Draft of a contractual framework  
for the provision of the GEMSS services



**This contract has to be fulfilled  
according to the applicable law.**



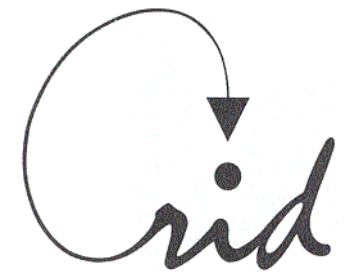
## Conclusions

### Privacy approach

The data controller may not choose any sub-contracting partner to process the patient's data on his behalf.

He has to choose a service provider providing sufficient guarantees concerning the security and the confidentiality of the processed data.

The use of a label may be a solution.

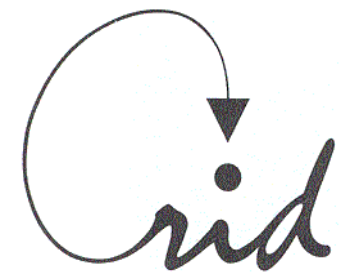


# Conclusions

## Contractual aspects

The writing of the contract obliges to articulate at least 2 different types of rules of conflict of laws :

- Convention of Rome (freedom to choose the applicable law etc.),
- Kind of material uniform rules via European Directives for certain contractual aspects of the provision of the GEMSS services.



## Questions?

Please feel free to contact

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