7th Annual Outsourcing in Clinical Trials DACH 2024

Transforming Clinical Trials: The Role of Blockchain in Revolutionizing Clinical Data Management

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1MED is a specialized medtech CRO with international reach, headquartered in Switzerland

- Medical Devices (MDR)
- IVDs (IVDR)
- Combination products

throughout Europe and Middle East

Company overview – key services

1MED provides client services in 4 key areas:

Preclinical

1MED supports clients in defining the proper preclinical pathway to assess medical devices' safety and performance features. It provides support for preclinical testing assessing medical devices and food supplement' safety and performance thanks to the acqusition of 1LAB.

Regulatory and Scientific Advice

1MED provides deep sector and regulatory expertise at all stages of a product's lifecycle, from preclinical assessment and clinical trials to marketing authorization and post-market surveillance. With our experts we can support our clients in the liaison with Regulatory Authorities.

Company overview – key services

1MED provides client services in 4 key areas:

Clinical

1MED is a full service CRO offering clinical research services and solutions for all clinical trials' needs. In-depth knowledge of regulatory and clinical trials' requirements across countries, enables a smooth and fast market access, while ensuring regulatory compliance.

Quality

In order to bring products to the market, it is mandatory for manufacturers to have a Quality Management System (QMS) in place.

1MED supports clients in making this requirement a reality, helping clients create an ISO 13485 QMS and/or GMP quality system implementing it and ensuring its maintenance.

Company overview – Summary

Overview and key numbers

1MED SA, an ISO 13485:2016 certified CRO, providing regulatory strategy, clinical trial management and quality assurance services to the medical device and pharma industry.

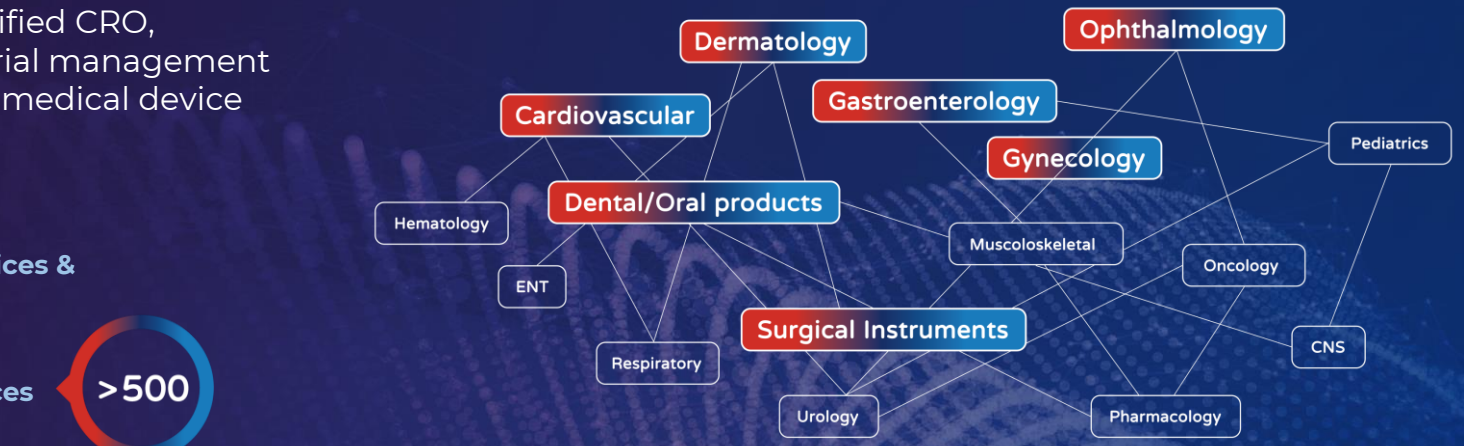
99% of Projects — **Class IIa - IIb - III Medical Devices & Combination Products**

CE-Marked Medical Devices — **>500**

14 — **Consolidated Relationships With EU Notified Bodies**

Clinical Evaluation Reports & Updates — **>500**

Key therapeutic areas



1MED has a broad focus across therapeutic areas with expertise in cardiovascular, dermatology, ophthalmology, GI, dental/oral, orthopedics, interventional oncology, implantable medical devices and drug/device combination products

Main Products

Cardiovascular & Peripheral Vascular products

- PV ablation catheters
- Aortic and coronary stents
- Aortic valves
- Annuloplasty rings
- Peripheral vascular catheters & grafts
- Aortic bendages
- LVADs
- Cardiopulmonary
- ECLS

Combination products

- Dermal fillers
- Eye drops, gel & opthalmic solutions
- Dermatological gel, spray, cream, foam
- Joints & muscles: pain relief products
- Wound dressings
- Wound rinsing solutions
- Skin patches
- Vaginal gel and solution
- ENT products

Innovative products

- Robotic assisted surgical system
- AI-based softwares
- Bioresorbable implants
- Nanoengineered implants

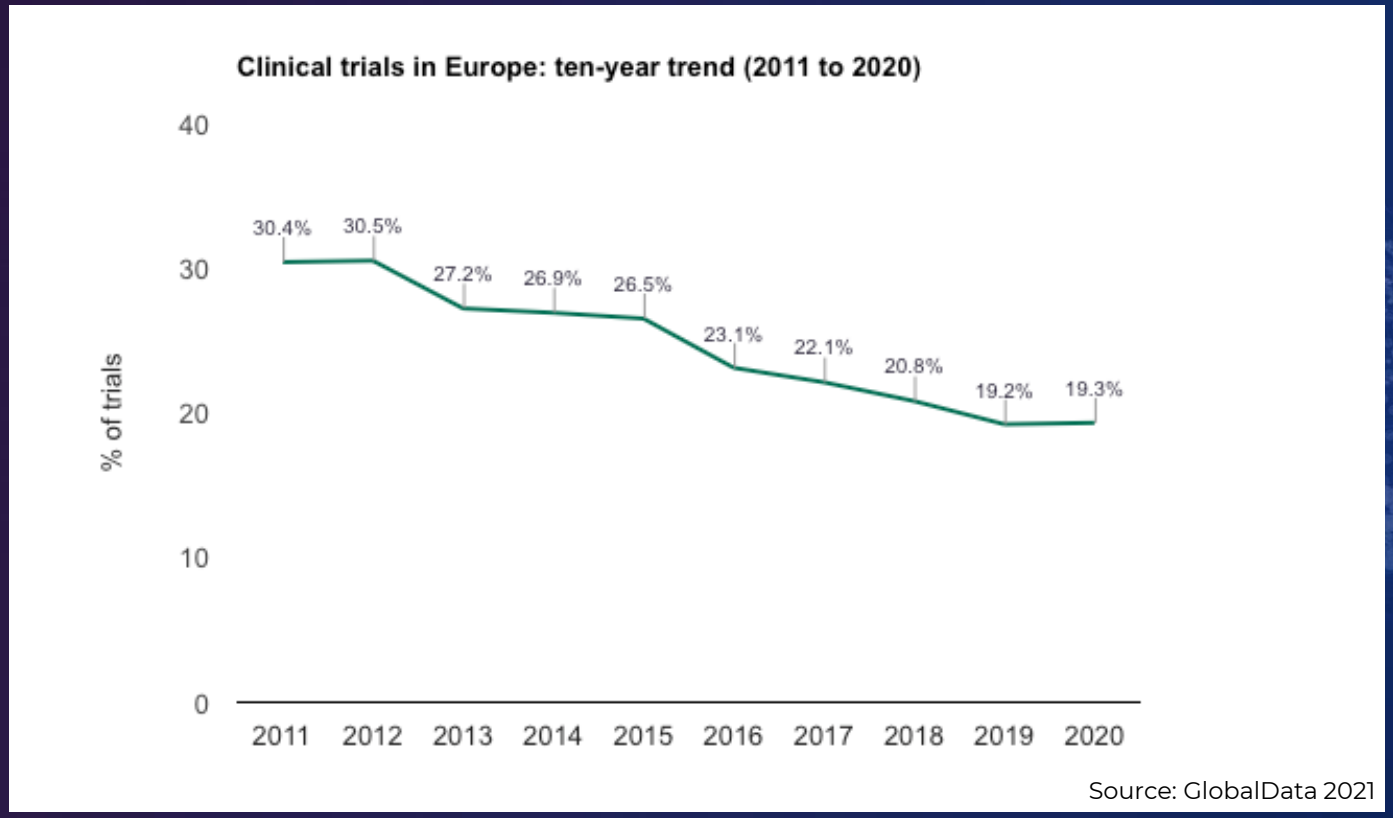
Orthopaedics & oral care

- Bone cement
- Knee ligaments
- Injectable solutions and implantable material
- Dental implants
- Electromedical instruments
- Gel and solutions for aphthae

Clinical Trials: Digital (R)Evolution

Number of clinical trials conducted in Europe

In the EU / EEA, approximately 2,800 clinical trials are authorised each year [1].



Source: GlobalData 2021

(1) https://www.ema.europa.eu/en/human-regulatory-overview/research-development/clinical-trials-human-medicines

Growth in clinical data generation

- Several studies published in Applied Clinical Trials have demonstrated the impact of **growing clinical trial data volume** and the increasing diversity of clinical data sources on **study timelines** and **inefficiencies**
- Tufts CSDD Impact report[1] states that:

«the typical late- stage protocol, for example, now collects on average 3.6 million data points, three times the number collected 10 years ago».

(1) Tufts CSDD Impact Report Volume 23, Number 1. January/February 2021

Technology that has become pervasive in clinical research has helped with the quantity of data collected that can be analyzed but has it helped with the quality?

Electronic Data Capture (EDC)

- A global survey was conducted between September and October 2020.
- In total, 194 verified unique individual responses were received and analyzed[2].
- More than twelve different EDC solutions were identified by respondents. Most organizations (73.9%) report using two or more and the remaining 26.1% of respondents report using only one EDC solution.

(2) Applied Clinical Trials-02-01-2021 Volume 30 Issue 1/2

Electronic Data Capture (EDC)

The table below shows the wide range of clinical data management pain points reported.

Pain Point (*n*=62)	Percent of Respondents Experienced
Planned Mid-Study Updates / Protocol Amendment Delays	56.5%
Unplanned Mid-Study Updates / Protocol Amendment Delays	48.4%
Flexibility and Customization Challenges	43.6%
Database Go Live Delays	32.3%
Lack of Integrated Patient Engagement / eCOA Applications	32.3%
Solution Cost	30.7%
Data Incompatibility Between Platforms	25.8%
Customer Support Problems	22.6%
Solution Complexity / Slow User Learning Curve	19.4%
Other	16.1%

(2) Applied Clinical Trials-02-01-2021 Volume 30 Issue 1/2

Clinical data collection threats

Threats to a dataset's integrity can include:

- **Human error**: For instance accidentally deleting a cell of data in a spreadsheet
- **Inconsistencies across format**: For instance, a set of data in Microsoft Excel that relies on cell referencing may not be accurate in a different format that doesn't allow those cells to be referenced
- **Collection error**: For instance, data collected is inaccurate or lacking information, creating an incomplete picture of the subject
- **Cybersecurity or internal privacy breaches**: For instance, someone hacks into your company's database with the intent to damage or steal information, or an internal employee damages data with malicious intent

Data Integrity

There are key aspects to focus during data collection:

- **Quality -** is the data being collected in a quality way that can be analyzed to support (or not) the hypothesis of the study?
- **Accuracy -** is the data being collected accurate?
- **Completeness -** is the data being collected complete?
- **Security -** is the data being protected from both external and internal threats and maintaining the privacy of its subjects?

Data Integrity

Data integrity

Ensuring integrity and accuracy of data all along the trial is pivotal for successful outcomes.

This is exactly why data managers should monitor, review, and audit the trial data at regular intervals during the trial, in order to detect inconsistencies and maintain data integrity.

Maintaining the integrity of trial data present a sizable challenge for clinical data managers (time/costs)

What is a possible solution?

Blockchain

Blockchain for patient data storage: full traceabiltiy

One of the standout features of blockchain is its ability to create immutable records.

Once patient data is entered into the blockchain, it cannot be altered or deleted. This immutability guarantees that the information remains trustworthy and tamper-proof, providing a permanent record of every data or update.

This is particularly crucial in healthcare, where the accuracy and integrity of medical records are of paramount importance.

Blockchain for patient data storage: security

To protect sensitive patient data, blockchain employs advanced encryption techniques and cryptographic hashing.

Before data is added to the blockchain, it is encrypted, ensuring that only authorized parties can view it.

Cryptographic hashing further enhances security by creating a unique digital fingerprint of the data. If any changes are made, the hash value changes, immediately signaling that the data has been tampered with.

This combination of encryption and hashing ensures that patient information remains secure and its integrity is maintained.

Blockchain for patient data storage: automation

Another powerful feature of blockchain is the use of smart contracts.

These are self-executing contracts with the terms of the agreement directly embedded in the code.

In healthcare, smart contracts can automate and secure data sharing between different parties, such as doctors, insurance companies, and patients.

For example, a smart contract could automatically authorize the sharing of patient records with a specialist once certain conditions are met, streamlining the process and reducing the risk of unauthorized access.

Data, once collected, cannot be locked away and never heard from again. It must be used to make things better, better for the research process, better for the site and ultimately better for the patients.

Questions?

Thank you

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& clinical
development