

Improvement in governance and regulatory functions: a prerequisite for progress in clinical research

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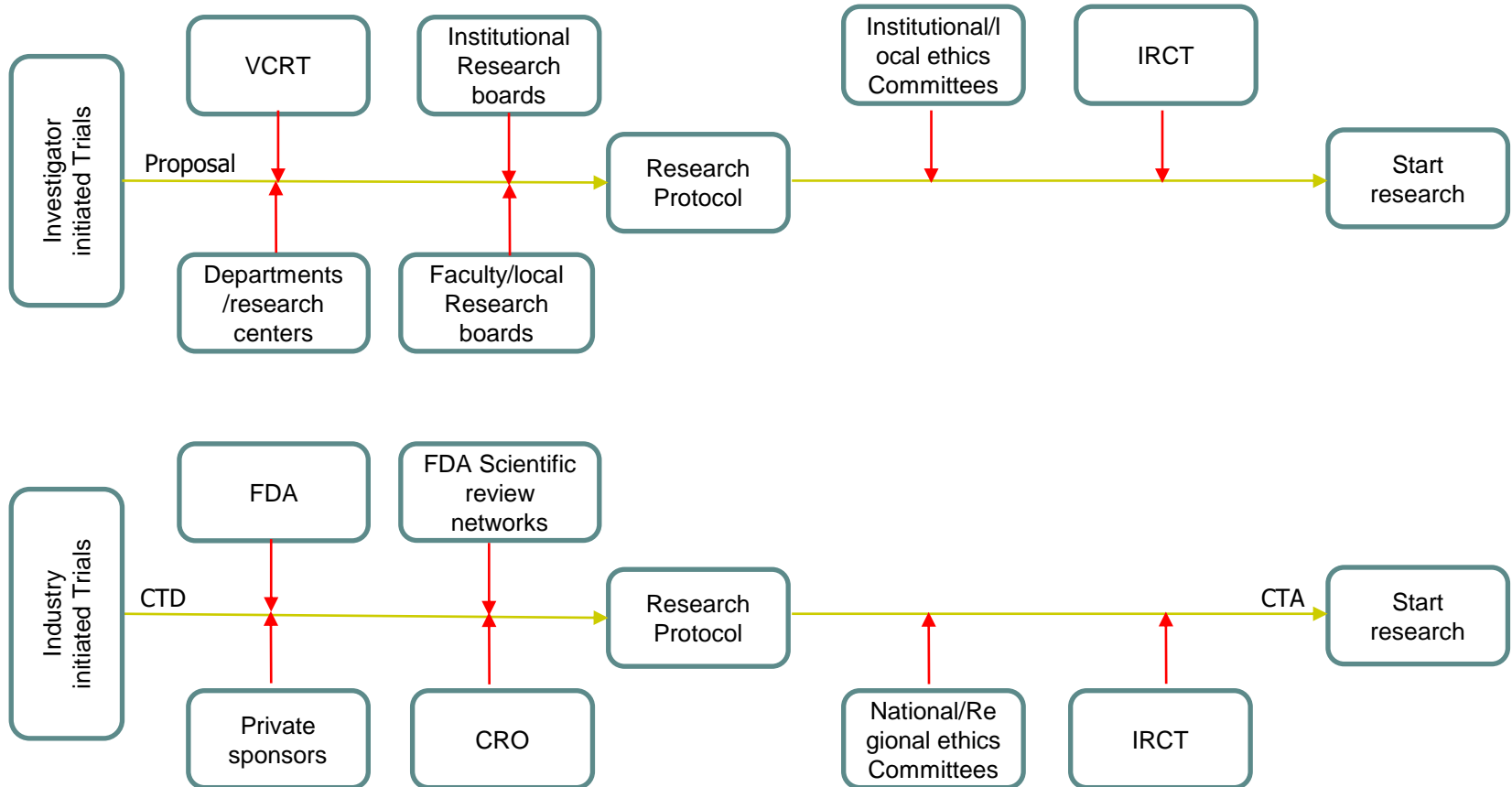
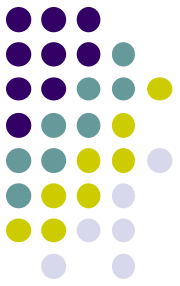
Manager, Iranian Registry of Clinical Trials (IRCT)

Head, IUMS Clinical Trial Centre (IUMS-CTC)



2016/03/03 09:41

Clinical trial governance/regulatory structures in Iran





National Ethics System for Medical Research

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سازمان اخلاق در پژوهش‌های زیست پزشکی
وزارت بهداشت، درمان و آموزش پزشکی

English

کارگروه وزارتی اخلاق در پژوهش

کمیته‌های اخلاق تابعه

آیین‌نامه‌ها

تخلفات پژوهشی

حیوانات آزمایشگاهی

منابع

ورود

جستجو

نام محقق

معرفی و تاریخچه

کارگروه‌های اخلاق در پژوهش مؤسسه/منطقه‌ای

کمیته‌های اخلاق در پژوهش‌های زیست پزشکی

کمیته اخلاق در کار با حیوانات آزمایشگاهی

کمیته ایمنی زیستی و استانداردهای آزمایشگاهی

درخواست تأسیس کمیته تخصصی

لیست مصوبات همه کمیته‌ها

جستجوی مصوبه اخلاق

یعنی الزام آزمایشگاه

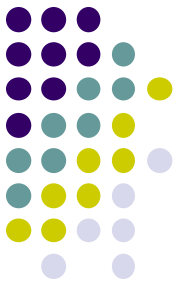
الزام بودن آزمایشگاه

جستجوی مصوبه

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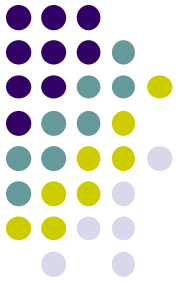
javascript:void(0)

Iran National Ethics System for Biomedical Research



- National Ethics Committee (1)
- Regional/Institutional Ethics Committees (129)
- Local/peripheral Ethics Committees (162)
- Ethic committees for animal research (52)
- Committees for Biosafety and laboratory standards (5)

Iranian Registry of Clinical Trials



IRCT

Iranian Registry of Clinical Trials - **Beta version**

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Iranian Registry
of Clinical Trials

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Welcome to Iranian Registry of Clinical Trials. This is a [Primary Registry in the WHO Registry Network](#) set up with the help from the Ministry of Health and Medical Education (MOHME) and hosted by [Iran University of Medical Sciences \(IUMS\)](#).

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Learning about trials

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37672 trials registered.

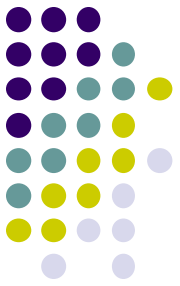
Search for Trials

Example: "Heart attack" AND "Tehran"

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Current WHO primary registries



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Data ▾

About WHO ▾

Primary registries

WHO Registry Criteria ▾

WHO data set ▾

Trial registration

Partner registries

Data providers

Registries factsheet

Registry network status update

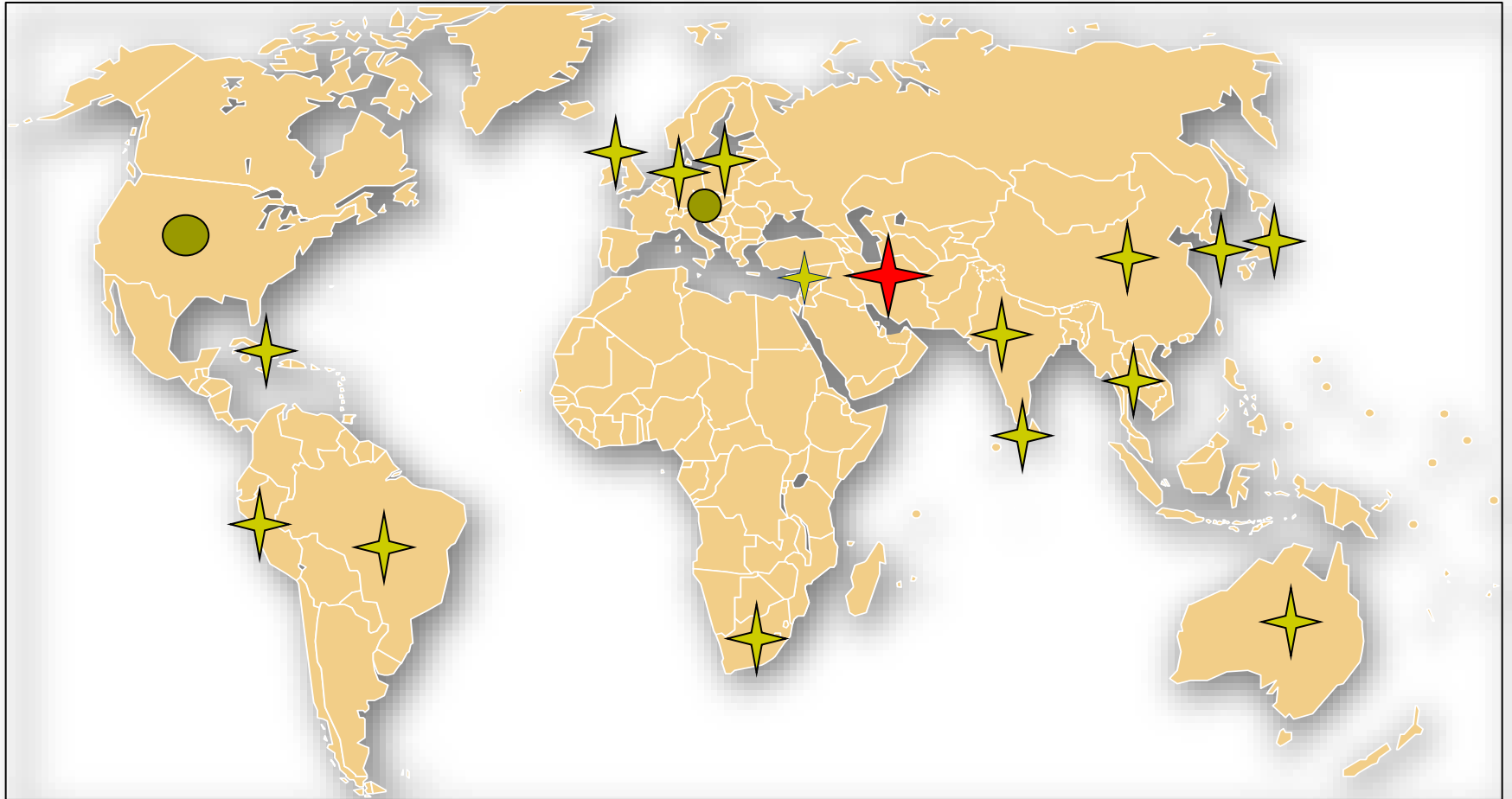
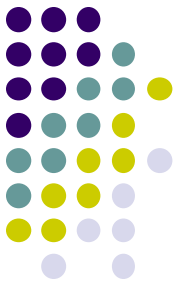
Orphanet collaboration

Process for becoming a Primary registry

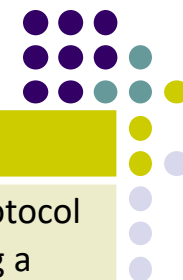
The registries that currently meet these criteria are:

Australian New Zealand Clinical Trials Registry (ANZCTR)	Profile (updated on 01-11-2022)	Website
Brazilian Clinical Trials Registry (ReBec)	Profile	Website
Chinese Clinical Trial Registry (ChiCTR)	Profile	Website
Clinical Research Information Service (CRIS), Republic of Korea	Profile	Website
Clinical Trials Registry - India (CTRI)	Profile (updated on 27-09-2023)	Website
Cuban Public Registry of Clinical Trials(RPCEC)	Profile (updated on 17-03-2023)	Website
EU Clinical Trials Register (EU-CTR)	Profile (updated on 27-01-2023)	Website
German Clinical Trials Register (DRKS)	Profile (updated on 12-06-2023)	Website
Iranian Registry of Clinical Trials (IRCT)	Profile (updated on 19-02-2023)	Website
ISRCTN	Profile (updated on 04-11-2022)	Website
International Traditional Medicine Clinical Trial Registry (ITMCTR)	Profile (updated on 29-03-2022)	Website
Japan Registry of Clinical Trials (jRCT)	Profile (updated on 26-10-2023)	Website
Lebanese Clinical Trials Registry (LBCTR)	Profile	Website
Thai Clinical Trials Registry (TCTR)	Profile	Website
Pan African Clinical Trial Registry (PACTR)	Profile	Website
Peruvian Clinical Trial Registry (REPEC)	Profile (updated on 10-02-2023)	Website
Sri Lanka Clinical Trials Registry (SLCTR)	Profile (updated on 07-07-2023)	Website

Primary Registry Network

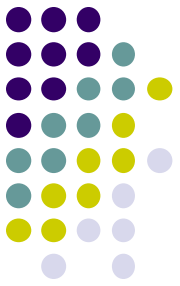


Summary of events in the path towards more transparency in the conduct of clinical trials



	USA	ICMJE	WHO	IRCT
Protocol registration	2000; registration became mandatory for trial protocols in the US	Sep 2004; simultaneous editorials in ICMJE journals asking for protocol registration, enforced within journals following ICMJE	Nov 2004; ICMJE initiative endorsed by WHO member states 2005; followed up ICMJE advice and started registration initiative by setting up ICTRP	4 th Dec 2008; started protocol registration by becoming a WHO primary registry (mandatory) 7 th April 2009; became data provider to ICTRP
Result and data sharing	2008; adding four components of results within 1 year of registration became law in the US	June 2017; Data sharing statement July 2018; sharing statement should accompany paper (enforced) Jan 2019; Data sharing plan should be declared at the time of registration (enforced)	2008; WHO discussion paper 2015; statement on public disclosure of trial results 2017; WHO recommends publication of summary results preferably within 1 year of completion day Jan 2019; enforced ICMJE policy on data sharing in WHO primary registries 2023; Discussions undergoing on TRDS expansion for summary results reporting	2008; summary results module were added (optional) Nov 2017; migration to The All new IRCT software Nov 2017; data sharing module were added (mandatory) Nov 2017; 4 components results module added. (capable of entering submitted results into review process) (optional)

Key dates



- 4th of December 2008 (IRCT became a primary register)
- 7th of April 2009 (IRCT became a data provider to ICTRP)
- Nov 2017 (The new software)



Iranian Registry of Clinical Trials

» English

خانه

37672 کارآزمایی ثبت شده

راهنمای جستجو

- چگونه جستجو کنیم
- چگونه خروجی جستجو را
پالایش کنیم
- چگونه نتایج را به همراه ببریم

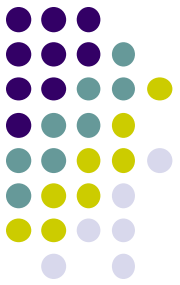
مثال: "سکته قلبی" AND "تهران"; جستجو

جستجوی کارآزمایی‌ها

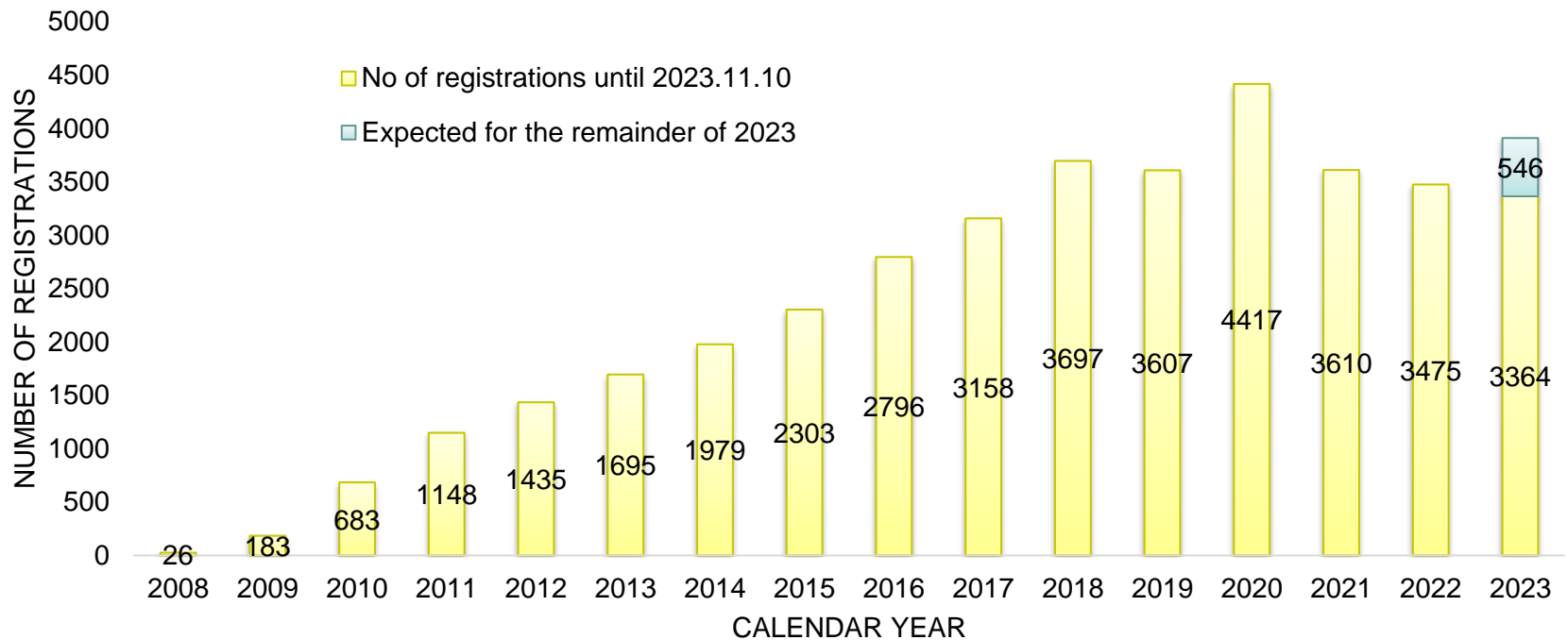
جستجوی پیشرفته

به مرکز بین المللی ثبت کارآزمایی های بالینی ایران، عضو مراکز بین المللی مورد تایید سازمان بهداشت جهانی خوش آمدید. این مرکز با حمایت معاونت تحقیقات و فناوری وزارت بهداشت، درمان و آموزش پزشکی راه اندازی شده و در حال حاضر میزبانی آن را دانشگاه علوم پزشکی ایران بر عهده دارد. این مرکز مورد تایید سازمان بهداشت جهانی است.

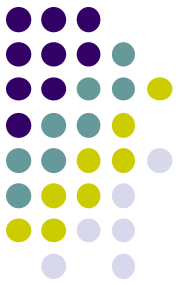
ادامه «



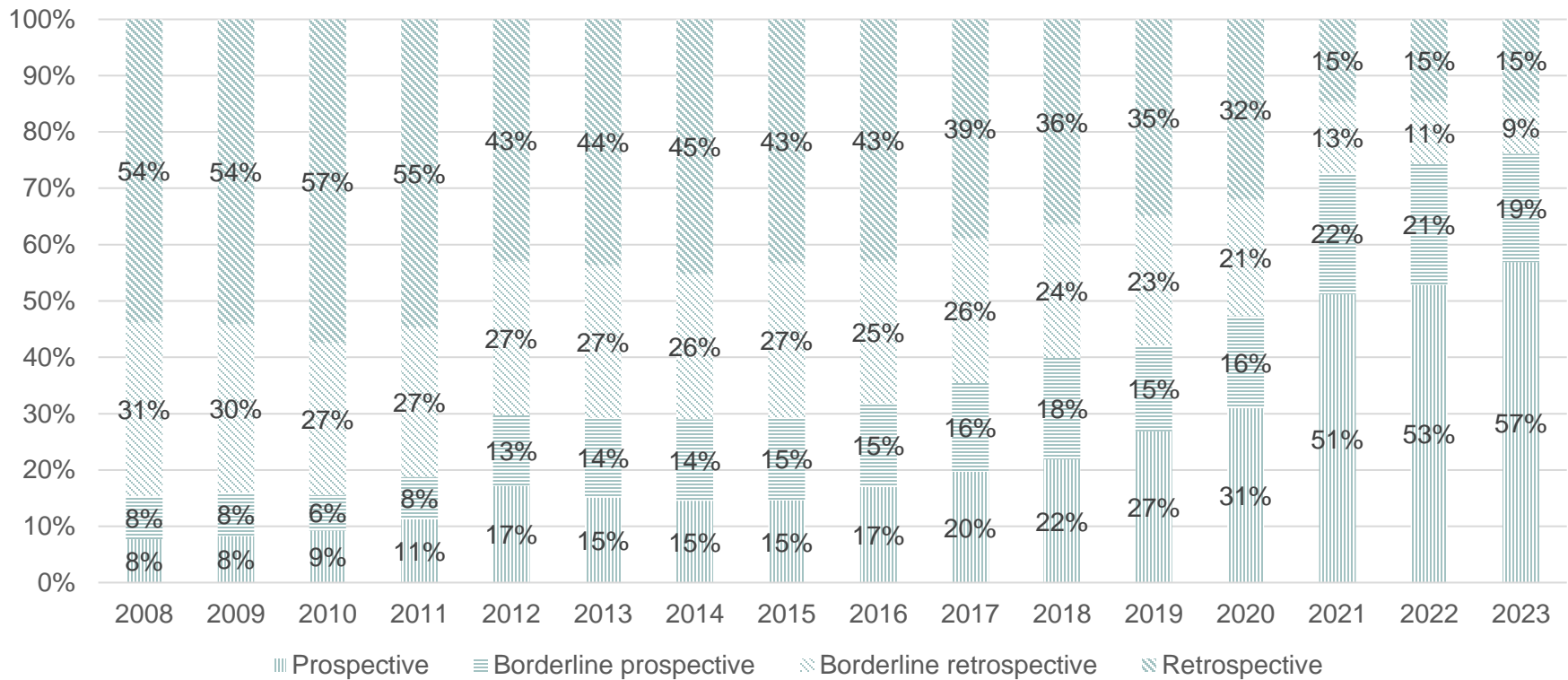
IRCT performance, number of registrations



Prospective versus retrospective registrations in IRCT over time



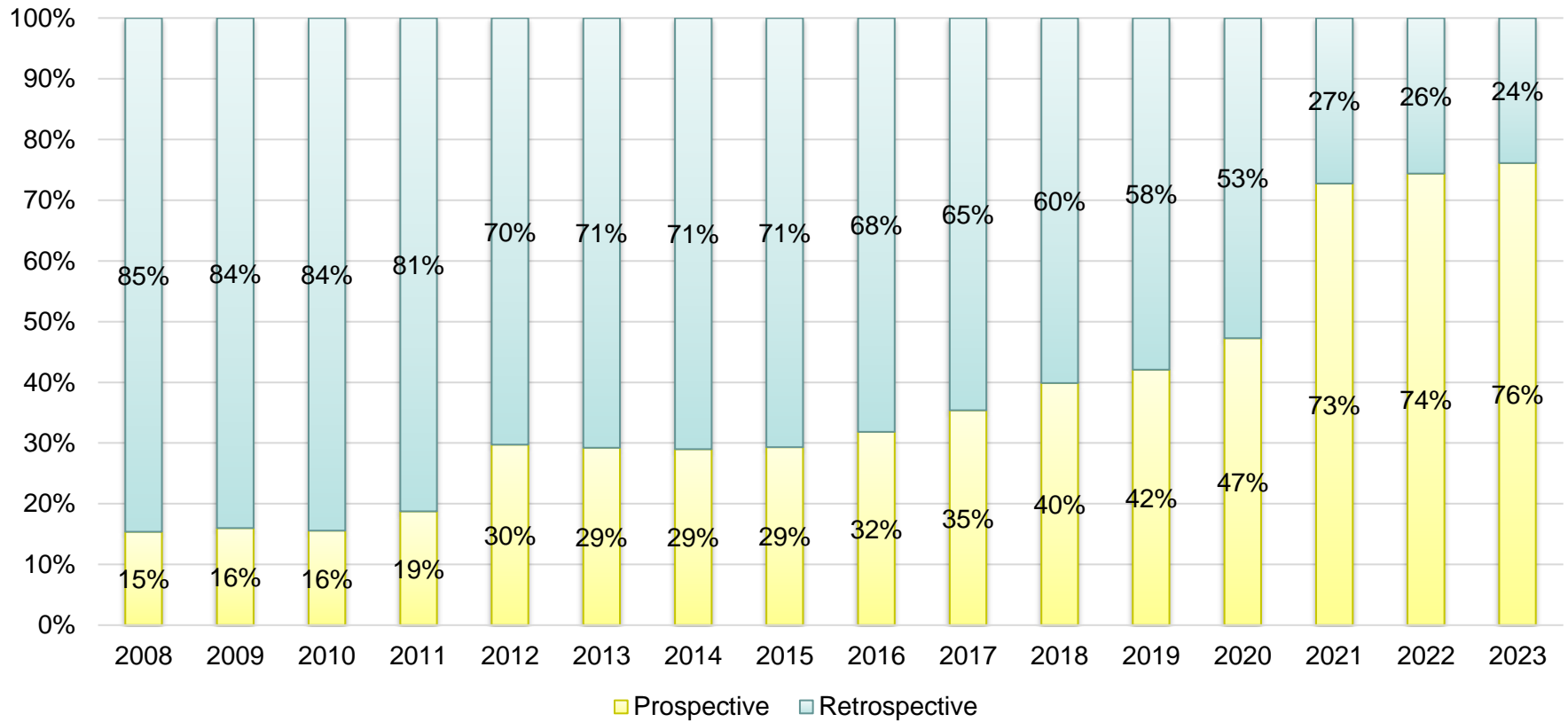
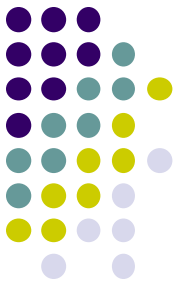
Prospective versus retrospective registration



Borderline prospective: registered within a month of start of recruitment

Borderline retrospective: registered after a month of start of recruitment and before trial recruitment ends

Prospective versus retrospective registrations in IRCT over time



IRCT Advance search



IRCT

Iranian Registry of Clinical Trials - **Beta version**

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Advanced search

(@scientific_title:COVID-19) AND @registration_date:[2022-01-01 TO 2022-12-31]

» [Basic search](#)

	Scientific title	▼	COVID-19	?	-	+			
AND	▼	Registration date	▼	2022-01-01	To	2022-12-31	?	-	+
AND	▼	In all fields	▼				?	-	+

[Search](#) or [add to search history](#)

Options	Add to builder	Query	Items found	Time
#1	Add	(@scientific_title:COVID-19) AND @registration_date:[2022-01-01 TO 2022-12-31]	144	1699607775

Organic link between Ethics and IRCT



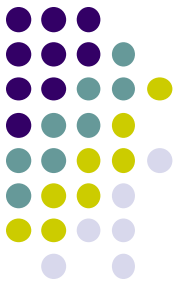
← → ↻ 🏠 🔒 https://www.irct.ir/admin/referee/trial/70116 90% ☆ 🔍 Search 📄 📧 📅 🔄 🌐 📄 ☰

Approval date 2023-05-01, ۱۴۰۲/۲/۱۲

Ethics committee reference number IR.SBMU.MSP.REC.1402.047

Validation result

Code	IR.SBMU.MSP.REC.1402.047
Type	2
Approval date	
Title - Persian	تاثیر درمان اس سیتالوپرام بر بهبود کیفیت زندگی و میزان بستری بیماران افسرده با نارسایی سیستولی قلب : یک مطالعه کار آزمایی بالینی دو سوکور تصادفی شده
Title - English	The effect of treatment withescitalopramonquality of life and hospitalization rate indepressed patients with systolic heart failure: a double blind randomized controlled trial
Pi First name	رکسانا
Pi Last name	صادقی
Pi 2 First name	رضا
Pi 2 Last name	میری
Student first name	فرناز
Student last name	پوررجب
Student 2 first name	
Student 3 last name	
Student 3 first name	
Student 3 last name	
Committee code	IR.SBMU.MSP.REC
Committee name - Pe...	دانشکده پزشکی - دانشگاه علوم پزشکی شهید بهشتی
Committee name - En...	School of Medicine - Shahid Beheshti University of Medical Sciences
Web link	http://ethics.research.ac.ir/EthicsProposalView.php?id=333289



- In summary, regulatory and governance structures are quite developed in Iran and we have moved forward with the rest of the developed world on this. These structures have facilitated the conduct of clinical trials in both investigator initiated and industry sponsored and initiated settings.

Thank you