

# Workshop : Open and Big Data for Life Imaging Legal and ethics questions

# Legal and ethics questions

A few words about Digital & Ethics and IDV

The legal framework today and tomorrow

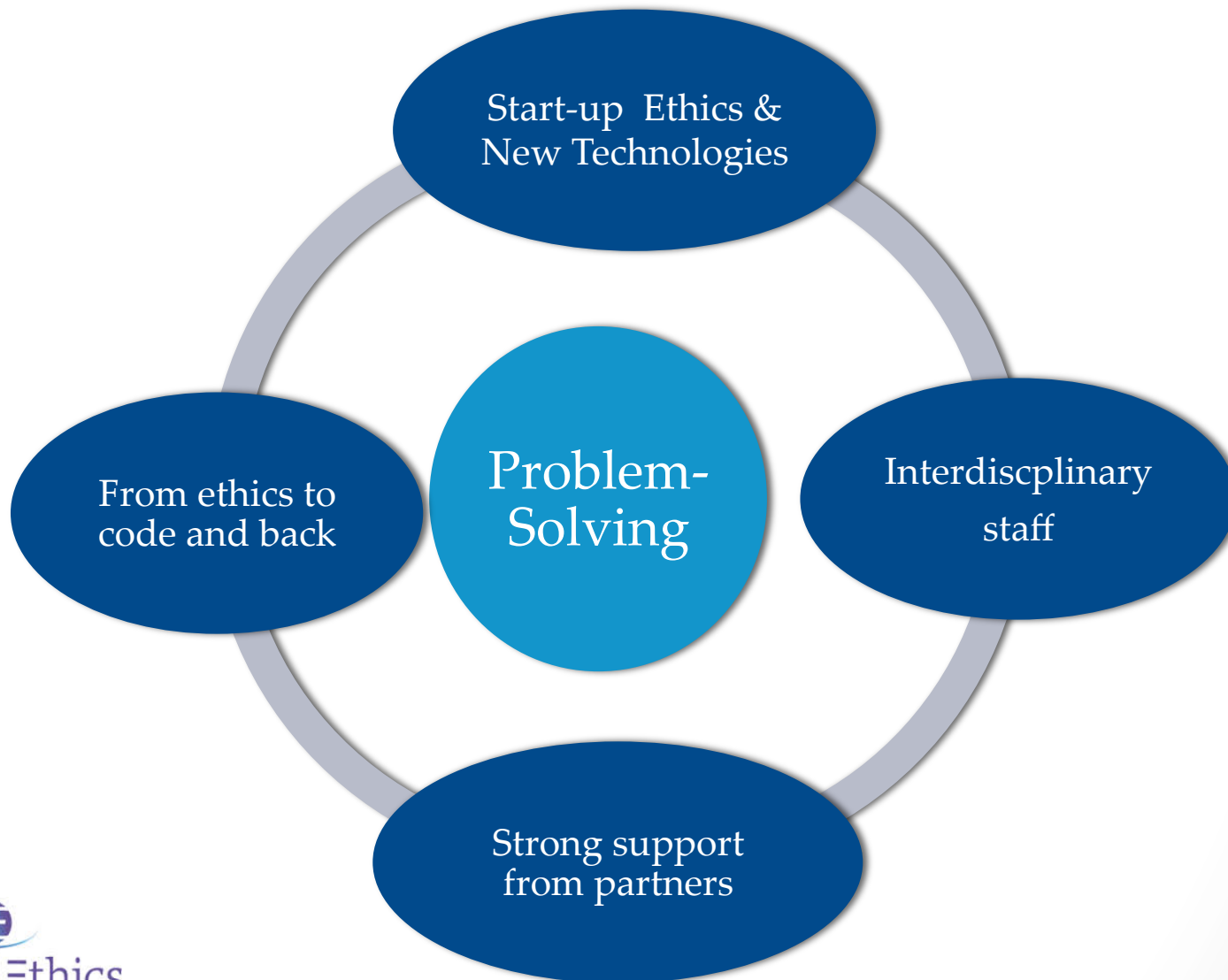
- The incoming points :
  - The status of data, meta data and derivatived data ?
  - To Whom data own ?

# Digital & Ethics

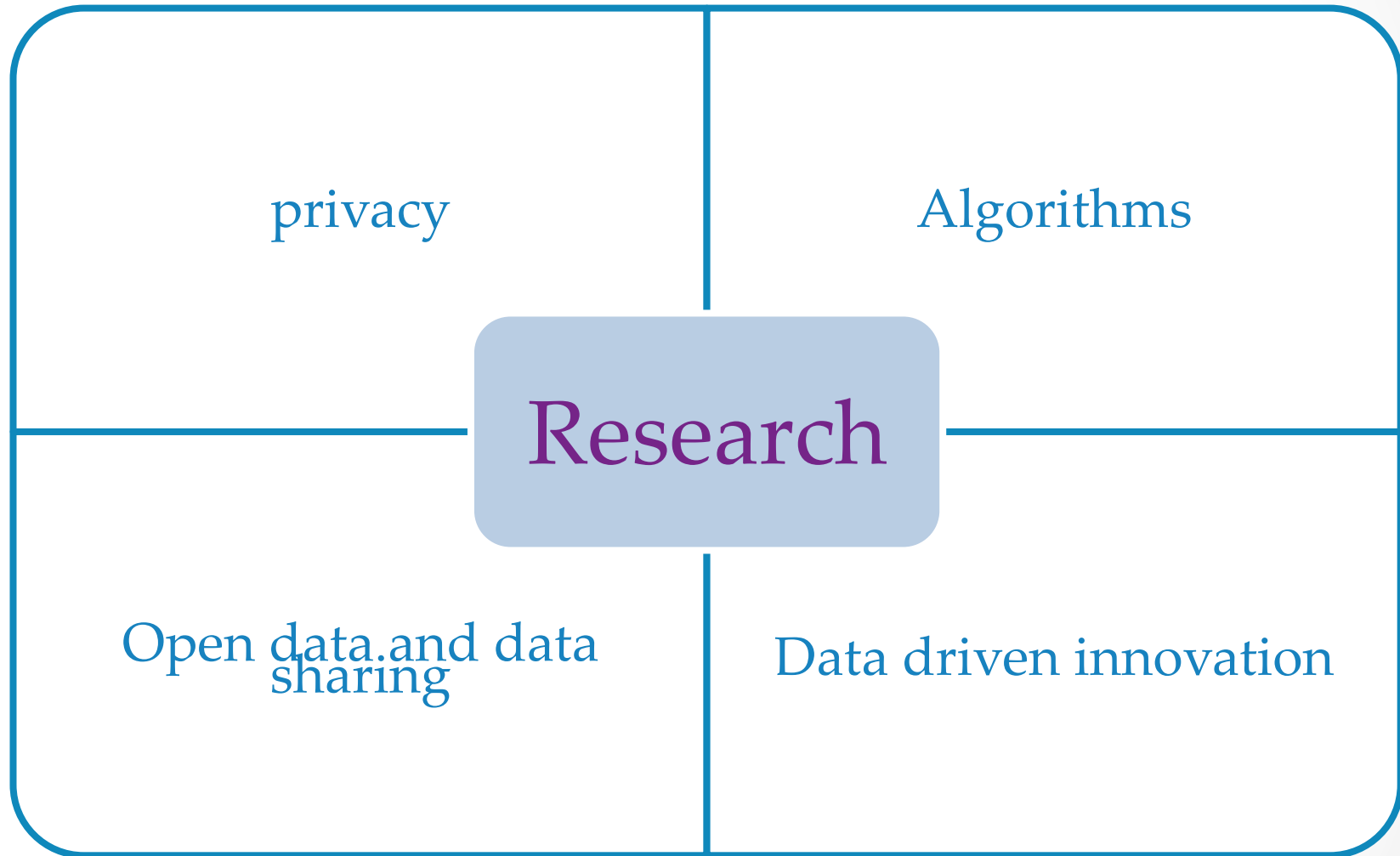
Be comfortable with data



# Key points



# D&E : « Problem-Solving » approach



# Imageries du Vivant, entre progrès et liberté

- creating an environment dedicated to the exploitation of large masses of data images for the development of new biomarkers.
- Project leaders
  - Pr Charles-André Cuenod (Paris Descartes),
  - Pr Françoise Dibos (Paris 13)
  - Pr Dominique Le Guludec (Paris Diderot),

# Imageries du Vivant, entre progrès et liberté

- Create an Atlas of multi-scales smart imaging to extract the generic information from the integration of Big Data.
- Emerge and validate biomarkers for with objective t develop personalized medicine and individualized education.
- Lighten the life Imaging societal challenges induced by the development of the two previous objectives

## **GENERAL LEGAL FRAMEWORK:**

### **RIGHTS OF USERS OF THE HEALTH SYSTEM**

**ACT NO. 2002-303 OF 4 MARCH 2002 ON THE RIGHTS OF THE PATIENTS AND THE QUALITY OF THE HEALTH CARE SYSTEM ESTABLISHES THE RIGHTS OF PATIENTS IN MEDICAL PROCEDURES FOR THERAPEUTIC, DIAGNOSTIC OR PREVENTIVE PURPOSES.**

**IT PLACES THE PATIENT AT THE HEART OF HIS HEALTH, INCLUDING:**

- THE FUNDAMENTAL RIGHT TO PROTECTION OF HEALTH.**
- THE RIGHT TO RESPECT FOR THE DIGNITY, WHICH INVOLVES INFORMATION AND CONSENT OF THE PATIENT.**
- THE RIGHT TO PROFESSIONAL SECRECY: GUARANTEE OF CONFIDENTIALITY ON THE PART OF THE MULTIDISCIPLINARY TEAM.**
- THE RIGHT TO NON-DISCRIMINATION.**



## **BIOMEDICAL RESEARCH**

**ACT NO. 2011-814, JULY 7, 2011 ON BIOETHICS SETS BIOMEDICAL RESEARCH AS "RESEARCH ORGANIZED AND PRACTICED ON HUMAN BEINGS FOR THE DEVELOPMENT OF BIOLOGICAL OR MEDICAL KNOWLEDGE" (ARTICLE L. 1121-1 CSP).**

**ARTICLE R.4127 - 15 OF THE PUBLIC HEALTH CODE INSISTS THAT THE DOCTOR CANNOT PARTICIPATE IN BIOMEDICAL RESEARCH ON HUMANS THAN IN THE CONDITIONS LAID DOWN BY LAW:**

**COLLECTION OF THE CONSENT;**

**SCOPE OF THE SEARCH;**

**PROTECTION OF THE PATIENT.**

**THE DOCTOR MUST ALSO ENSURE THE RELEVANCE OF ITS RESEARCH, AND THE REGULARITÉ AND THE OBJECTIVITÉ OF THEIR FINDINGS.**

**THE ATTENDING PHYSICIAN IS INVOLVED IN BIOMEDICAL RESEARCH AS AN INVESTIGATOR MUST ENSURE THAT THE STUDY DOES NOT ALTER NEITHER THE RELATIONSHIP OF TRUST WHICH BINDS IT TO THE PATIENT OR THE CONTINUITÉ OF CARE.**

- **PERSONAL DATA PROTECTION**
- **ACT NO. 78-17 OF 6 JANUARY 1978 ON DATA PROCESSING, FILES AND FREEDOMS DEFINES THE PRINCIPLES TO BE RESPECTED IN THE COLLECTION, THE TREATMENT AND CONSERVATION OF PERSONAL DATA.**
- **IT ALSO SETS OUT THE RIGHTS OF THE PERSONS CONCERNED, INCLUDING:**
- **THE RIGHT TO INFORMATION,**
- **THE RIGHTS OF ACCESS, RECTIFICATION AND OPPOSITION TO THE PROCESSING OF PERSONAL DATA**

# Regulatory keys points

**The patient's consent**

**The patient data must be stored securely.**

**The authorization of the CNIL**

# Legal and regulatory developments

The draft law on October 15, 2014 health contains provisions that will, according to the statement of the Council of Ministers of October 15, 2014, "opening (Open Data) public data and access compatible with the secrecy of personal data.

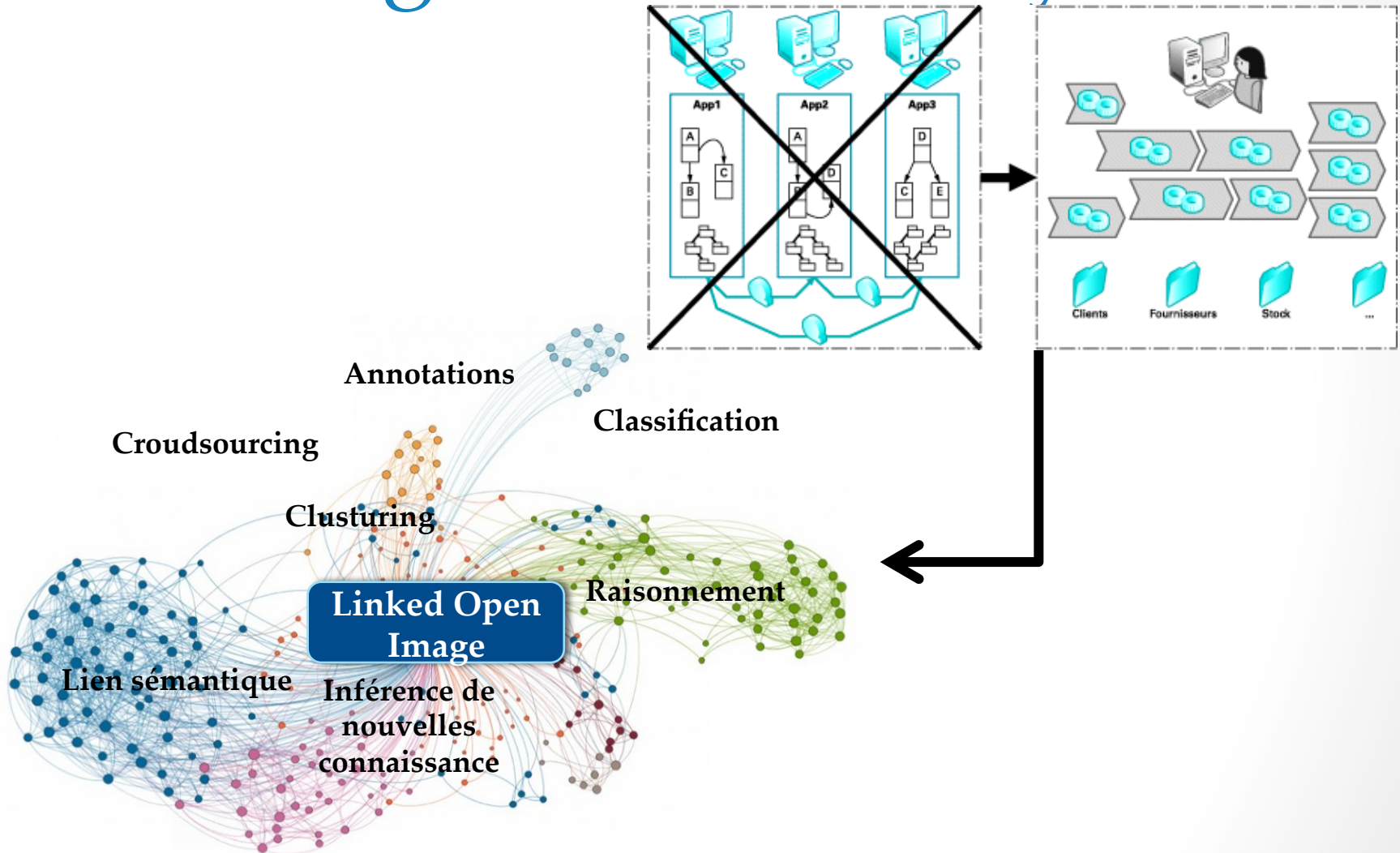
In may 2013, Didier Sicard, former Chairman of the Advisory Committee national of ethics and current president of the Committee of experts of the IDS, explained the reluctance of the Ministry of health:

**"these resistances are multiple origin but they have one thing in common. Not knowing anything to not have to toil this or that lobby, maintain the illusion that the french health is managed with rigour and discernment.**

It is easy to shake the spectrum of breach of anonymity which is a fiction to arise lazy demand for status quo. It's what is happening. It remains to be seen now how parliamentarians will welcome this text.

# Current context

## Evolving Information systems



# Qui maîtrise ces données?

**The production of the data may be a relatively complex process combining:**

- human activity;
- sensors;
- one or more treatments;
- various enhancements by different actors

**Different contributors can claim participation in the value created by the use of data**

Thank You !  
Merci !