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KerusCloud

Overview

Software Validation

Delivering a robust product to meet market needs.

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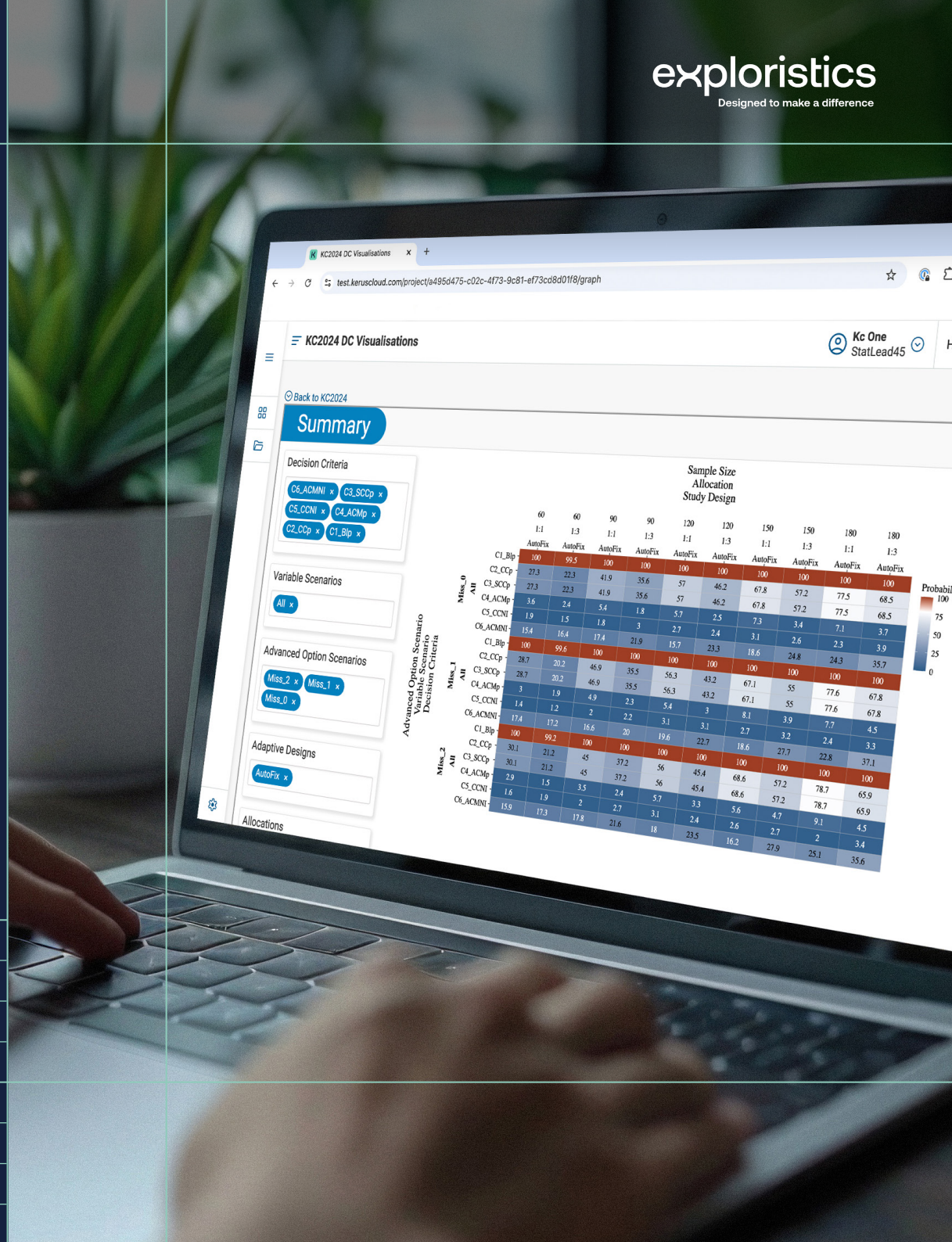
KerusCloud

Software Validation

KerusCloud is a cloud-based clinical trial simulation software that is revolutionising the clinical trial design process. It delivers state-of the-art study simulation to support clinical trial design decision-making so that real clinical studies can be extensively derisked in silico, alleviating patient burden and saving development time and costs.



Delivering a robust product to meet market needs

KerusCloud has undergone more than **150,000 hours** of development and testing to date. To ensure that it is a robust software product that can meet growing market needs, it goes through a rigorous validation process. This involves four key steps.

The four steps of software validation for KerusCloud:

Governance & Oversight

Software Validation & Release

Security Validation

Software Qualification

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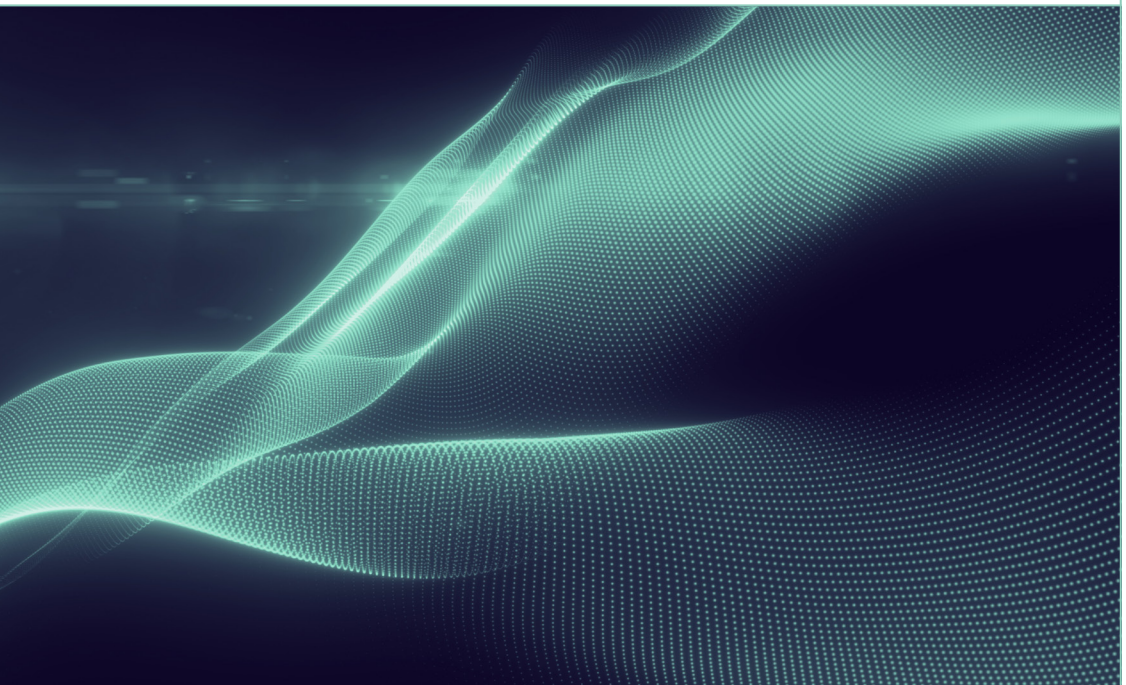
Step 1

Governance & Oversight

Exploristics has a formal governance process in place for KerusCloud. This provides a robust framework against which the company can track its development, ensuring that development goals are met and are fully aligned with the market need and the overarching business strategy. Within Exploristics, overall governance of the software is carried out by the **Product Matrix Group.**



Product Matrix Group

The **Product Matrix Group** consists of a range of stakeholders from across the company including the Product Owner, CEO, representatives from Sales & Marketing, key users and integration partners. The group sets out the Product roadmap for KerusCloud which outlines the vision, direction, priorities and progress of the software over time.

The Product Matrix group meets every six weeks to review progress, prioritising and planning key areas for development. It provides internal and external validation in relation to the market fit, tracking emerging trends in the industry and gathering feedback from stakeholders, users within the company and customers. Informed by these insights, the group oversees progress on KerusCloud development by the **Product Development Team.**

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Software Validation Step 1 Governance & Oversight

Product Development Team

The **Product Development Team** have a structured approach to developing the software, following a set of **developer guidelines** that outline quality and processes. Work is planned using software development tool, **Jira®**, which provides an essential framework for building and managing the product development pipeline.

Building the Development Pipeline

This involves gathering the requirements for each new software feature. These are captured in a user story which describes what the user will need from a feature. The story informs a product backlog which is a prioritized list of software functionality to build to meet user requirements.

Software Validation Step 1 Governance & Oversight

The Development team works within an **agile framework** to break up the planning and development of features into three-week sprint cycles (see sprint overview). Throughout the development process the team follow a set of standard operating procedures (SOPs) and guidance documents that cover Product Management and Development and Product Verification and Validation to embed consistent cultural, verification and validation practices. These cover all aspects of quality assurance (QA), including the process for review and revision. This process includes software testing with code verification at all stages, working towards an applicable ISO **ISO (International Organization for Standardization)** standard.

Sprint Overview

Each sprint cycle supports continuous development of the software. For each sprint the **Product Development Team** defines:

- what's being worked on
- what needs to be completed
- any issues that arise
- what was delivered
- how to improve the process for the next sprint

Step 2

Software Validation & Release

Work for each yearly software release is composed of 4 sprint-based planning and development cycles. During each sprint planned work follows a test centric development process.

The process begins with user stories which must contain clear detail of acceptance criteria. It is strongly focused on developer testing, and multi-peer reviews, before formal verification and validation. New software releases are available only after the series of **verification and validation** processes is completed.

Verification & Validation

Software verification involves an:

- independent code review
- regression tests
- manual tests
- automated tests
- test cases

Unit testing is conducted to ensure that each individual software unit developed is independently scrutinised for proper operation.

Any numerical values that are created during simulation are subject to additional validation where the numerical outputs are directly compared with the same results from an independent source to ensure they match.

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Software Validation Step 2 Software Validation & Release

Software Release & Lifecycle

When complete, the new software features and updates developed are released and verified in sequence across three distinct environments:

- the **Development environment** (Testing Stack),
- the **Beta environment** (Prerelease stack) for verification and validation of new and existing features
- the **Production environment** (Production stack) which is the live, customer-facing environment.

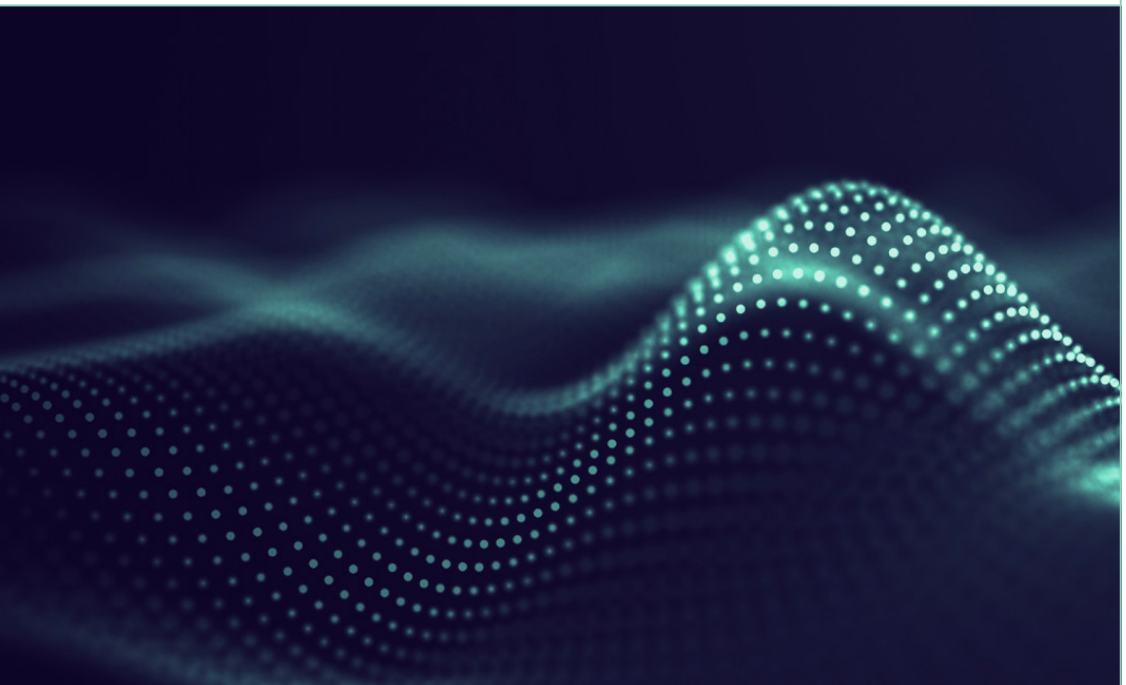
Daily smoke tests are carried out against Production and Beta environments to identify any defects or bugs and ensure that the system is available and accessible. Defects and bugs can originate from a variety of sources such as external users, internal users or can arise from the software development life cycle. All bugs are entered and tracked to resolution in Jira.®

Bugs are prioritised with the highest targeted for the current or next sprint.

Step 3

Security Validation

Each release of the KerusCloud software offers best-in-class security. This is ensured by regular external penetration testing to determine if its security systems satisfy client requirements. **Security validation** is based on **AWS** (Amazon Web Services) best-in-class security features.



These include:

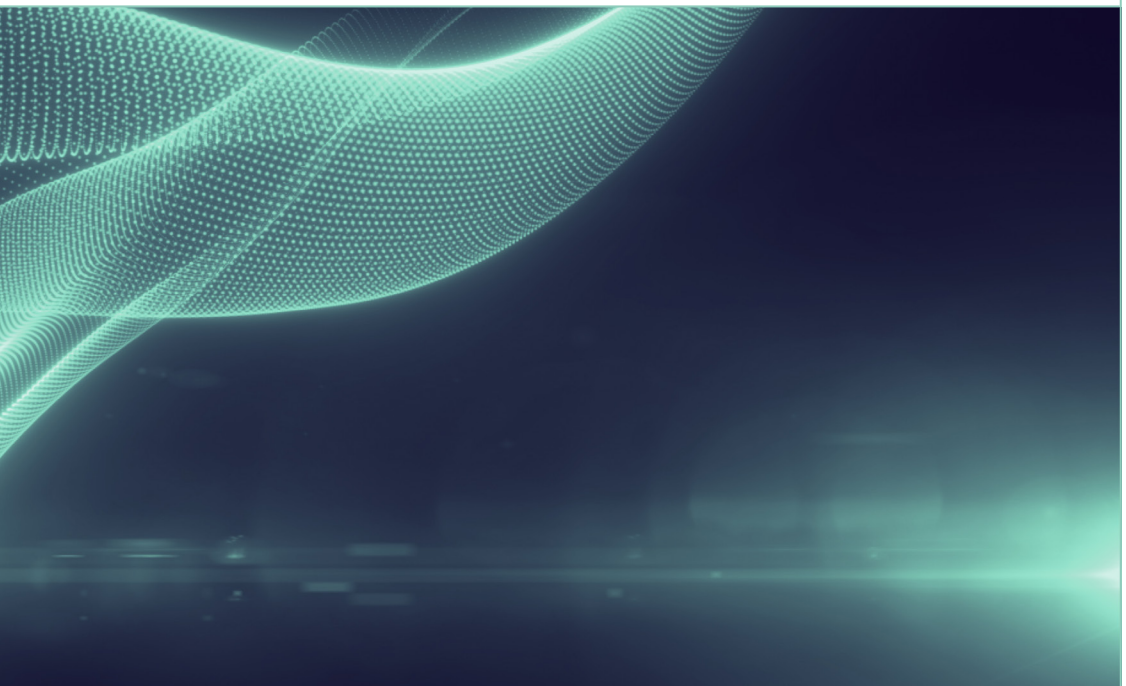
- Login via **AWS Cognito** with **Amazon Cognito Adaptive Authentication,**
- **Amazon Web application firewall,**
- **AWS API Gateway** and
- **data encryption.**

Security and penetration testing include both automated tests and regular testing. Regular periodic penetration testing is also provided by accredited external cyber security company, **Vertical Structure.**

Step 4

Software Qualification

The final stage of KerusCloud Validation is **software qualification**. Software qualification ensures that the integrated software is tested in a real world setting to provide evidence for compliance with the software requirements, to assess the performance and to measure the impact. This process involves both internal and external user validation.



Internal User Validation

Internal user validation comes from the numerous clinical trials being designed for customers using KerusCloud by Exploristics statisticians. This provides an opportunity to test and validate all of KerusCloud's features, performance and experience from the user perspective. All outputs are verified prior to releasing results to a customer. The software is tested in real life setting using historical test cases and current projects before any external usage.

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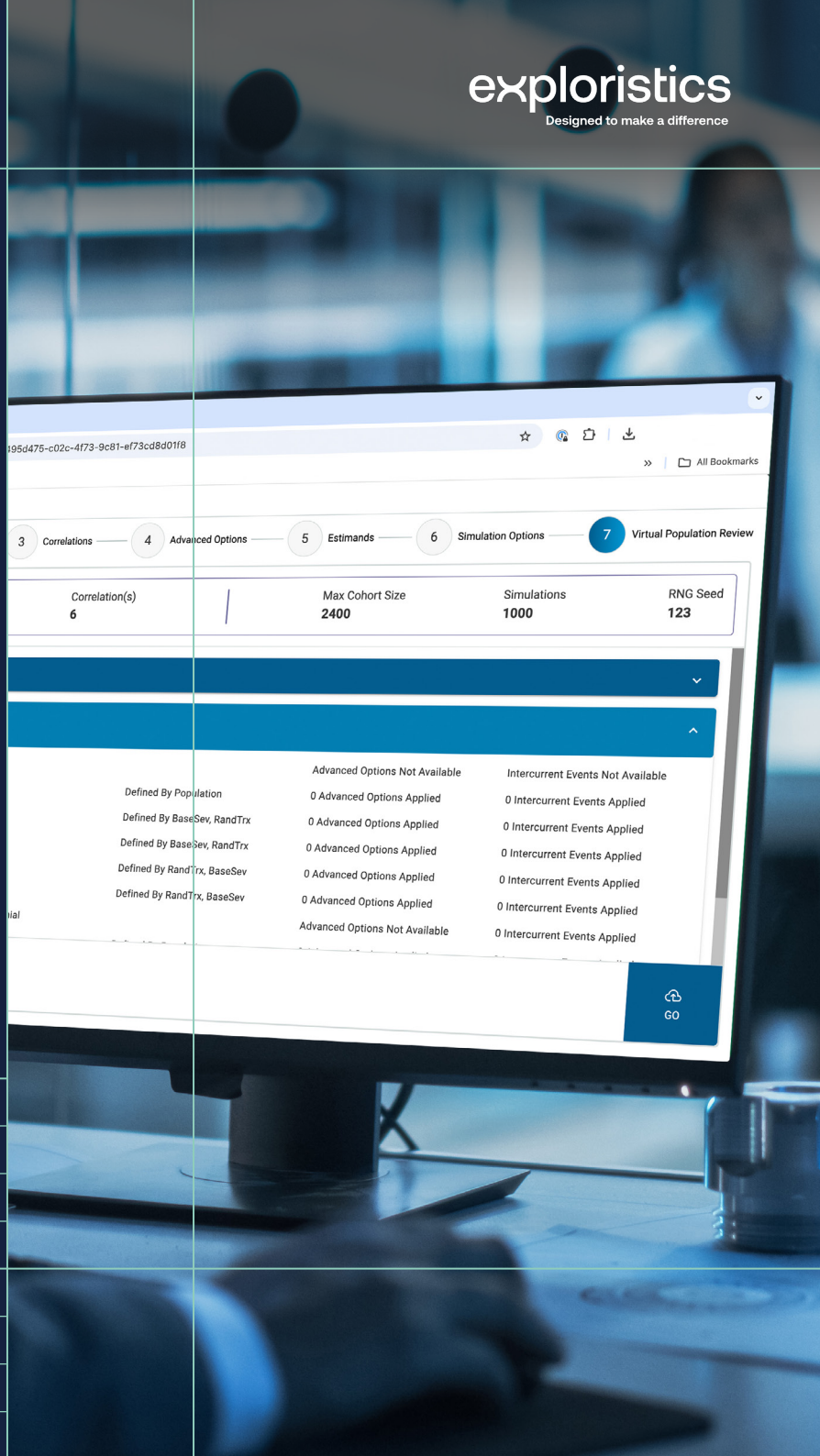
Software Validation Step 4 Software Qualification

External User Validation

KerusCloud is also validated externally by current users and customers. External statisticians have **independently verified** KerusCloud outputs as part of the quality control (QC) process.

They have shown that KerusCloud has delivered **enormous value** in terms of reducing the risks, costs and duration of studies and studies have progressed to completion with clear study outcomes. Often, customers go on to integrate KerusCloud into their standard processes.

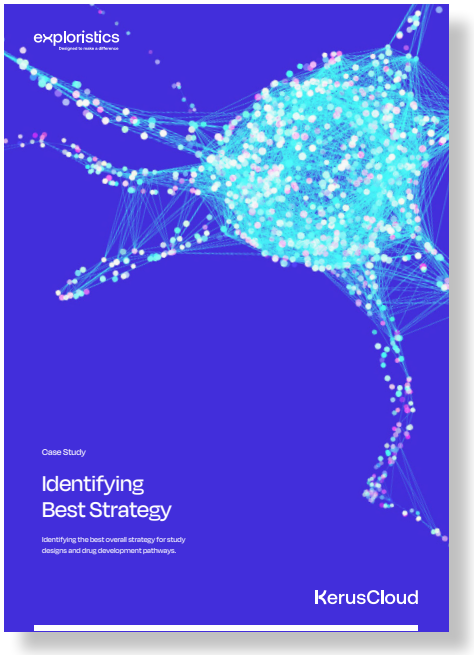
Further external validation comes via our interaction with regulatory bodies such as the **FDA, MHRA** and **EMA.** KerusCloud has followed regulatory quality processes and allows access to simulation code. However, while there is currently no formal approval for the software from regulators it has been used to support multiple successful submissions and initiatives, such as the **breakthrough therapy initiative** and the **medicines adaptive pathways for patients (MAPPs).**



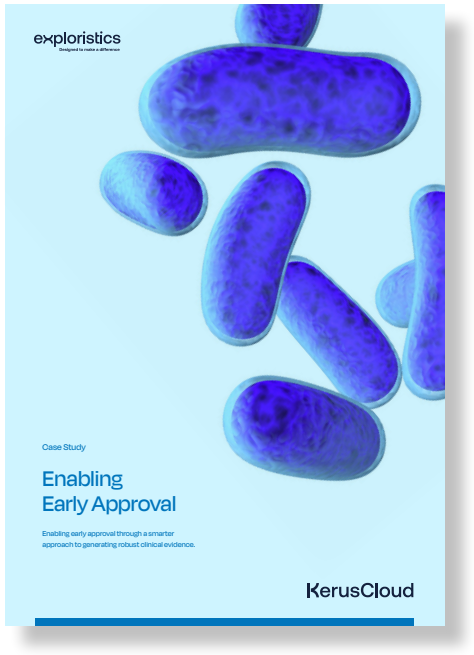
Software Validation Step 4 Software Qualification

Discover more on how KerusCloud has been used:

Support for early approval initiatives by Regulators

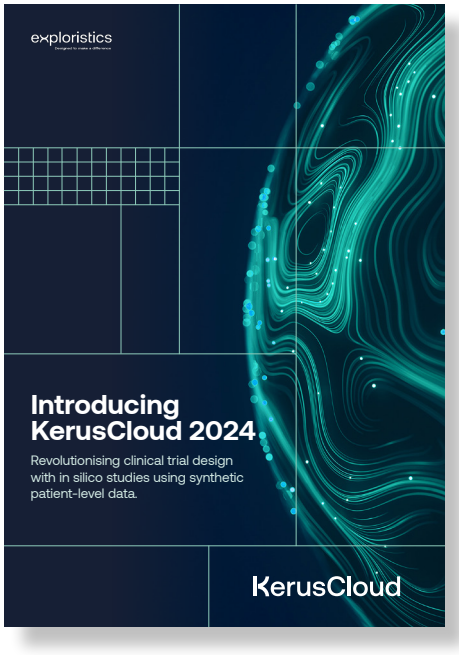


Identifying Best Strategy with KerusCloud



Enabling Early Approval with KerusCloud

Revolutionising study design with Synthetic Data



In silico studies using synthetic patient-level data with KerusCloud