Medical registries: An illustration of how governance works at the university hospital level

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Interview with Julia Parafita, project leader for data registries, medical direction, CHUV

To gain a better understanding of how the governance of medical registries (MRs) works at the university hospital level, *RA Watch* editor Séverine Méance spoke with Julia Parafita, the project leader for data registries at Lausanne University Hospital (CHUV).

CHUV is a huge source of health-related data. How is it organised internally to manage MRs?

MRs have existed for a long time at CHUV. The hospital started an inventory of its internal MRs following the first recommendations published in 2016 by the ANQ (Swiss National Association for Quality Development in Hospitals and Clinics), FMH (Swiss Medical Association), H+ (the association of Swiss hospitals), SAMS (Swiss Academy of Medical Sciences) and unimedsuisse (an association of university medicine in Switzerland). On 3 July 2019, an institutional directive called *Création et exploitation de registres de données cliniques au CHUV* (Creation and Operation of Clinical Data Registries at CHUV) was published (available on request). This directive describes the rules and principles that apply to MRs as well as the governance that should be put in place to manage them. To ensure the proper application of this directive at the hospital level, a project leader from the medical direction assists all registry managers and staff involved in registry operations. We have operated until now in a project mode and plan to move to a routine mode by the end of 2020. So far, the main aspects of the project have consisted of informing and training the teams of the different services at CHUV. We also connected with the ethics committee (EC) of Vaud to validate the newly developed regulation form that each registry manager has to fill out. In addition, we completed our organisation with a dedicated operational committee for biobanks and registries, which is internally called the COB (Comité opérationnel des biobanques et registres). It is like a control tower that reviews, approves, and records all registries. There are three persons involved in the COB and they meet twice a month: a legal representative, the research consent unit manager, and the project leader for data registries. Since the publication of the directive, the COB has already approved 66 registries (status as of 30 June 2020).

What types of registries are we talking about?

There are three types of registries: (1) clinical registries for following patients' clinical evolution and the quality of care, (2) research registries, and (3) mixed registries. The proportion of each category is illustrated

in **Figure 1**. There is a clear trend toward increasingly mixed registries to keep open the possibility of using data for future research.

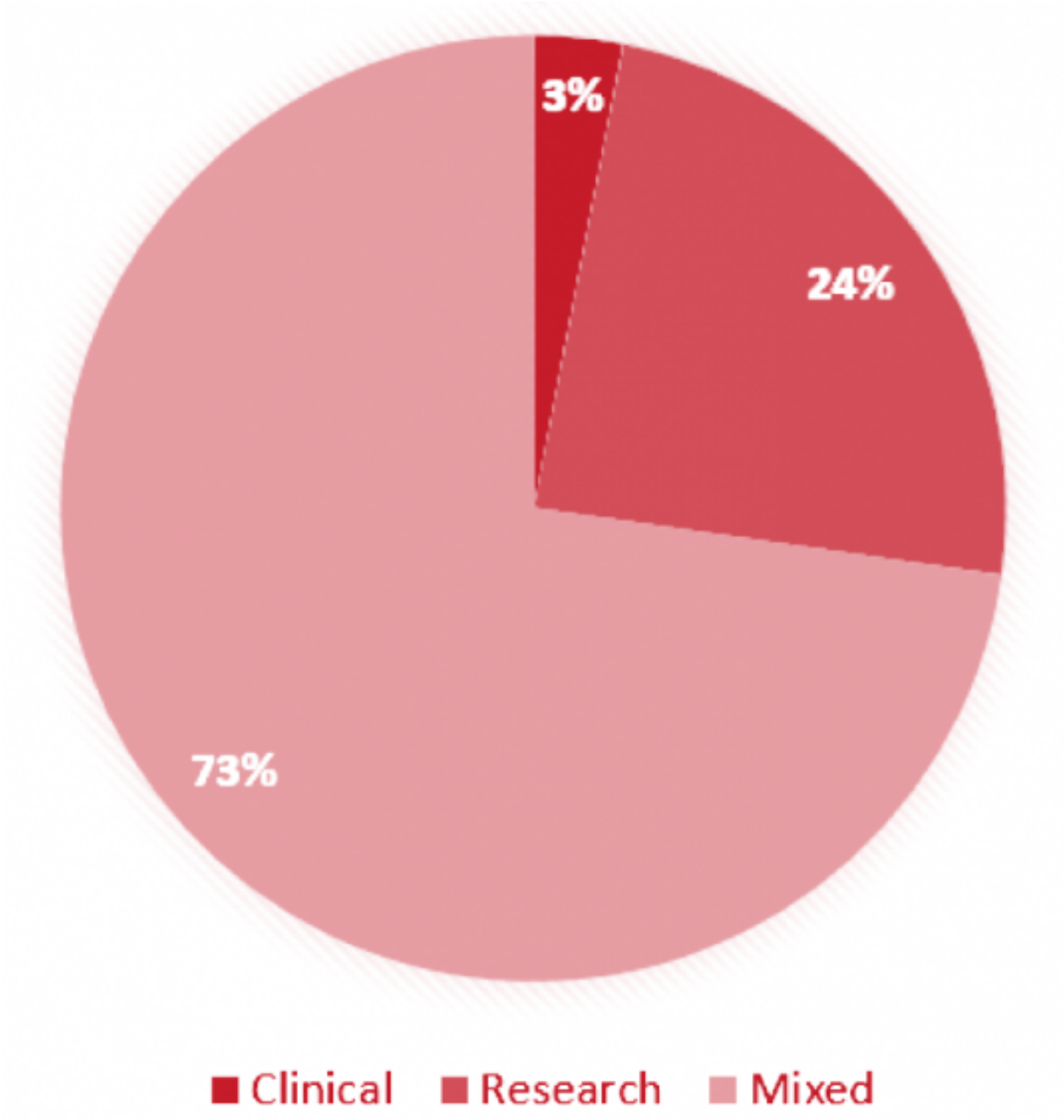

Figure 1: Registry categories at CHUV

A selection of active registries at CHUV with their date of creation:

2020: Registre EuroLVD (liver venous deprivation registry); Registre RegCOVID-19 (COVID-19 registry)

2018: Registre du Centre des tumeurs neuroendocrines (neuroendocrine cancer centre registry)

2017: Registre du Centre des tumeurs gynécologiques (gynecological cancer centre registry)

2016: Registre carcinose péritonéale (peritoneal carcinomatosis registry)

2015: Registre du Centre des Sarcomes (sarcomas centre registry)

2014: Registre de la Chirurgie viscérale complexe-MHS (complex visceral surgery, highly specialized medicine registry); Registre du Centre des tumeurs thoraciques (thoracic cancer centre registry); Registre du Centre de la Prostate (prostate cancer centre registry)

2012: Registre de la Filière Brûlés (burns registry); Registre du Centre Universitaire Romand de Chirurgie Thoracique (Romand university centre for thoracic surgery registry)

2010: Registre du Centre du sein (breast centre registry)

2008: Registre des patients blessés graves du CHUV (CHUV registry of severely injured patients)

2005: Registre des implants lausannois (Lausanne implants registry)

1997: Registre ganglions sentinelles pour mélanome (registry of sentinel lymph nodes in melanoma)

Could you describe the main steps a registry needs to take to be approved and the organisations involved?

Any new or existing registry at CHUV should take the following steps to comply with the institutional directive:

1. Notify the COB, which keeps an updated list of registries run at CHUV.
2. Fill out a regulation form describing the aim and inclusion criteria of the registry; how data are collected, transmitted, and used; registry governance; and so forth.
3. Define and document a quality control process to ensure data quality, protection, security, and

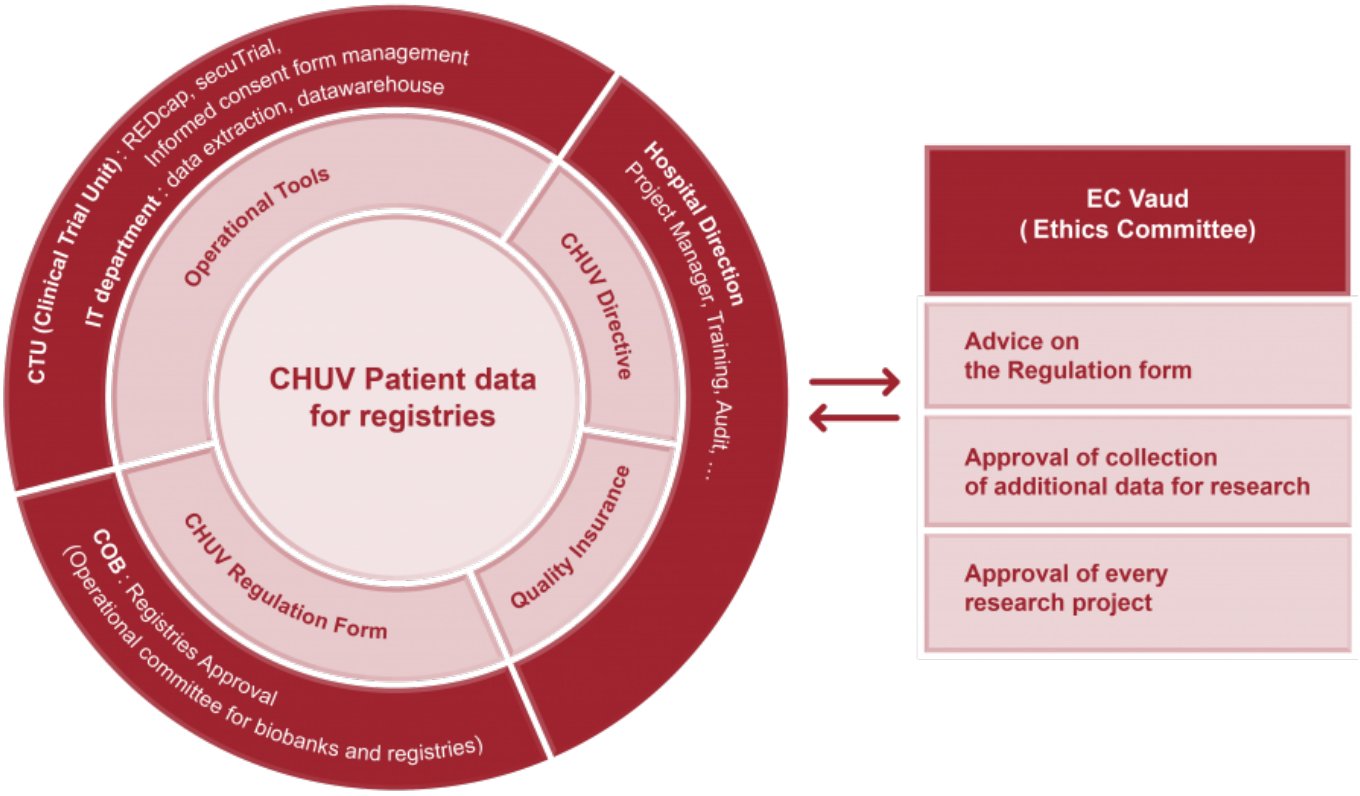

Figure 2: The registry process at CHUV and organisations involved