TrialHub

Decentralized Clinical Trial Regulations: A 2022 Report

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About the data in this report

We are a team of feasibility and patient recruitment experts within **TrialHub** - the most comprehensive clinical trial planning platform. TrialHub relies on state-of-the-art algorithms for collecting thousands of data sources and a network of local experts to provide a 360-degree overview of the clinical research landscape.

This report was generated thanks to our latest analysis of the international and country-specific guidelines and regulatory documents regarding the use of decentralized trial components and reflects the **current state of affairs in 15 countries** as of **January 2022**. All data sources are included in the report for your convenience.

Disclaimer: Covid-related guidelines might change often due to the circumstances that dictate them.

If you'd like to know **which DCT components are allowed in your target countries** or would like the most **up-to-date information about regulations, sites and patients**, reach out to us at patientsfirst@findmecure.com - we can support you with data and insights.

Regulations Overview

Color Code

RED:	YELLOW:	GREEN:
not allowed	no regulation found	allowed

DCT Components by Country

	eConsent	eSignature	ePRO	IP supply	telemedicine	wearables	home nursing	home sampling
AU								
BE								
BR								
CA								
CN								
FR								
DE								
IL								
IT								
IN								
PL								
RU								
KR								
ES								
GB								

Australia

Color Code

RED:	YELLOW:	GREEN:
not allowed	no regulation found	allowed

DCT Components

	eConsent	eSignature	ePRO	IP supply	telemedicine	wearables	home nursing	home sampling
AU	1, 2	2		1	1			

Sources:

1. COVID-19: Guidance on clinical trials for institutions, HRECs, researchers and sponsors (Apr. 2020)
2. National Standard Operating Procedures for Clinical Trials, including Teletrials, in Australia (Feb. 2021)

Belgium

Color Code

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DCT Components

	eConsent	eSignature	ePRO	IP supply	telemedicine	wearables	home nursing	home sampling
BE	1, 2	1, 2, 3		1	4		1	

Sources:
1. Addendum to the Guidance on the Management of Clinical Trials During the COVID-19 (Coronavirus) Pandemic v.3 (FAMHP, Sep. 2021)
2. Guidance for Sponsors on the use of e-Consent for Clinical Trials in Belgium (WG ICF, Sep. 2020)
3. Regulation (EU) No 910/2014 (eIDAS). Art 25. §2. (European Parliament)
4. Telemedicine and Health mobile applications (INAMI, Jun. 2020)

Do you need a more in-depth analysis of Belgium's clinical research landscape?
Contact us at patientsfirst@findmecure.com

Brazil

Color Code

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DCT Components

	eConsent	eSignature	ePRO	IP supply	telemedicine	wearables	home nursing	home sampling
BR	2		1, 2	1, 2	1			

Sources:

1. Technical Note No. 23/2020/SEI/COPEC/GGMED/DIRE2/ANVISA (ANVISA, Jul. 2020)
2. Guidelines for procedures in research with any step in virtual environment (Ministry of Health, Executive Secretariat of the National Health Council, National Research Ethics Commission, Mar. 2021)

Canada

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DCT Components

	eConsent	eSignature	ePRO	IP supply	telemedicine	wearables	home nursing	home sampling
CA	1			1				

Source:

1. Management of clinical trials during the COVID-19 pandemic: Notice to clinical trial sponsors (Health Canada, May 2021)

China

Color Code

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DCT Components

	eConsent	eSignature	ePRO	IP supply	telemedicine	wearables	home nursing	home sampling
CN	1	2		1	1	1		1

Sources:

1. Guidelines for the Management of Drug Clinical Trials During the Coronavirus Pandemic 2020
2. Regulations for Good Clinical Practices (Ministry of Health and Welfare, amended Aug. 2020)

Do you need a more in-depth analysis of China's clinical research landscape?
Contact us at patientsfirst@findmecure.com

France

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DCT Components

	eConsent	eSignature	ePRO	IP supply	telemedicine	wearables	home nursing	home sampling
FR		4, 5		2	1, 2		3	

Sources:

1. The French Public Health Code (FPHC) Chapter VI: Telehealth (Articles L6316-1 to L6316-2)

2. France (ANSM) Ongoing clinical trials in relation to COVID 19 (ANSM, Feb, 2021)

3. EMA Good Clinical Practice (GCP) Q&A

4. French civil code, Art. 1366 read in conjunction with Art. 29 of the REGULATION (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC.

5. Regulation (EU) No 910/2014 (eIDAS). Art 25. §2. (European Parliament)

Germany

Color Code

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DCT Components

	eConsent	eSignature	ePRO	IP supply	telemedicine	wearables	home nursing	home sampling
DE	1, 2	2, 3	2	1	1, 4	2		

Sources:

1. Guidance on the management of clinical trials during the COVID-19 (coronavirus) pandemic, version 4 (EMA, Feb. 2021)
2. Draft guideline on computerised systems and electronic data in clinical trials (EMA, Jun. 2021)
3. Regulation (EU) No 910/2014 (eIDAS). Art 25. §2. (European Parliament)
4. Hinweise und Erläuterungen zu § 7 Absatz 4 MBO-Ä (Fernbehandlung) (BAK, Dec. 2015)

Israel

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DCT Components

	eConsent	eSignature	ePRO	IP supply	telemedicine	wearables	home nursing	home sampling
IL	1, 2	1, 2		1, 2	1, 2		1, 2	1, 2

Sources:

1. Guidelines for Sponsors, Investigators, Helsinki Committees and Hospital Directors regarding Medical Research Conduct in the Upcoming Period (Israeli Ministry of Health, Mar. 2020)

2. Revocation of guidelines for conducting research in the corona period and new guidelines for returning to routine - Pilot until the end of 2021 (Israeli Ministry of Health, Jul. 2021)

(*Note:* According to the Revocation of guidelines for conducting research in the corona period the new considerations and guidelines for clinical trials are in force until 01.2022 Extension of the pilot for research management until the end of 2022)

Do you need a more in-depth analysis of Israel's clinical research landscape?
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Italy

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DCT Components

	eConsent	eSignature	ePRO	IP supply	telemedicine	wearables	home nursing	home sampling
IT	1	2		1			1	1

Sources:

1. Management of clinical trials in Italy during the COVID-19 emergency (coronavirus disease 19) (Version 3 of 17 September 2020)
2. Regulation (EU) No 910/2014 (eIDAS). Art 25. §2. (European Parliament)

India

Color Code

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DCT Components

	eConsent	eSignature	ePRO	IP supply	telemedicine	wearables	home nursing	home sampling
IN	1	1		2	2			

Sources:

1. National Guidelines For Ethical Committees Reviewing Biomedical And Healthcare Research During COVID-19 Pandemic (Indian Council of Medical Research, Apr. 2020)
2. Guidance for the Management of Clinical Trial Activitiesin response to COVID-19 Pandemic (ISCR, 2020)

Poland

Color Code

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DCT Components

	eConsent	eSignature	ePRO	IP supply	telemedicine	wearables	home nursing	home sampling
PL	1	1, 3		1, 2	2, 3			1

Sources:

1. Good clinical practce of medicinal products during the COVID-19 pandemic (Jan, 2021)
2. Mapping and analysis of the EU legislation on Remote Decentralised Clinical Trials including legal, regulatory, ethical and stakeholder recommendations for the conduct of the pan-EU pilot (Trials@Home, Feb., 2021)
3. Ordinance of the Health Minister of August 12, 2020 on the organizational standard of teleporting in primary health care
4. Regulation (EU) No 910/2014 (eIDAS). Art 25. §2. (European Parliament)

Russia

Color Code

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DCT Components

	eConsent	eSignature	ePRO	IP supply	telemedicine	wearables	home nursing	home sampling
RU				1	1		1	1

Sources:

1. Ministry of Health letter from 27/03/2020 #20-1/*И*/2-3651 regarding clinical trials conduct during COVID-19 pandemic situation

Do you need a more in-depth analysis of Russia's clinical research landscape?
Contact us at patientsfirst@findmecure.com

South Korea

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DCT Components

	eConsent	eSignature	ePRO	IP supply	telemedicine	wearables	home nursing	home sampling
KR	1			1	2			

Sources:

1. Clinical Trial Considerations for COVID-19 (MFDS, Mar. 2020)
2. Considerations when developing a treatment for COVID-19 (MFDS, May 2020)

Spain

Color Code

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DCT Components

	eConsent	eSignature	ePRO	IP supply	telemedicine	wearables	home nursing	home sampling
ES	1, 2	3	2	1, 2	1, 2		1	2

Sources:

1. Exceptional measures applicable to clinical trials to manage problems arising from the COVID-19 emergency (AEPMS, Jul. 2020)
2. Decentralized CT and digitalization - Comments including the feedback of Ethics Committees (CEIm) participating in the Grupo de Coordinación de Ensayos Clinicos chaired by AEMPS (AEMPS, Jul.2020)
3. Regulation (EU) No 910/2014 (eIDAS). Art 25. §2. (European Parliament)

Do you need a more in-depth analysis of Spain's clinical research landscape?
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The UK

Color Code

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DCT Components

	eConsent	eSignature	ePRO	IP supply	telemedicine	wearables	home nursing	home sampling
GB	1, 2	1, 2		3, 4			3	

Sources:

1. Joint statement on seeking consent by electronic methods (MHRA, HRA, Sept. 2018)
2. Consent and Participant Information Guidance (Medical Research Council, NHS)
3. Guidance on minimising disruptions to the conduct and integrity of clinical trials of medicines during COVID-19 (MHRA, Nov. 2020)
4. Managing clinical trials during Coronavirus (COVID-19) (MHRA, March 2020)

Do you need a more in-depth analysis of The UK's clinical research landscape?
Contact us at patientsfirst@findmecure.com

Would you like to know more?

Are you planning a decentralized clinical trial? Or maybe you are trying to make your trial more patient-friendly as a way to speed up recruitment?

We know how overwhelming it can be, especially when you have to deal with the international landscape of regulations and figure out what patients really want. This is why we built **TrialHub**.

TrialHub is for biotech, pharma, and CRO companies that want a unique combination of data and local experts' insights in order to analyze the clinical research landscape from all perspectives (**sites, regulations, and patients**). The final goal is for you to know what it will take to complete your trial successfully.

If you are one of the people who understand that spending millions on advertisements and simply adding another app or wearable is not the way to go, then reach out to our team and see what **TrialHub** can do.

Email: patientsfirst@findmecure.com

LinkedIn: https://www.linkedin.com/showcase/trialhub-findmecure/