

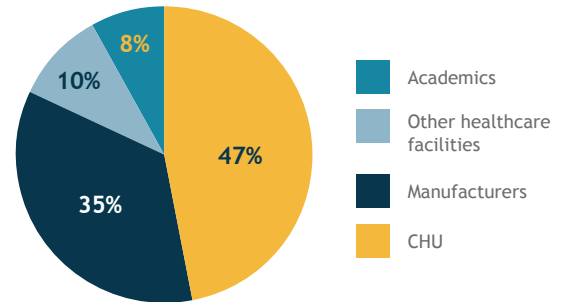
Clinical Trials: CHUs* as sponsors

SPONSORING IN FRANCE

Volume

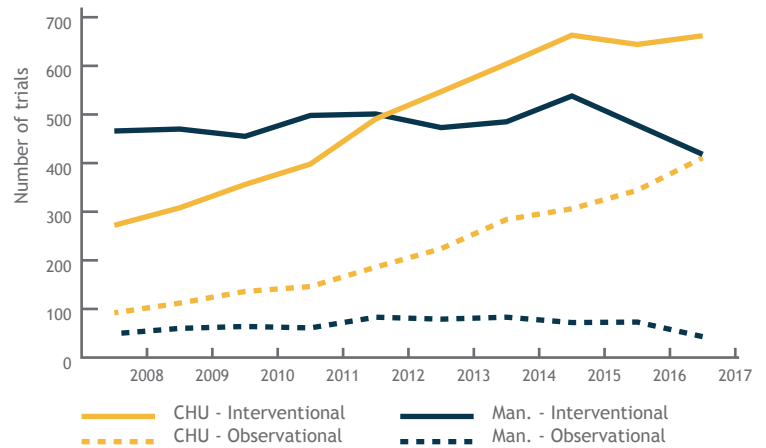
Over the 2008-2017 period, about 15,500 studies were opened in France. Out of these 15,500 studies, 5,450 were sponsored by manufacturers, 8,700 by healthcare facilities, among which 7,200 by CHUs. Over that period, the number of studies declared by CHUs in ClinicalTrials (CT) tripled, from 364 in 2008 to 1,073 in 2017. These 1,073 studies represent 55% of the studies started in France in 2017 and declared in CT.

Distribution of the 15,500 trials by type of sponsors between 2008 and 2017



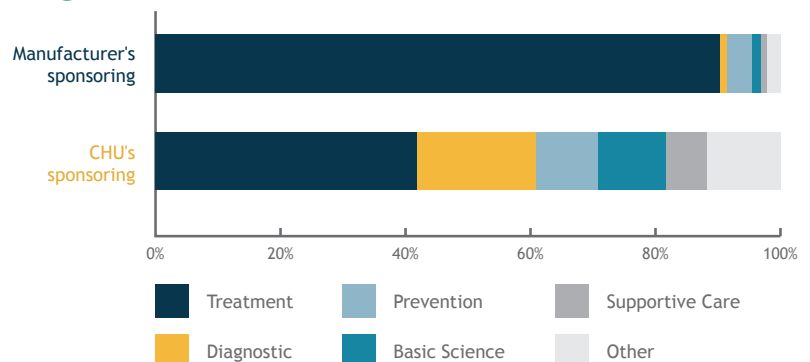
Growth

ClinicalTrials distinguishes between interventional studies and observational studies, interventional studies in CT being different from the regulatory definition in France. The total number of interventional studies sponsored by manufacturers and CHUs is almost the same over the last 10 years, but observed annual growths are different. The number of observational studies (cohorts, registers, ...) declared by CHUs kept increasing over the last 10 years.



From better understanding to better care

While 90% of manufacturers' clinical trials are drug studies, the spectrum of interventional clinical trials sponsored by CHUs is wide: treatments (42% among which more than 500 phase 1 or 2 studies), diagnostic studies (19%), and Basic Science, in particular translational studies.



Better prevention and better screening

CHUs carry out very wide studies with inclusion of thousands even tens of thousands of patients. For example, DEPISTREC (NCT02244450, generalized neonatal screening of severe combined immunodeficiencies), OXYNAT (NCT03078218, pulse oximetry systematic screening of critical congenital heart disease in new-borns), or DICI-VIH (NCT02127424, HIV screening in Emergency departments).

In the studies declared as observational in CT, are to be found many studies of follow-up of cohorts aiming at finding the prevalence, the incidence or determine the risk factors of diseases.

METHODOLOGY

Data from ClinicalTrials (July 2018). All the studies claiming at least a trial site investigator in France. Analysis and typology of the sponsors according to the declared sponsor. ClinicalTrials is an open access database by the U.S. National Library of Medicine. It lists clinical trials made in all countries, by all types of sponsors.

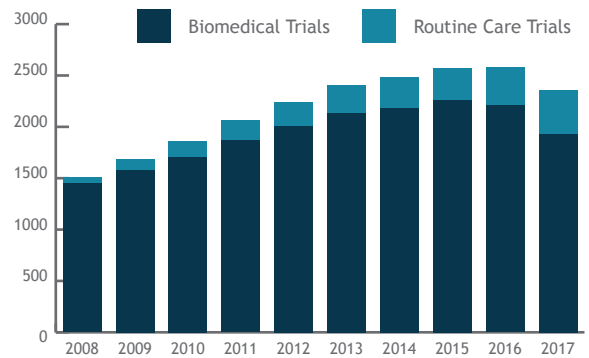
*The area of trial includes the 32 CHU-CHR. The term used throughout the document is CHU. CHU stands for Centre Hospitalier Universitaire (University Hospital Centre).

SPONSORING IN CHUs

Volume

In 2017, SIGREC counts 7,959 interventional studies sponsored by a CHU, active during the 2008-2017 period (with at least 1 patient included during the considered period). The number of active trials grew significantly between 2008 and 2014 and has remained stable since then (about 2,500 trials per year). The routine care trials represent 13% of the trials but their part is in constant growth. 3,728 trials are multicentre trials (47%), among which 233 are international trials.

Among these trials, 21% of drug trials (among which more than 550 phase 1 or 2 studies), 14% of medical device trials are to be found.



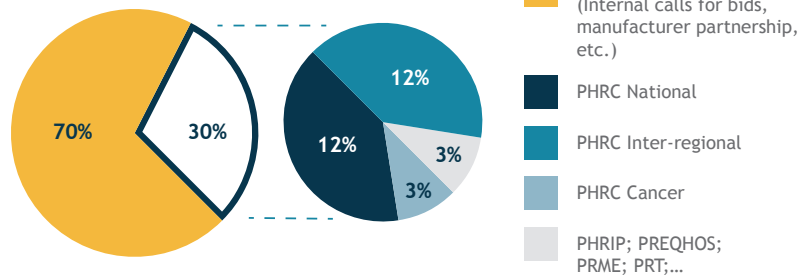
27%
of the trials have a
therapeutic
aim

14%
of the trials have a
diagnostic
aim

32% of the trials are
**Physiology or
Physiopathology studies,**
which again confirms the major role of CHUs
in the translational clinical trials.

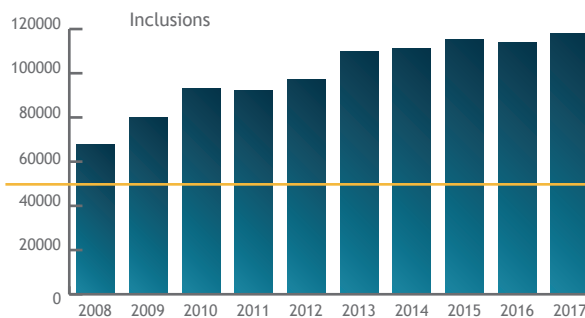
Financing

30% of the clinical trials sponsored by CHUs were financed by the DGOS, the remaining 70% were financed by other sources (ANR, EU, manufacturer, own funds, ...). The trials financed by the DGOS represent about half of the multi-center trials and about half of the inclusions carried out.



Inclusions

The number of inclusions carried out in trials sponsored by CHUs sharply grew between 2008 et 2013, then it stayed stable, with about 115,000 inclusions per year. These totals do not take into account the 18 big diagnostic trials with more than 5,000 patients that total to about 400,000 inclusions.

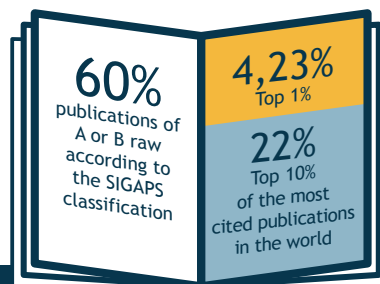


TIME OF INCLUSION



Scientific Impact

The trials sponsored by CHUs lead to publications in the most famous scientific journals:



1,400
publications

show the results of clinical trials sponsored by CHUs over the 2015-2017 period.

**Clinical trials are essential to advances in medical care.
They are necessary to better understand how diseases appear and develop,
and to improve patient care.**

METHODOLOGY

Scope: Interventional trials sponsored by the 32 CHUs/CHRs with at least one inclusion over the 2008-2017 period. Data extracted from the June 2018 export. The SIGREC software was rolled out in 2008 by the DGOS, thanks to MERRI financing. It is used to follow up the interventional trials sponsored by healthcare facilities.

