

WORKSHOP #3 Data Governance & Data exchange

Session 3

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Facilitators

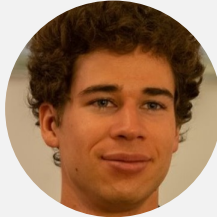
Michel COLEMAN - London School of Hygiene & Tropical Medicine

Chuck WIGGINS - New Mexico Tumor Registry

Subtheme

- What policies and infrastructure need to be in place for users to access the data in a secure environment?

Discussants



Hugo CROCHET

France

Léon Bérard Centre

Chief information system and
data officer



Dr Tomohiro MATSUDA

Japan

National Cancer Center

Head, Office of International
Affairs, Strategic Planning Bureau

Centralized, Federated and semi Federated approaches, why does it matter ?

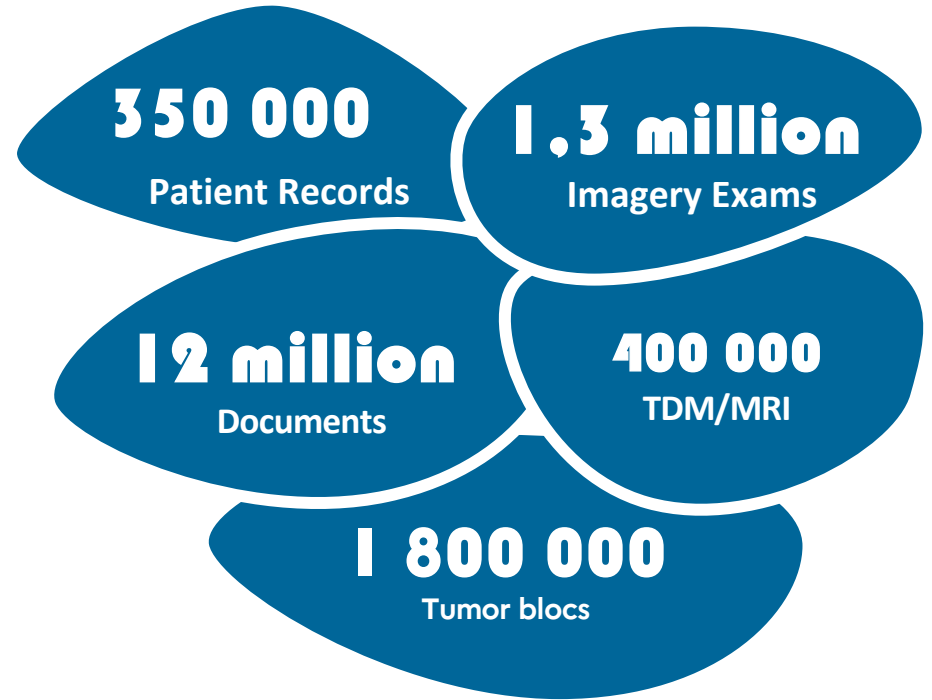
Hugo Crochet

Chief Information and Data Officer

Centre Léon Bérard, Lyon, France

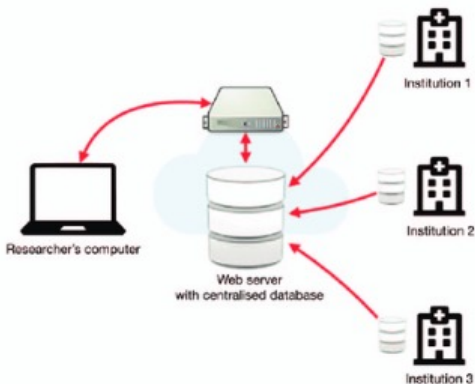
Comprehensive Cancer Treatment Center

Centre Léon Bérard, Lyon – 100% Dedicated to cancer research and treatment

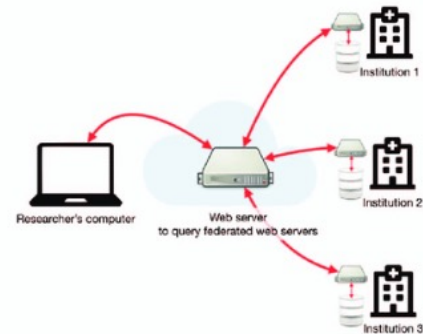


Different approaches for data sharing

Centralized



Federated



Federated counting and centralized study



Centralized Approach – One for all high investment



French - national scale project

20 partners ,

1,3M€

Genomics, transcriptomics, proteomics and methylome data

400 tumors in 2 years

Pros

- Only one center has to invest on the infrastructure
- Once in place, relatively straightforward:
 - reglementary wise (MR 004)
 - For scientists

Cons

- Health Data Warehouse according to French Regulator (CNIL) → Expensive and long !
 - Very high security level (encryption, isolation, remote access, MFA, ...)
 - Requires CNIL approval
 - Scientific Comitee
- Hard Data Update
- Very complicated out of EU

Federated Approach - The most GDPR compliant approach



European Project

7 partners

7 M€

Clinical and PROMs Data of AYA (15<X<25)

10 000 patients data

Pros

- Less risk for patient data
- Easy data update
- Easier reglementary process – One MR 004
- **Easiest across borders**

Cons

- Lot of infrastructure investment for partners, especially if GPU is needed
- Harder to maintain
- Harder to operate for scientists

Federated counting and centralized study based on

Compte-rendu de consultation

Annoter

06/09/2019 : CR - 11488-4 - CR ou fiche de consultation ou de visite - Compte-rendu de consultation (CR ou fiche de consultation ou de visite)

Bilan biologique du jour : Hb à 119 g/L, **calcémie corrigée légèrement élevée à 2.66µmol/L, le CA 15-3 est à 62 kU/L.**

On réalise également un ECG pré-thérapeutique. Le QTcF est à 411ms.

La patiente a également réalisé une **scintigraphie osseuse** qui confirme **l'atteinte métastatique** au niveau de T5-T12, du gril costal, de la scapula gauche, du bassin, du trochanter gauche, du tiers inférieur de la diaphyse fémorale droite.

Je revois donc la patiente en présence de sa sœur et de son fils pour discuter de la prise en charge thérapeutique. Je lui explique qu'elle a bien, comme on le suspectait, un **cancer du sein d'emblée métastatique au niveau de fos et de la plèvre.**

Cette maladie **rest pas accessible** à un traitement curatif, mais du fait de la forte hormonopositivité de la maladie, on peut espérer un contrôle tumoral pendant plusieurs années.

On va donc démarrer un traitement standard par une combinaison d'**hormonothérapie (LETROZOLE 2,5 mg) et inhibiteur de CDK4-6 (RIBOCICLIB à la dose de 600 mg, 3 semaines sur 4)**. J'explique les modalités de prise à la patiente à l'aide d'un schéma. Les effets secondaires de ce traitement sont les bouffées de **chaleur** et les **douleurs articulaires** pour l'hormonothérapie, les **nausées, vomissements, diarrhées, diminution** des globules blancs, des globules rouges et des plaquettes pour le **RIBOCICLIB**. On va donc effectuer une **surveillance** biologique rapprochée.

En parallèle, la patiente va démarrer le **traitement par XGEVA 1 injection sous-cutanée tous les 28 jours (sans supplémentation calcique)**, puisque nous avons eu le feu vert du dentiste.

En pratique : Je reverrai la patiente dans 15 jours pour l'évaluation de la tolérance précoce et la réalisation d'un électrocardiogramme de contrôle. On prévoit un premier bilan de réévaluation par scintigraphie osseuse et scanner thoraco-abdomino-pelvien dans 3 mois. Cette décision sera validée en comité **sein métastatique**.

- medicaments**
 - M1039 - CODEINE
 - M16954 - LETROZOLE
 - M23275 - XGEVA
 - M25166 - RIBOCICLIB
 - M2649 - EFFERALGAN
- negotons**
 - Pas d'anomalie de l'examen ...
 - n'est pas accessible
 - non accessible
 - non pris
- sans supplémentation calcique**
 - récidives et métastases**
- métastases**
 - Localisation : C77 - ganglionnaire, C42.1 - osseux, C39.8 - pleuro-pulmonaire, C41.9 - os, C38.4 - plèvre, C30 - sein
- récidives**
 - Localisation : C30.0 - mamelon, C44 - peau
- tumeurs**

NLP to structure data from reports + Structured Data from EMR

Cancer	C44.5 : TUMEUR MALIGNE DE LA PEAU DU TRONC				C43.5 : MÉLANOME MALIN DU TRONC				C34.1 : TUMEUR MALIGNE DU LOBE SUPÉRIEUR, BRONCHES OU PO			
Evolution	Tumeur Initiale		Surveillance		Tumeur Initiale		Surveillance		Récidive Locale		Métastase	
Chimiothérapie CR												
Radiothérapie												
Chirurgie												
	juil.	oct.	janv.	avr.	juil.	oct.	janv.	avr.	juil.	oct.	janv.	avr.
	2013		2014				2015				2016	

Cohort Creation and data transfer to centralized data warehouse

Saisissez vos critères de recherche

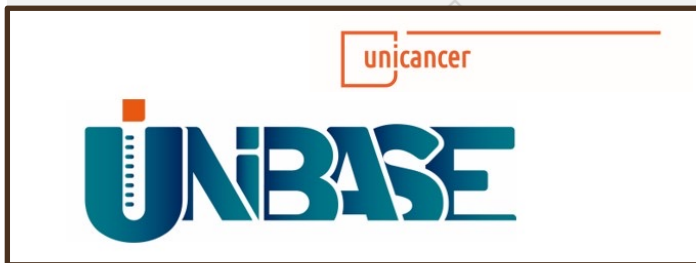
🔄 Réinitialiser

ET			Patient		+ Ajouter un bloc/critère		226 patients
ET			Cancer		+ Ajouter un bloc/critère		679 patients
+	Age au diagnostic	≥			18	204137 patients	✕
+	Date de début	≥	01/01/2012			98323 patients	✕
+	métastases ?	Oui				84457 patients	✕
+	D'emblée métastatique ?	Non				173045 patients	✕
+	Diagnostic (malin)	dans	C61 - Tumeur maligne de la prostate (cim10-tumeur-maligne) x			16126 patients	✕
ET			Images		+ Ajouter un bloc/critère		50001 patients
+	Modalité	=	Positron emission tomography (PET)			50001 patients	✕
ET			Documents		+ Ajouter un bloc/critère		34792 patients
+	Type de document	=	CR d'imagerie médicale - CR d'imagerie médicale (typeDocument)			198806 patients	✕
+	Texte	=	Filtres (3) adénopathie*adénomégalie*			120588 patients	✕

🌸 Voir les patients

Résultats Autres Centres

- Bordeaux (0)
- Clermont (3)
- Curie (125)
- Dijon (0)
- GustaveRoussy (1)
- Lille (1)
- Lyon (226)
- Marseille (90)
- Montpellier (1)



UNI AJA = Application project, 400k€
12 partners
Clinical Data of AYA

Dedicated
Data Factory
Team

In House
EMR



Data
Structuratio
n Tools

CONSORE
continuum soins recherche

**Centre Leon
Berard
A Key Actor in
Cancer Data !**

Strong
partnership



Data Sharing



**Thanks for your
attention !**



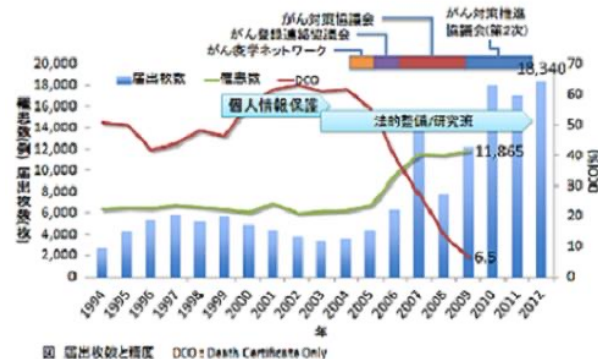
International research collaboration under data protection regulations

Tomohiro Matsuda

National Cancer Center, Japan

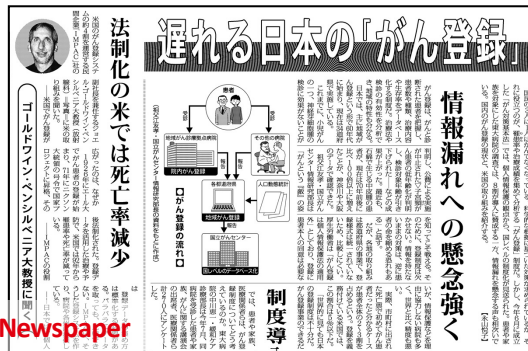
Act on the Protection of Personal Information and Act on Promotion of Cancer Registry

Example of Gunma Prefecture, where the Act on the Protection of Personal Information has led to a sharp decline in the number of notifications to the cancer registry.



2006/9/18 Mainichi Newspaper

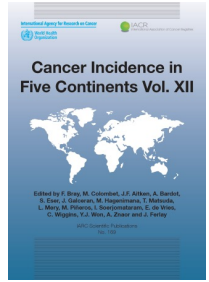
- Act on the Protection of Personal Information was promulgated in May 2003 and fully enforced in April 2005



- Act on the Promotion of Cancer Registry in 2016.
- Configuration based on "secondary" use, not limited to purpose
- All people, including private companies, are data users

We thought everything would be resolved and international collaboration would proceed...

Data submission to IARC/IACR's "Cancer Incidence in Five Continents, Vol. 12"



- **Committee** of the MOH led to the decision that sending National Cancer Registry anonymous data to overseas **requires the same very strict security controls as for non-anonymous data.**
- **Reasons: Penalties are difficult to apply to the users in foreign countries**

CONDITIONS for providing anonymous data overseas

1. A **national** research project
2. Co-researchers abroad must be **international research institutions/government agencies**, etc.
3. A domestic researcher must be responsible
4. Explain the Japanese cancer registry and data use rules to overseas users in English.
5. The **original of the written pledge** signed by the user
6. Floor maps and photos of all data use locations
7. Data management status regularly supervised and reported.
8. Documentation explaining the mechanics of the data transfer
9. Original data must be completely erased after a certain period of time...

Anonymization and Pseudonymization under the Amended Act on the Protection of Personal Information (2020)

Anonymous information

is "processed information that the specific individual cannot be identified and the personal information cannot be restored" (Article 2, Paragraph 6 of the Act).

⇒ Can be provided to a 3rd party without the consent of the person

⇒ Data that contains personal information at the time of acquisition cannot be anonymized with a little processing

Pseudonymized information is

"information about an individual obtained by processing personal information so that the individual cannot be identified unless it is cross-checked with other information" (Article 2, Paragraph 5 of the Act).

⇒ **pseudonymized information, it is often considered to fall under the category of "personal information"** (Article 2(1) of the Act).

Feature of cancer registry data and other medical information

Clinical trials in hospitals: Contain very sensitive information, but each patient agrees to participate and allows information to be shared with foreign countries.

Medical Information: Research use is permitted by blanket consent at the time of the hospital visit.

Cancer registry data: Since consent for data acquisition is not obtained from patients, the data is handled in accordance with the Act on Promotion of Cancer Registry.

⇒ More detailed, more personally identifiable information is easier to provide to foreign countries procedurally.

caseno	birth_dt	sex	diag_dt	age	icdot	icdom	behavior	conf	iarc_flg	extent
10000001	19379999	1	20179999	80	C619	8000	3	9	1	9

I don't think the review committee has ever seen the data.

Conclusion

GDPR allows us to exchange the data

Adequacy decision (Article 45)

...Such transfers shall **not require specific authorization**. Countries and regions determined to be "adequate": Andorra, Argentina, Canada, Faroe Islands, Guernsey, Isle of Man, **Japan**, Jersey, New Zealand, Korea, Switzerland, United Kingdom

- **The two acts** promote the data use, however in reality, international data sharing is restricted by cumbersome rules that are unbalanced with the sensitivity of the information and an unstable system based on case-by-case decisions.
- Even if **temporary data sharing** were possible, a permanent international integrated database would be difficult to realize

1. Need to use the data anyway, and get rid of the uncertainty of the general public
2. "What do other countries do?" is very important for Japanese government, accordingly international cooperation is crucial
3. Necessary to be prepared for other options, such as Federated Learning