

| CRISPNet

Clinical Research IMP Supply and Processing Network
High-Level Overview Document

1 | Purpose

This document provides a high-level, non-technical overview of the Clinical Research IMP Supply & Processing Network (CRISPNet).

2 | Scope

This document is intended for executives, sponsors, trial management staff, and other stakeholders requiring a high-level understanding of CRISPNet's functionalities and benefits.

3 | Document Objectives

- Provide use cases and scenarios, including justifications for the chosen methodologies.
- Explain relevant security measures and core features.
- Offer a high-level description of CRISPNet implementation.

What Is CRISPNet?

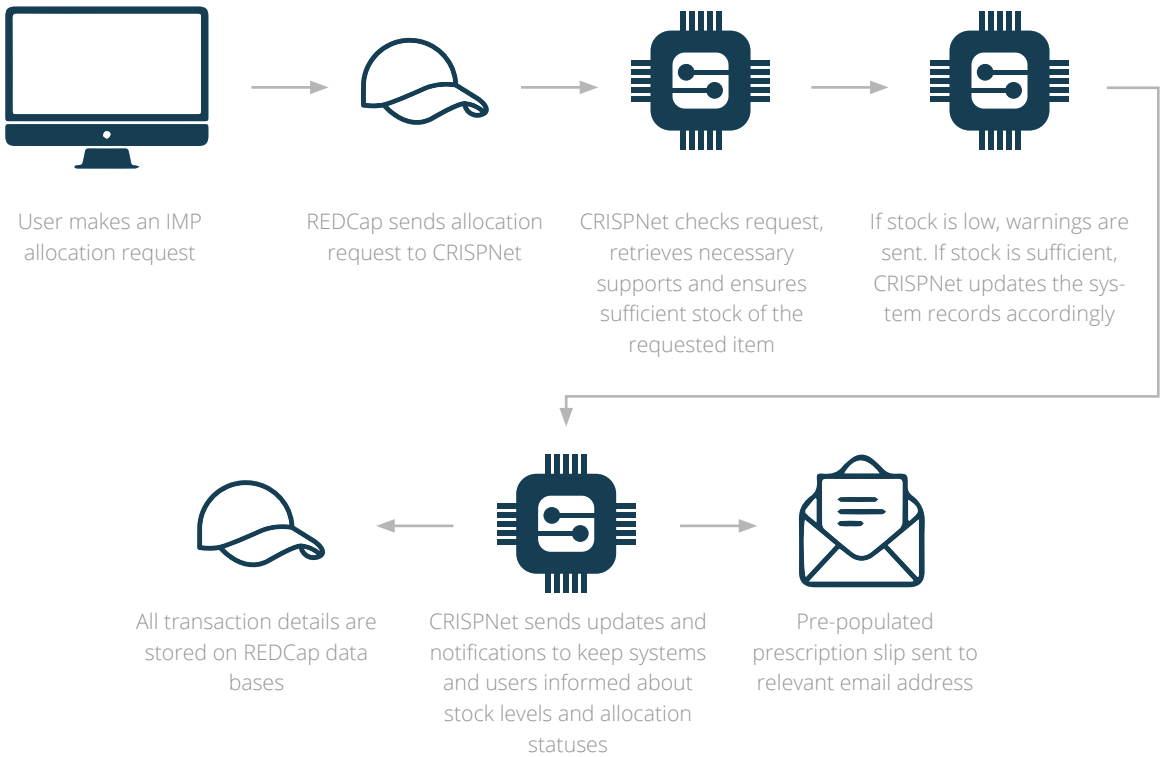
CRISPNet, short for Clinical Research IMP Supply & Processing Network, is an advanced system designed to operate alongside existing API-compatible databases, enhancing functionality and enabling seamless data management across clinical research projects. Tailored for managing Investigational Medicinal Products (IMPs) in clinical trials, CRISPNet offers a robust, secure, and efficient solution that integrates effortlessly with established databases like REDCap.

CRISPNet acts as a “bolt-on” addition, easily integrating with existing database infrastructures, making it valuable in research environments needing enhanced data processing without the need to develop a new system from scratch.

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Key Benefits of CRISPNet

- Improved IMP Management: Manages IMP complexities, including allocation, tracking, and emergency unblinding, ensuring the integrity of double-blind studies.
- Security and Compliance: A comprehensive security framework protects sensitive clinical data, adhering to regulatory standards like GDPR with features such as two-factor authentication, encryption, and audit trails.
- Seamless User Experience: CRISPNet operates in the background, allowing research staff to continue using their usual databases without direct interaction, minimizing workflow disruptions.

In summary, CRISPNet enhances the capabilities of existing clinical research databases, particularly in IMP management, with a strong focus on security, compliance, and seamless integration.

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Adoption and Implementation

CRISPNet has been adopted as the preferred method for CTIMP IMP management in the studies, EPiC2 and MAC-Endo studies at the University of Edinburgh combine with REDCap. Its cost-effective nature and ability to integrate with existing databases without requiring a fully bespoke system have made it an attractive solution for research institutions aiming to enhance their data processing capabilities without significant additional costs.

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System Details

- 5.1 Technology and Infrastructure** CRISPNet operates on an Amazon Web Service (AWS) European Union (EU) cloud platform, ensuring robust, secure, and scalable operations. By leveraging AWS's advanced cloud infrastructure, CRISPNet benefits from high availability, flexibility, and compliance with European data protection regulations (such as GDPR). Currently, CRISPNet integrates with REDCap but is designed for easy integration with any API-compatible platform, making it a versatile solution for various clinical research environments.
- 5.2 Security and Core Features** CRISPNet is designed with a comprehensive security framework to protect sensitive clinical research data and ensure compliance with relevant regulations. Key security features include:

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Secure API Communication

All API calls between CRISPNet and local databases use HTTPS, ensuring data transmission is encrypted and protected from unauthorized access during data transit.



Two-Factor Authentication

CRISPNet supports two-factor authentication, adding an extra layer of security for users accessing the system, ensuring that only verified individuals can interact with CRISPNet.



Activity Logging and Audit Trails

The platform maintains detailed logs of all user activities and system interactions. These audit trails provide transparency and allow institutions to monitor and review all actions within the system, ensuring compliance with policies and regulations.



End-to-End Encryption

CRISPNet supports end-to-end encryption for data exchanges between systems, ensuring data remains secure both in transit and at rest.



Compliance with GDPR and Other Regulations

Fully compliant with the General Data Protection Regulation (GDPR) and other data protection laws. Hosting its API on a secure EU cloud platform ensures all data handling processes meet regulatory standards.



Data Residency and Processing

Most research data remains on the institution's local servers, with essential non-personal data processed externally, balancing local control with effective data processing.



Emergency Unblinding Procedures

The platform includes secure, authorized-only procedures for emergency unblinding, allowing rapid response in critical situations without compromising data integrity or confidentiality.



Regular Security Assessments

CRISPNet undergoes regular security assessments to identify and mitigate potential vulnerabilities, ensuring the platform remains secure and compliant with the latest standards.



Accessibility for End Users

CRISPNet operates seamlessly in the background, allowing research staff to continue using their usual databases without needing to interact directly with CRISPNet.