xclinical

marvin DIRECT

Technical Factsheet
Marvin Direct

Version 1.9.36 / July 8th, 2020

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Introducing Marvin Direct

“Marvin Direct is a fully GDPR-compliant communication framework for secure video and chat communication. The product is designed to meet the regulatory requirements of the life science industry, in particular in the area of clinical trials.”

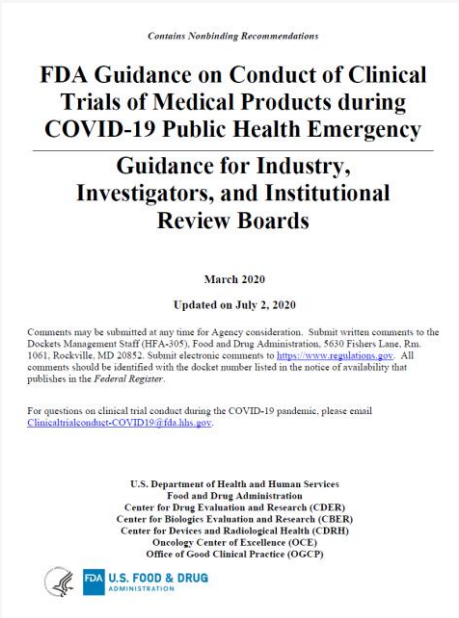
Franciscus Pijpers :: Chief Executive Officer, XClinical

Marvin Direct comes with two components to empower the communication in clinical trials between site user (e.g. investigator, study site staff) and subjects (patients) or CRAs leveraging video calls or chat.

Find out how the security of your data is being protected and how you may set up accounts for your investigators. Learn how easy it is to customize the back end of Marvin Direct and how quickly you can roll out a convenient communication infrastructure for your study participants.

COVID-19

A Special Situation Demands New Tools



Contains Nonbinding Recommendations

FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Public Health Emergency

Guidance for Industry, Investigators, and Institutional Review Boards

March 2020

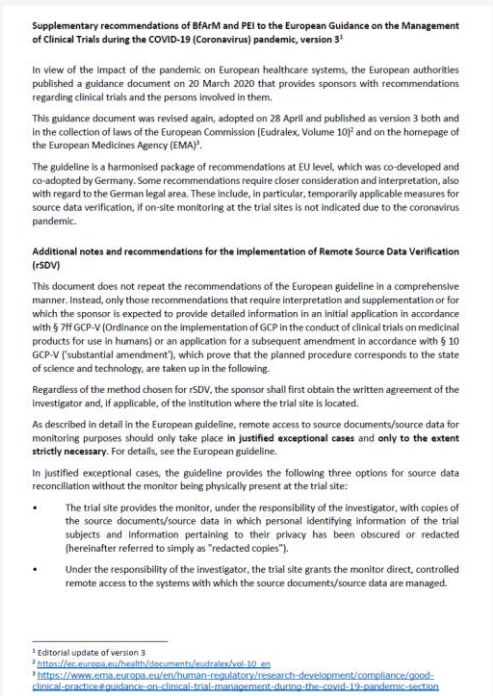
Updated on July 2, 2020

Comments may be submitted at any time for Agency consideration. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Submit electronic comments to https://www.regulations.gov. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions on clinical trial conduct during the COVID-19 pandemic, please email ClinicalTrialConduct-COVID19@fda.hhs.gov.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Center for Devices and Radiological Health (CDRH)
Oncology Center of Excellence (OCE)
Office of Good Clinical Practice (OGCP)

FDA U.S. FOOD & DRUG ADMINISTRATION



Supplementary recommendations of BfArM and PEI to the European Guidance on the Management of Clinical Trials during the COVID-19 (Coronavirus) pandemic, version 3[1]

In view of the impact of the pandemic on European healthcare systems, the European authorities published a guidance document on 20 March 2020 that provides sponsors with recommendations regarding clinical trials and the persons involved in them.

This guidance document was revised again, adopted on 28 April and published as version 3 both and in the collection of laws of the European Commission (Eudralex, Volume 10)[2] and on the homepage of the European Medicines Agency (EMA)[3].

The guideline is a harmonised package of recommendations at EU level, which was co-developed and co-adopted by Germany. Some recommendations require closer consideration and interpretation, also with regard to the German legal area. These include, in particular, temporarily applicable measures for source data verification, if on-site monitoring at the trial sites is not indicated due to the coronavirus pandemic.

Additional notes and recommendations for the implementation of Remote Source Data Verification (rSDV)

This document does not repeat the recommendations of the European guideline in a comprehensive manner. Instead, only those recommendations that require interpretation and supplementation or for which the sponsor is expected to provide detailed information in an initial application in accordance with § 7ff GCP-V (Ordinance on the implementation of GCP in the conduct of clinical trials on medicinal products for use in humans) or an application for a subsequent amendment in accordance with § 10 GCP-V ('substantial amendment'), which prove that the planned procedure corresponds to the state of science and technology, are taken up in the following.

Regardless of the method chosen for rSDV, the sponsor shall first obtain the written agreement of the investigator and, if applicable, of the institution where the trial site is located.

As described in detail in the European guideline, remote access to source documents/source data for monitoring purposes should only take place **in justified exceptional cases** and **only to the extent strictly necessary**. For details, see the European guideline.

In justified exceptional cases, the guideline provides the following three options for source data reconciliation without the monitor being physically present at the trial site:

- The trial site provides the monitor, under the responsibility of the investigator, with copies of the source documents/source data in which personal identifying information of the trial subjects and information pertaining to their privacy has been obscured or redacted (hereinafter referred to simply as "redacted copies").
- Under the responsibility of the investigator, the trial site grants the monitor direct, controlled remote access to the systems with which the source documents/source data are managed.

[1] Editorial update of version 3
[2] https://ec.europa.eu/health/documents/eudralex/vol-10_en
[3] https://www.ema.europa.eu/en/human-regulatory/research-development/compliance/good-clinical-practice#guidance-on-clinical-trial-management-during-the-covid-19-pandemic-section

- This product was inspired by the COVID-19 guidance papers from EMA and FDA
- Meets all regulatory guidelines including the strict requirements of the German Data Protection Supervisory Authority audited by an independent party
- Audit Trail for GCP compliance based on communication logs not on the communication data itself
- Use Cases:
  - ✓ Site-Patient Communication
  - ✓ Communication between site and CRO/sponsor

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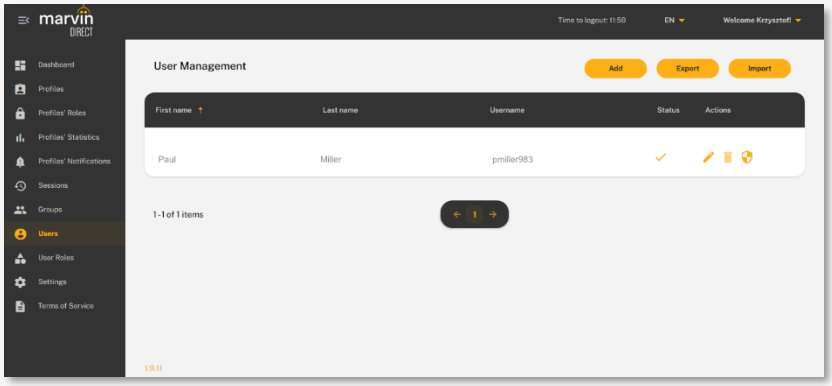
Features:

- Available for iOS (from 13) and Android (from 10) devices
- Video call and chat communication
- Back end portal for the customer to create users, profiles (App) and groups
- Fine-grained permission framework for user, profile and group settings
- Fully GDPR-compliant incl. encryption, decentralized storage, identity protection, etc.
- Communication audit trail can be exported via the back end
- Send centralized push notifications to all trial participants using the app
- Multi-language support (currently EN/DE/NL)
- Back end can be customized

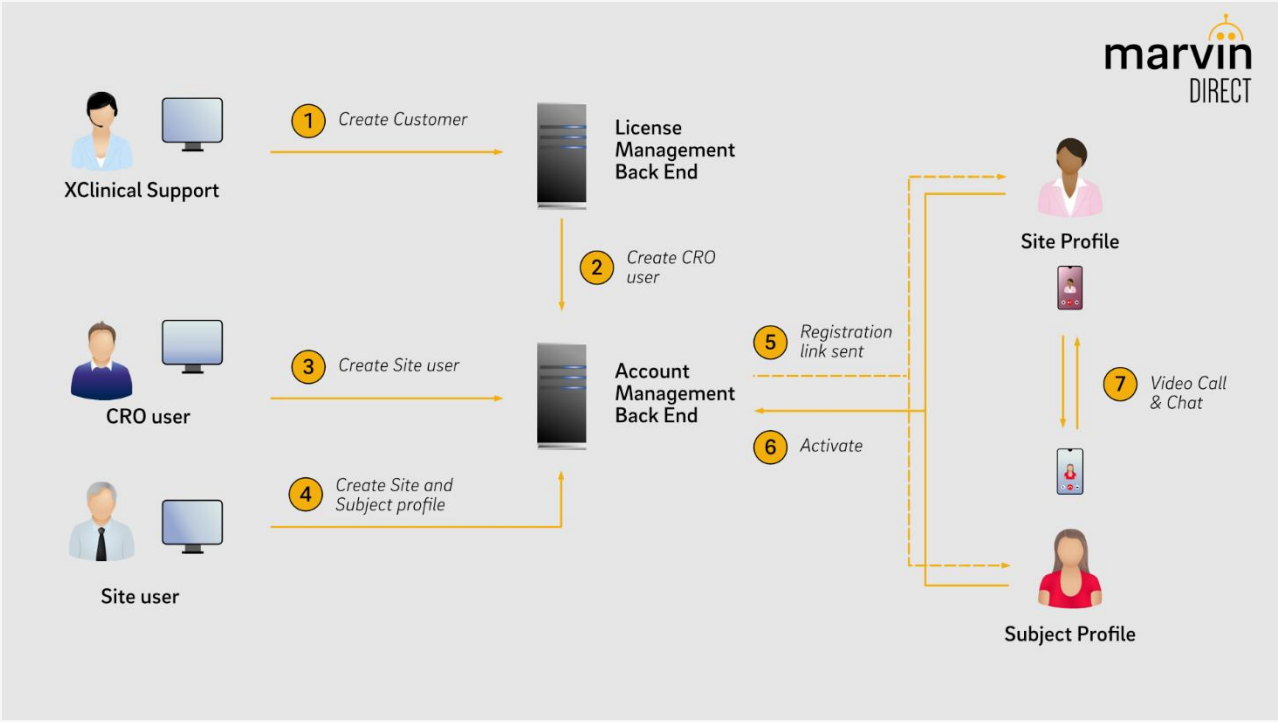
Marvin Direct Components:

1. **Back end: Administration Console**
    - Create users, groups and profiles (App users)
    - Assigning rights and permissions

2. **Marvin Direct App**
    - Communicate via chat or video using a mobile device
    - Available for Download on Google Play and Apple Store
    - Important: the app is only applicable through users who have been set up as “profiles” in the back end within their organization



Marvin Direct: Subject and Site communication

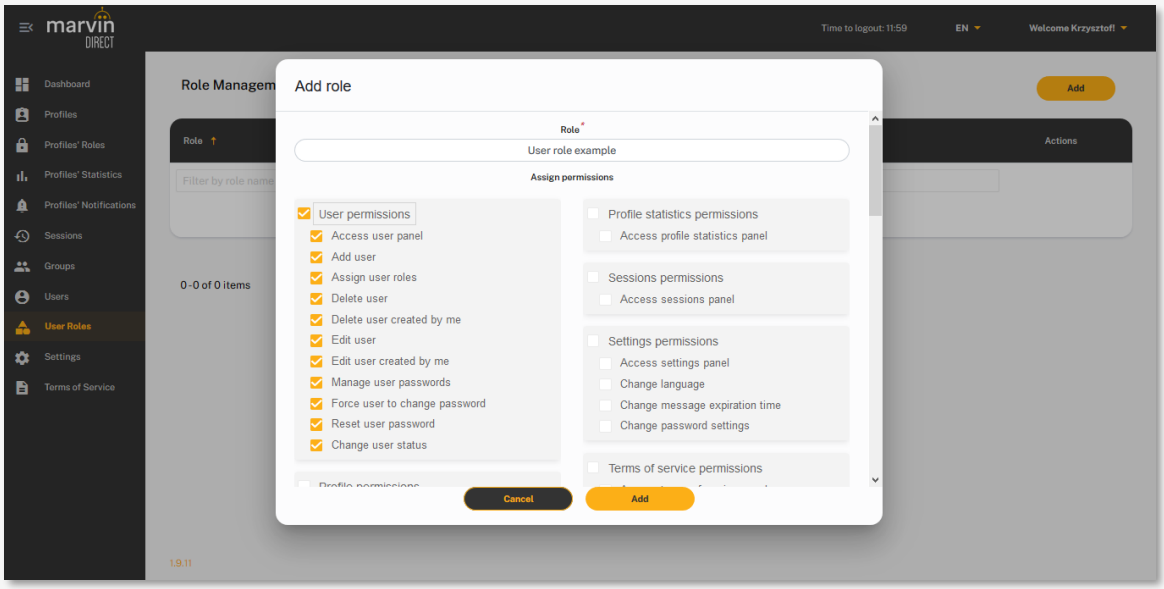


Workflow

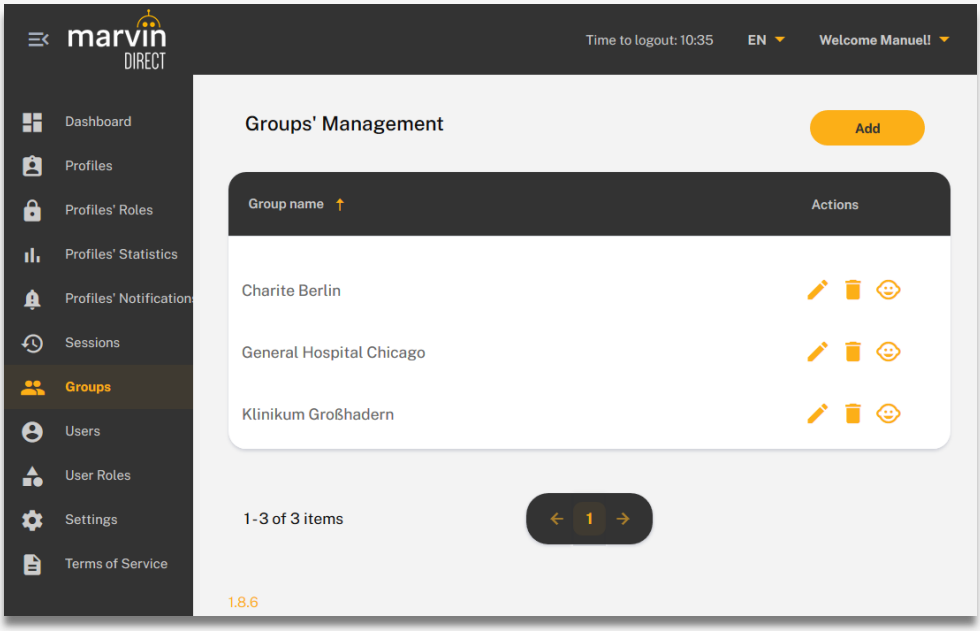
1. XClinical configures the customer back end
2. And creates only a CRO user
3. The CRO creates site users in the back end
4. The site users create profiles for other site personnel and patients
5. The profiles (App user) receive a link to register their App
6. The profiles (App user) activate their accounts
7. Now all is ready to start your first video call and/or chat

Using the Administration Console

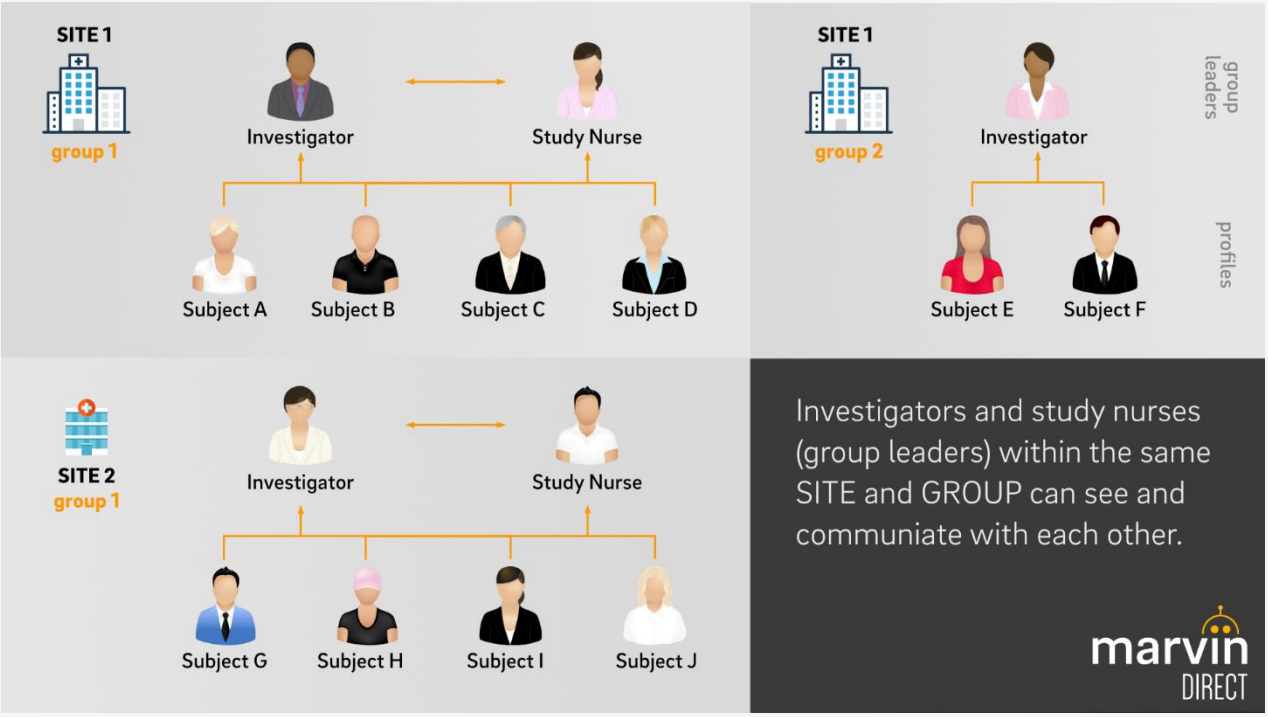
Before the end user may use the app, a profile needs to be created in the administration portal (back end).



Marvin Direct is a closed system. You can only contact somebody within your group. Depending on the use case, groups can be e.g. sites.



Subject and site communication



Identity protection

- Other subjects (app user) can be found in contacts
- A leader e. g. investigator can communicate with all other contacts in the group
- Subjects can **only** see and communicate with the investigator and/or study nurse within the same group and site.
- They can **never** see nor communicate with other subjects
- There is no communication possible between different groups

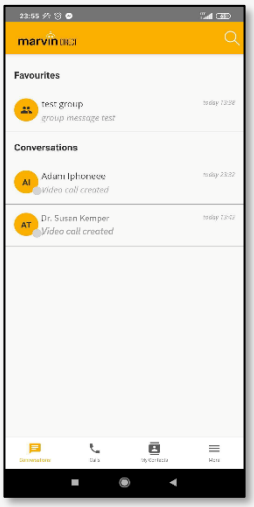
Marvin Direct App

The App is simple to use:

Log in

Register

Contacts from the group



Call a single person or a self-defined group

About XClinical

XClinical offers an integrated suite of software products unified under the name *Marvin* that accelerate the clinical trial process.

Our solutions for clinical data management, document management and trial communication can significantly help CROs, pharmaceuticals and medical device corporations to improve their throughput in clinical research.

Fast setup, an all-in-one platform and no need for programming enables customers to get started fast in order to streamline the process of delivering vital medications and devices to the market.

With **Marvin Direct**, the newest member of the XClinical family of products, we want to contribute a communication platform to support the fight against the Covid-19 pandemic, available for both iOS and Android devices.

Discover Marvin Direct for your clinical trials:

direct @xclinical.com

news.xclinical.com/marvin-direct-video-chat-app-for-clinical-trials

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