



Digitalization, Registries and Decentralized Clinical Trials

FICOG
22Jun2026

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Strategic Site Solutions IQVIA



Agenda

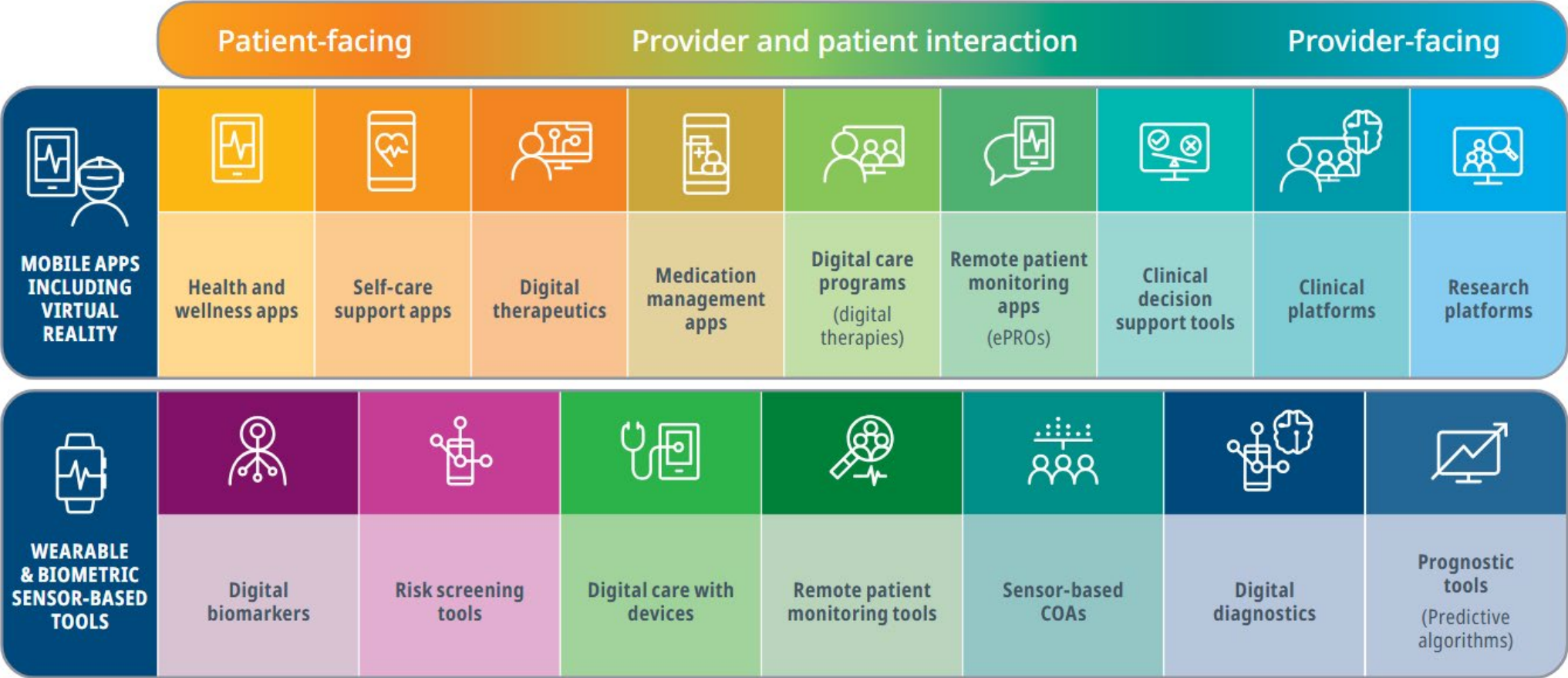
- + Digitalization
- + Registries
- + Decentralized Clinical Trials
 - Definition and elements
 - Regulations and Guidelines
 - IQVIA experience
- + Final remarks

Digitalization



The landscape of digital health innovation has expanded and diversified over the past few years

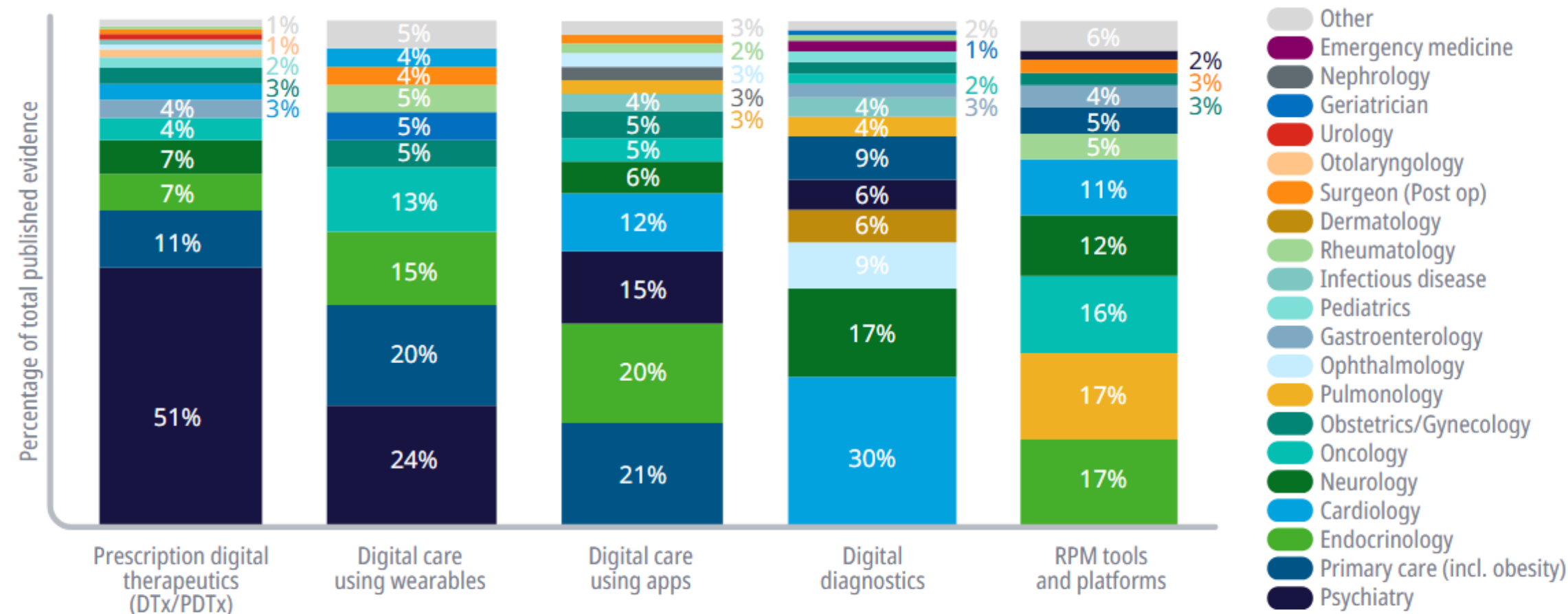
Segments of digital health and their use by stakeholder



Source: Adapted from: Digital Health Trends 2024: Implications for Research and Patient Care. IQVIA Institute for Human Data Science, December 2024.

<https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/digital-health-trends-2025>

Medical areas of application for digital products, based on published evidence



Source: IQVIA AppScript Clinical Evidence Database, May 2024.

Notes: Digital care includes all coached interventions. Bottom 10% in each category assigned to other for visualization purposes.

<https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/digital-health-trends-2025>

Digitalization: where Europe & Italy stand today



Europe

- **Regulatory submission & transparency are now strongly digital-by-design** through **CTIS**, which supports sponsor–authority interactions and provides a public portal for trial information.
- **Decentralized/digital trial elements are explicitly legitimized** at EU level via **ACT EU recommendations** (remote visits, remote monitoring, direct-to-patient IMP shipment, and eConsent as examples).
- **eConsent acceptance remains heterogeneous across Member States**, creating friction for multinational digital workflows even when EU-level principles exist.



Italy

- **Italy historically had a comparatively mature e-submission layer** for CTs via **AIFA's OsSC**, enabling digital submission flows to AIFA and Ethics Committees and interfacing with EU databases.
- **Italy's regulatory framework for decentralized elements has been strengthened** with AIFA guidelines focusing on simplification/decentralization and digital tools (including remote conduct and wearables).
- **Health-data infrastructure is being industrialized nationally** via **FSE 2.0/Ecosistema Dati Sanitari**, explicitly aiming at interoperability and secondary use (research/governance), using standards (e.g., HL7 FHIR) in the architecture.

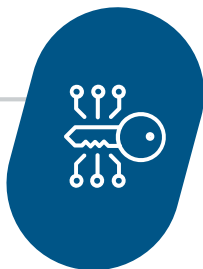
Interoperability with healthcare data

EHR/FSE, data standards, secondary use readiness



Strategic Objectives

- ❖ Nationwide adoption and uniformity
- ❖ Single access point to SSN services (cross-region)
- ❖ Data-driven ecosystem for clinicians
- ❖ Support prevention, care, and healthcare planning



Key Transformation Pillars

- ❑ Standardization of data, services, UX, and portability
- ❑ Interoperability across regions (HL7 FHIR & CDA)
- ❑ Shift from documents: structured data enable secondary use (research & governance)



Distributed model: Regional + Central systems

- Gateway validates standards and ensures interoperability
- Health Data Ecosystem (EDS) manages and shares data
- Integration with telemedicine platforms



Value and Impact

- Continuity of care across regions
- Improved clinical decision-making and personalization
- Strong foundation for digital health and research

Registries



Real-world data (RWD) and registries

Definition and key pillars

RWD and registries: structured, continuous, digital data collection systems embedded in routine clinical care (outside traditional trials), which can then be reused for research



Registries already collect patient-level data electronically



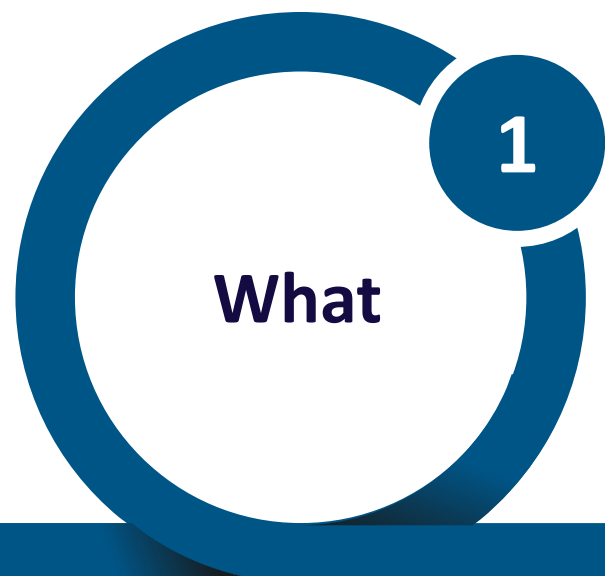
Registries follow defined data standards and workflows



Registries can cover entire treated populations

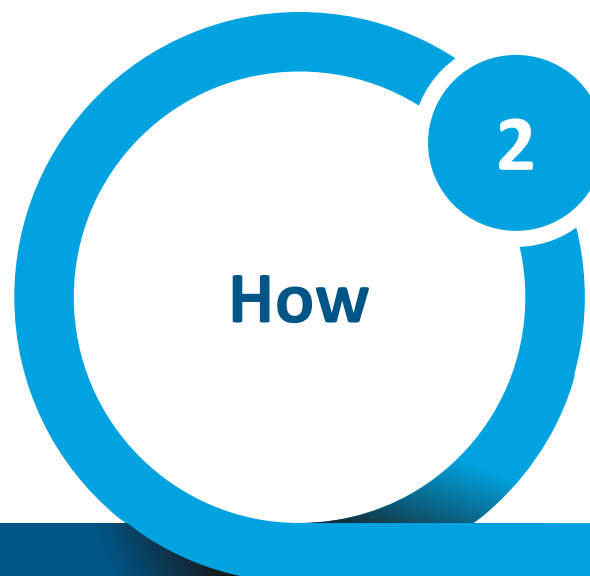
National registries

Strong, national, mandatory registry system



Italy is one of the few countries where:

- For certain reimbursed/innovative drugs, physicians must enter data into national registries
- Pharmacists also enter dispensing data
- Regional authorities ensure data quality control



This creates:

- Near-complete population coverage (not sample-based)
- Standardized datasets across regions
- Real-time (or near) data availability
- High compliance (because it is tied to reimbursement)



- Every treated patient becomes part of a structured digital dataset
- Data is not “collected for research” but is ready to be reused for research

[AIFA Monitoring Registries Platform](#) | [HMA-EMA Catalogues of real-world data sources and studies](#)

Decentralized Clinical Trials





Definition and elements



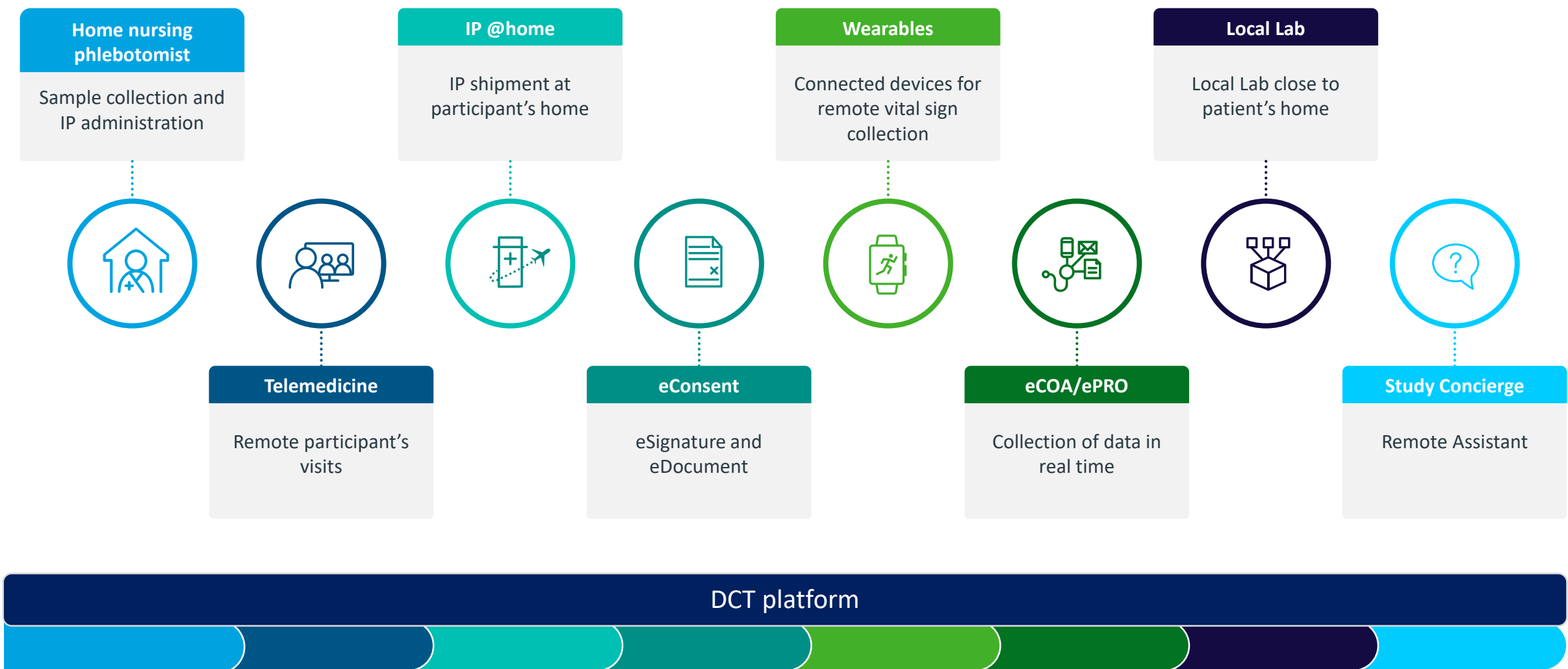
Decentralized Clinical Trials (DCT) are defined as:

Any trial that leverages **technology and specialized services** to engage participants in the community and facilitate patient-centric care, including:

- remote pre-screening,
- telemedicine visits,
- at-home treatment, or mobile research nurses and staff.

This approach aims to **bring the patient voice** into the trial, **reduce the burden** on sites and patients, and increase representative participation by expanding traditional site boundaries to deliver **a more personalized trial experience**.

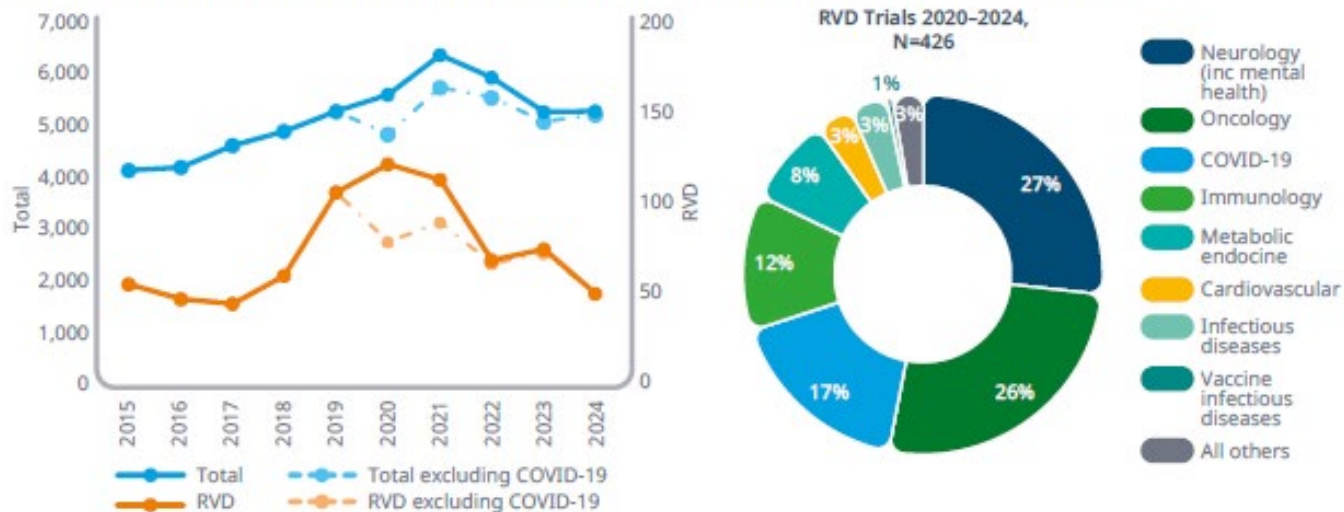
DCT elements



Industry trends and attracting investment in Clinical Research

Impact of DCT in Pharmaceutical Industry

Exhibit 69: Trial starts for all trials and remote, virtual or decentralized trials (RVD), 2015–2024



Source: Citeline Trialstrove, Jan 2025; IQVIA Institute, Jan 2025.

The level of remote, virtual or decentralized **returned to pre-pandemic levels**, indicating that untapped opportunities remain.

RVD trials were most prominent in **neurology** (accounting for 27%) of DCT trials, **oncology** (26%), and COVID-19 (17%), followed by **immunology** (12%); notably **oncology studies are more hybrid designs** with remote portions while retaining in-person aspects of patient treatment.

Decentralized Clinical Trials can be an operational solution which can address low patient recruitment rates, proving to expand patient pools, improve recruitment and retention, and reduce burdens in logistics and costs.

Company investments could be addressed towards countries with **adoption of DCT models and with high healthcare system digital maturity**.

<https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/global-trends-in-r-and-d-2025/iqvia-institute-rd-trends-2025-forweb.pdf>

<https://www.iqvia.com/library/white-papers/attracting-investment-in-clinical-development>



Regulations and Guidelines

EMA Recommendation Paper on Decentralized Clinical Trials

Version 02, 01 October 2025

Informed Consent

- Remote consent is allowed ensuring participant understanding, identity verification, and data security
- Electronic signatures are accepted according to national requirements
- Participants should receive copies of signed consent forms

Trial Procedures at Home

- Home procedures must be safe, feasible, and performed by qualified individuals
- Training and support for participants and site are crucial
- Insurance/indemnity must cover home-based procedures

Monitoring

- Monitoring strategies should address risks of decentralised processes
- Centralised and remote monitoring are possible, with confidentiality and security safeguards.



Oversight & Responsibilities

- Clear definition of roles
- Delegation of tasks must be documented
- Effective communication and training

IMP Delivery & Administration at Home

- Risk assessment is mandatory for home delivery/administration of IMPs
- Delivery logistics, storage, and administration procedures must be robust and compliant
- Personal data protection during delivery is required

Data Collection & Management

- Data flow diagrams and robust validation of digital tools are recommended
- GDPR compliance and secure data handling are mandatory
- Investigators must have continuous access to source data

General Considerations and National Provisions Overview

- Investigators/healthcare professionals **should be involved in the design, development, and implementation** of the clinical trial
- Any transfer of **burden of trial related procedures to trial participants and/or investigators** should be weighed against the potential benefits of using DCT elements in the clinical trial
- The **risk benefit assessment** as well as any risk mitigation action taken should be clearly described in the clinical trial protocol or other protocol related document

Please see relevant footnotes for responses marked with an asterisk. A footnote may be raised even though no response is given.	AT	BE	BG	CY	CZ	DE	DK	EE	EL	ES	FI	FR	HR	HU	IE	IS	IT	LI	LT	LU	LV	MT	NL	NO	PL	PT	RO	SE	SI	SK	
The delivery of IMPs from sponsor/site, in relation to RP section 4.																															
Q1: Is it possible to deliver IMPs directly to trial participants from their associated trial site?	No *	No *	Yes *	No *	Yes *	Yes *	Yes *	Yes *	*	Yes *	Yes *	*	No *	Yes *	Yes *		Yes *		Yes *	Yes *	Yes *	Yes *	Yes *	Yes *	Yes *	Yes *	Yes *	Yes *	Yes *	No *	Yes *
Q2: Is it possible to deliver IMPs directly to trial participants from the pharmacy associated with the trial site?	No *	No *	Yes *	No *	Yes *	Yes *	Yes *	No *	*	Yes *	Yes *	*	No *	Yes *	Yes *		Yes *		No *	No *	Yes *	Yes *	Yes *	Yes *	Yes *	Yes *	No *	Yes *	Yes *	*	Yes *
Q3: Is it possible to deliver IMPs directly to trial participants from any delegated pharmacy?	No *	No *	No *	No *	Yes *	Yes *	Yes *	No *	No *	No *	No *	No *	No *	Yes *	Yes *	Yes *	Yes *		No *	No *	Yes *	No *	Yes *	Yes *	Yes *	No *	No *	Yes *	No *	No *	Yes *
Q4: Is it possible to deliver IMPs directly to trial participants from the IMP manufacturer with a MIA license?	No *	No *	No *	No *	No *	No *	*	No *	No *	No *	No *	No *	No *	Yes *	No *	No *	Yes *		No *	No *	Yes *	No *	No *	No *	No *	Yes *	No *	No *	No *	No *	No *
Q5: Is it possible to deliver IMPs directly to trial participants from the trial sponsor (sponsors intermediaries/deposits)? If yes, footnote states if a licence is required for the depot to carry out this task and how to obtain this licence.	No *	No *	No *	No *	No *	No *	*	No *	No *	No *	No *	No *	No *	No *	No *	Yes *	Yes *		No *	No *	Yes *	No *	No *	No *	No *	No *	Yes *	No *	No *	*	No *
The shipment of IMPs from sponsor/site across borders within the EU, in relation to RP section 4.																															
Q6: Is it possible to deliver IMPs directly to trial participants from e.g. distribution/manufacturing/pharmacy licence holders located in other EU MSs if legally allowed to carry out this task in the country of origin?	No *	No *	No *	No *	No *	No *	Yes *	No *	No *	No *	No *	No *	No *	No *	Yes *	Yes *	Yes *		No *	No *	Yes *	No *	No *	No *	No *	No *	Yes *	No *	No *	No *	No *
Q7: Is it possible to deliver IMPs directly to investigators from e.g. distribution/manufacturing/pharmacy licence holders located in other EU MSs if legally allowed to carry out this task in the country of origin?	Yes *	Yes *	No *	*	Yes *	Yes *	Yes *	Yes *	Yes *	No *	No *	Yes *	Yes *	Yes *	Yes *	Yes *	*		Yes *	No *	Yes *	Yes *	Yes *	Yes *	Yes *	Yes *	Yes *	No *	No *	Yes *	Yes *
Labelling of IMP, in relation to RP section 4.																															
Q8: Is it possible for any delegated pharmacy to label IMP or is this restricted to the pharmacy associated with the trial site?	No *	No *	No *	*	Yes *	*	Yes *	*	Yes *	Yes *	No *	No *	No *	Yes *	Yes *	Yes *	Yes *	Yes *	Yes *	Yes *	No *	No *	No *	No *	No *	No *	No *	Yes *	*	Yes *	Yes *

Please see relevant footnotes for responses marked with an asterisk. A footnote may be raised even though no response is given.	AT	BE	BG	CY	CZ	DE	DK	EE	EL	ES	FI	FR	HR	HU	IE	IS	IT	LI	LT	LU	LV	MT	NL	NO	PL	PT	RO	SE	SI	SK	
The shipment and hand-out of IMPs from pharmacies. This is currently not included in the recommendation paper but may be relevant in next version of the RP.																															
Q9: Is it possible to deliver or dispense authorised IMPs directly to trial participants from pharmacies not associated with the clinical trial sites? This include authorised investigational medicinal products <u>not</u> used according to their SmPC.	Yes *	No *	No	No	No *	Yes	Yes *	No *	No *	No *	No *	No *	No *	Yes	Yes *		Yes *		No *	No	Yes	No	Yes *	Yes *	No *	No *	No *	Yes *	*	Yes *	
Q10: Is it possible to deliver or dispense non-authorised IMPs directly to trial participants from pharmacies not associated with the clinical trial sites?	No	No *	No	No	No *	Yes	No*	No	No	No	No	No	No	Yes	No		Yes *		No *	No		No	Yes *	Yes *	No *	No *	No *	Yes *	*	Yes *	
The eConsent process, in relation to RP section 3.																															
Q11: Is a physical face to face meeting between the trial participant and the PI or a member of the research team always mandatory during the consent procedure (even if the rest is conducted remotely)?	No	No	Yes *	Yes	No *	Yes *	No*	*	*	No *	No *	No *	Yes *	Yes *	No		No *		No	Yes	No	No	No *	No *	No *	Yes *	No	No	*	No	
Q12: Is it possible to use electronic signatures instead of wet ink? If yes, please specify in the footnotes which eIDAS category is expected for the electronic signature.	Yes *	Yes *	Yes *	Yes	Yes *	Yes *	Yes *	Yes *	*	Yes *	Yes *	Yes *	Yes *	Yes *	Yes *	Yes *	Yes *		Yes *	Yes *	No	Yes *	Yes	Yes *	Yes *	Yes *	Yes *	Yes *	Yes *	Yes *	
Trial participant oversight and home visits, in relation to RP section 2 and 5.																															
Q13: Is it possible for the PI to delegate tasks under their responsibility to a qualified (for the delegated task) external healthcare provider?	Yes	Yes *	Yes *	*	Yes *	Yes *	Yes	Yes *	Yes *	Yes *	Yes *	Yes *	Yes *	Yes *	Yes *	Yes *	Yes *		Yes *	Yes *	No	Yes	Yes	Yes *	Yes *	Yes *	Yes *	Yes *	Yes *	Yes *	Yes *
Q14: Certain tasks/procedures carried out at home may require supervision of the investigator (a physician). Is it allowed for the physician to supervise remotely?	Yes	Yes *	Yes *	*	No *	Yes *	Yes	*	*	*	Yes *	*	Yes *	Yes *	Yes *	Yes *	Yes *		Yes	Yes *	Yes *	*	Yes	Yes *	Yes *	Yes *	No *	Yes *	*	No	
Trial Monitoring using remote access to source data, in relation to RP paper section 7																															
Q15: Is remote access to the medical records allowed by the monitor or auditor?	Yes *	No *	Yes *	*	Yes *	Yes *	Yes *	*	No	*	Yes	Yes *	No *	Yes *	Yes *	Yes *	Yes *		Yes *	Yes *	No	*	Yes	Yes *	*	*	Yes *	No	No	No *	N

Determina AIFA 2024/424

GU Serie Generale n.194 del 20-08-2024

Compensation for Lost Earnings

Criteria and methods for compensation must be detailed in the trial **contract and ICFs**

Reimbursement to Patient/Cargiver

Participants/Cargivers can be reimbursed for travel, accommodation, and meal expenses incurred to visit the trial site

Use of Third-Party Service Providers

Responsibilities and roles of **sponsors, sites, and service providers** must be clearly defined

Direct Delivery of IMPs

IMPs can be delivered **directly to participants' homes** by hospital pharmacies, delegated territorial pharmacies, or service providers

Cost Allocation

Sponsors are responsible for **IMPs, AxMPs and necessary materials costs**, ensuring no additional financial burden on participants or public finances

Clinical Trials in Non-Hospital Settings

Trials can be conducted in **non-hospital settings**



Goal

The guideline aims to **clarify organizational aspects of clinical trials** in Italy, ensuring compliance with EU regulations and **facilitating the use of decentralized elements**

Decentralization and GCP (E6) R3 updates

Glossary



Updated some definitions to adapt for clinical trial operations in decentralized settings:

- Data Acquisition Toll (DAT)
- Direct Access
- Informed Consent
- Investigator Site
- Metadata
- Source Record

Principles



7. Proportionate Measures: Trial processes should be proportionate to the risks to participants and the importance of the data collected

9. Reliable Results: Trials should generate reliable results

10. Clear Roles and Responsibilities: Roles and responsibilities in clinical trials should be clear and documented

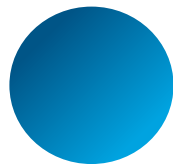
Annex 2



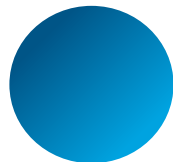
DCTs defined as trial-related activities conducted **outside the investigator's location**

- trial visits conducted at participant's home
- local healthcare sites
- mobile medical units
- data acquisition performed remotely using digital health technologies (DHTs)

Other applicable Guidelines and Regulations

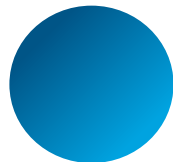


AICRO plus - Studi Clinici Decentralizzati nei Clinical Trial Center Ospedalieri Italiani, October 2025



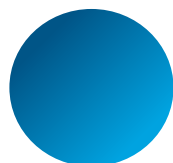
Guideline on Computerized Systems and Electronic Data in Clinical Trials, 9 March 2023

https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/guideline-computerised-systems-electronic-data-clinical-trials_en.pdf



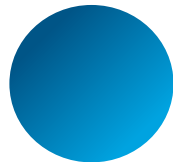
Rapporto ISTISAN 22/4 IT - Decentralized Clinical Trial e telemedicina: nuovo approccio alla sperimentazione clinica per facilitare il paziente e velocizzare la ricerca, Mar 2022

https://www.iss.it/-/rapporti_istisan_22_4_it



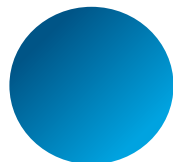
Implementazione degli Studi Clinici Decentralizzati in Italia: perché e come?, June 2022

<https://www.tendenzenueve.it/2022/07/28/tendenze-nuove-numero-speciale-1-2022-volume-completo/>



Medical Device Regulation (MDR) EU 2017/745 <http://data.europa.eu/eli/reg/2017/745/oj>

In Vitro Diagnostic Regulation (IVDR) EU no 2017/746 <http://data.europa.eu/eli/reg/2017/746/oj>



EUCTR 2014/536, 16 April 2014 <https://eur-lex.europa.eu/legal-content/IT/TXT/PDF/?uri=CELEX:02014R0536-20221205>

Regulation (EU) 2016/679 (General Data Protection Regulation), 4 May 2016 <https://gdpr-info.eu/>



IQVIA experience



IQVIA

Decentralized Trials Experience



Over 116,501
active
participants

2,500+

Clinicians who've
provided
study support, globally



75+

Countries
served
worldwide

Dedicated
operational
site and
participant
support



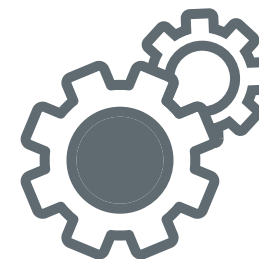
76 Indications
across **11** Therapeutic areas
including:

- Vaccines & therapies
- Oncology
- CNS & Psychiatry
- Diabetes
- Respiratory
- Dermatology
- Allergies
- Nephrology
- Endocrine
- Rheumatology
- GI

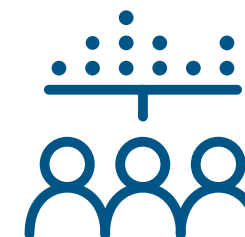


IQVIA DCT Program

achieved
GDPR
Validation
Compliance



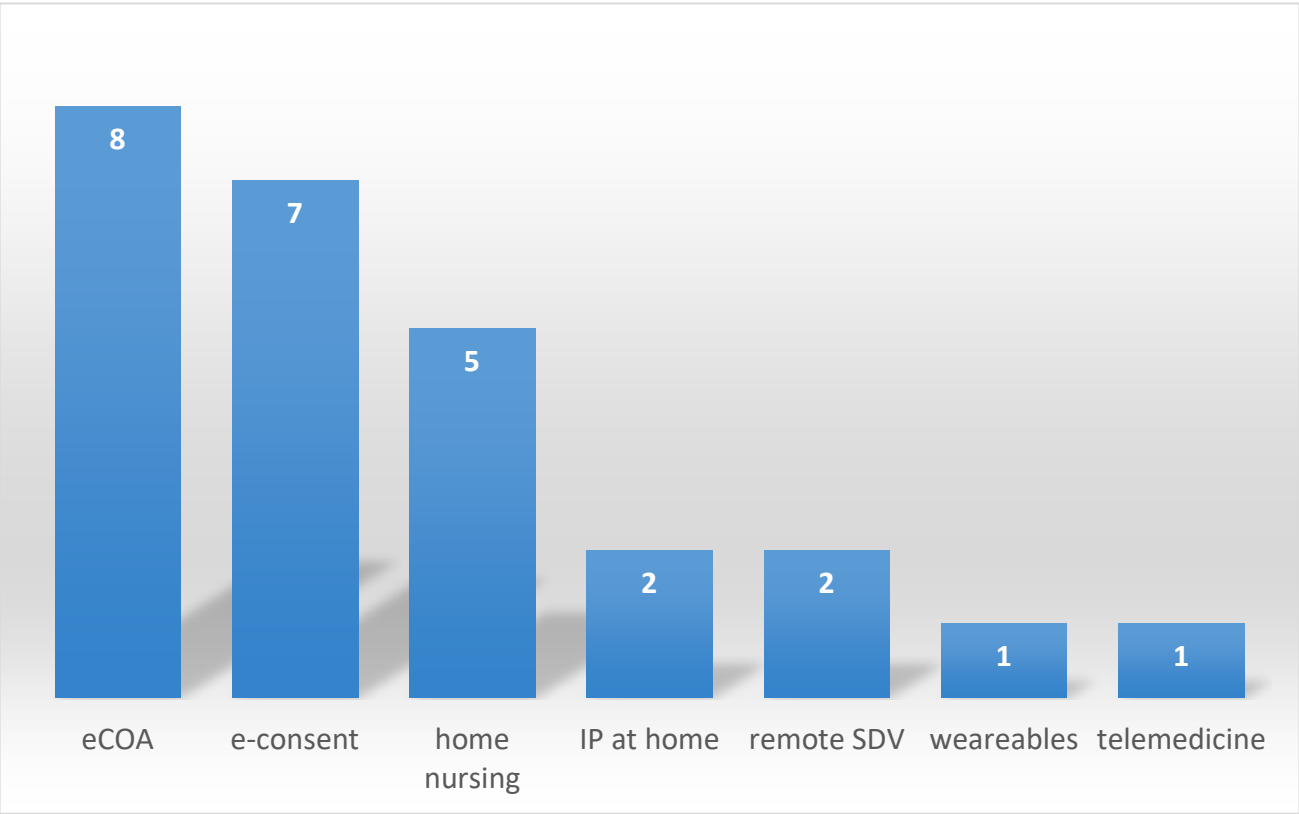
550+
Active trials
underway



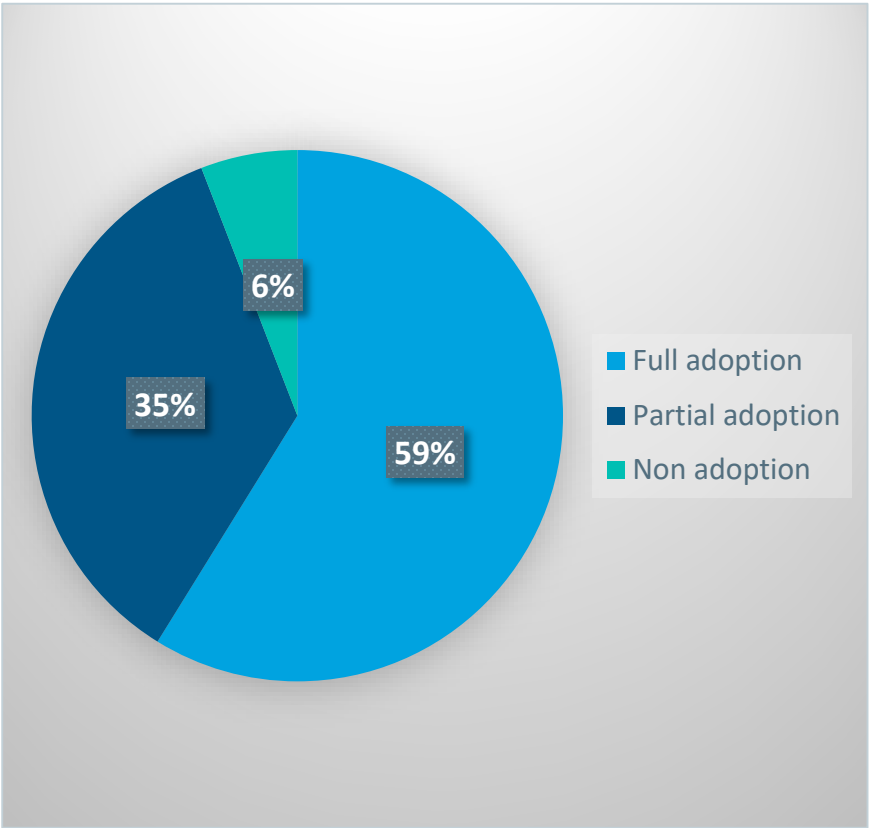
DCT and adoption in Italy 1/2

Survey results done in 2026 – sample 17 trials ph1-3b

DCT Elements approved by CET and used at site

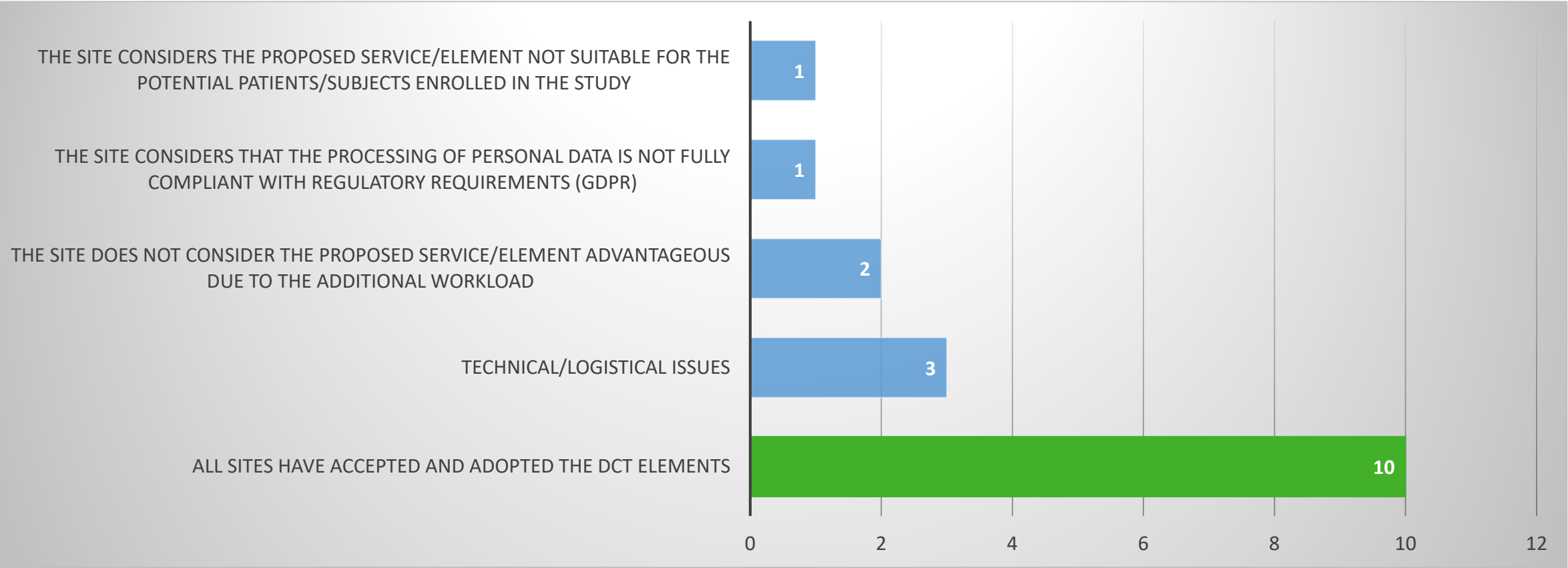


DCT Elements adoption by sites



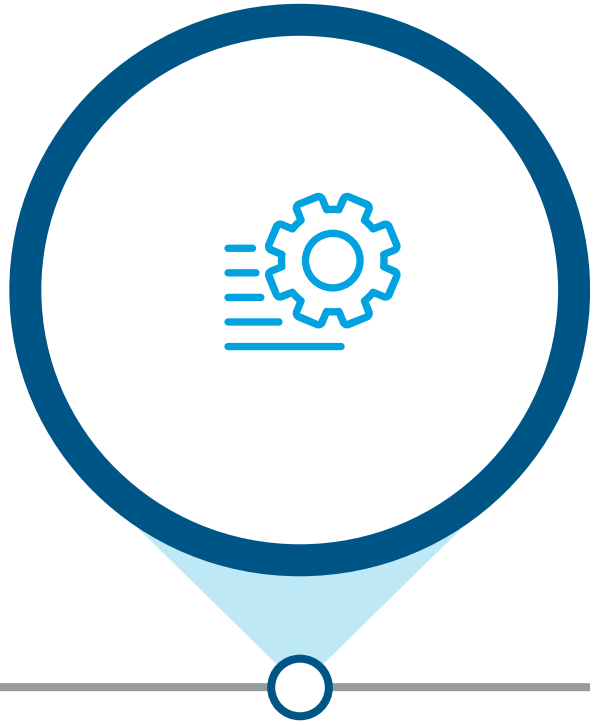
DCT and adoption in Italy 2/2

Site-Specific reasons for non-adoption



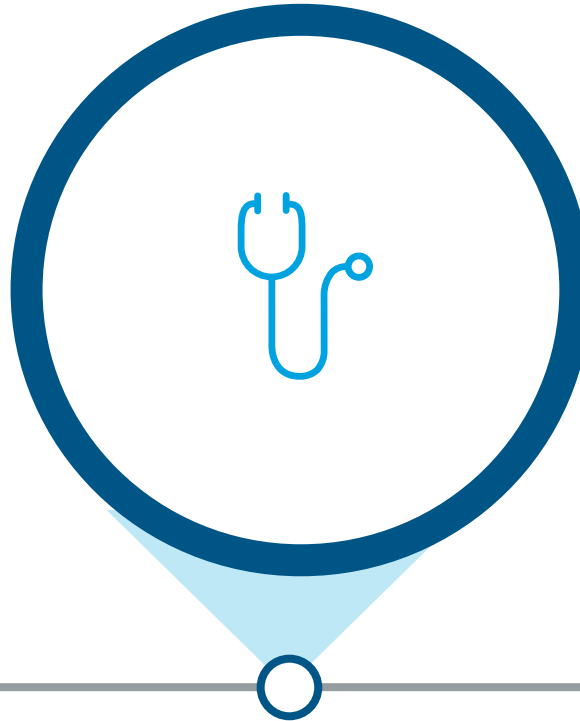
Privacy and PI oversight concerns clarified during start up stage

DCTs across EU Countries



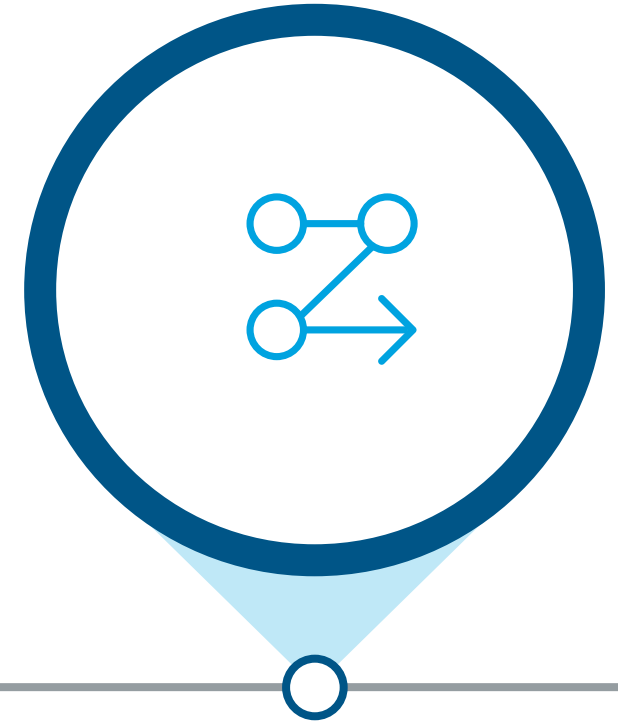
Widely diffuse elements

- ePROs
- Home Nursing
- Telemedicine
- Wearables
- eConsent



Adoption

- Limited across EU Countries



Challenges

- Local regulations
- Concerns on external resources
- Burden related DCT activities

Final remarks



Final considerations

PROS



**Flexibility of models
and systems**



**Available Regulations
and Guidelines**

CONS



**Technical issues still
relevant**



**Openness to alternative
models**

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Thank you!

