

Almac Clinical Technologies **Solutions Suite**

The Most Flexible IRT in the Industry





Simplify PLUS



UNLIMITED

IXRS°3

BUILT TO ADAPT

INTERACTIVE RESPONSE TECHNOLOGY With over 20 years in the industry, we know very well the challenges and the pressures our sponsors experience when building and running a clinical study: patient recruitment, protocol adaptations, site and vendor selections - the list is long, and expectations are high. Almac Clinical Technologies Solutions Suite solves your Patient Randomization and Supply Management challenges and allows you to cross IRT off your list.

520+ 11,000+ 3800+ IXRS®3 live studies **IXRS** studies site activations per year

67,000+ **65**+ 120+

languages

Alerting

countries

Open Close

Caps

Cohorts

UNLIMITED

Flexible startup mode for complex and adaptive protocols

the most configurable and customizable technology available

IRT Platform

Setup Speed

Customization

Before Go Live

Tailor your IXRS®3 platform with

IXRS®3

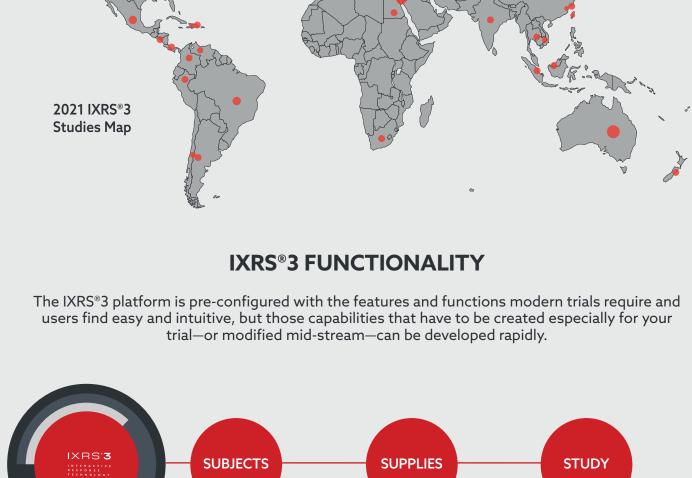
From 8 Weeks

customizations

\$\$\$

Unlimited

current patients



Screening • Rescreening • Failure **Supply Release Management** Study Management Configuration Settings Country Settings Randomization Enrollment **Supply Ordering** Automated **Enrollment Controls** Manual Scheduled • Unscheduled

Shipment Acknowledge

Skipped Visits



Pre-built Connectors

We've already anticipated the type of third-party integrations that you'll need - and keep adding more



Different studies have different IRT needs. Almac Clinical Technologies' Solution Suite offers

Simplify PLUS

three approaches to starting up your IXRS®3 platform, meeting the varying needs of

Rapid startup mode, plus,

Add select features and add-ons

before day one to our fastest IRT

IXRS®3

From 5 Weeks

select upgrades

start-up mode in the industry

select upgrades

IRT Platform

Setup Speed

Customization

Before Go Live

configuration, speed to go live, and cost constraints.

Simplify

Launch your trial in as little as

2 weeks - configure on the go

From 2 Weeks

Out-of-the-box

open-ended requirements

Unlimited

Rapid startup mode for

simple protocols

IRT Platform

Setup Speed

Before Go Live

Customization

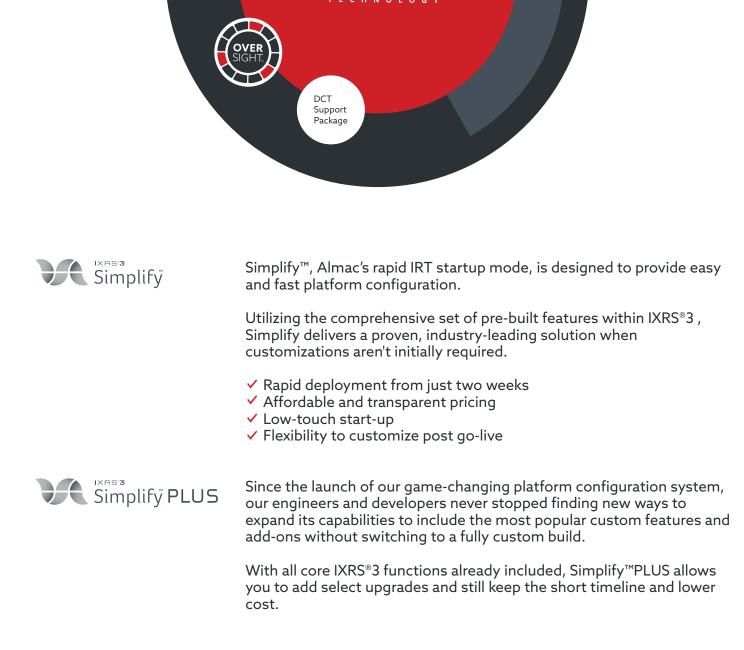
After Go Live

Perfect for

Customization After Go Live Customization Unlimited Unlimited After Go Live Protocols requiring select Complex and adaptive Simple protocols without Perfect for Perfect for feature upgrades or studies and unique

add-on components

Out-of-the-box, plus,



UNLIMITED

OUR FAVORITE SIMPLIFY™

Expandable Core

& SIMPLIFY™ PLUS FEATURES

Never get "locked in." If unexpected protocol

necessary customizations using a validated

software delivery methodology.

amendments become a reality after your initial

system is delivered, we rapidly and safely layer the

Master Protocols

✓ Platform

any third-party system. IXRS®3 UNLIMITED is the result of over two decades of Almac's IRT experience. From complex to adaptive, there isn't a protocol this startup mode can't accommodate:

✓ Basket

ADD-ONS

UPGRADE YOUR IRT EXPERIENCE

Accountability and Reconciliation Tracking

ART™ is a completely configurable solution for accountability and reconciliation that conforms to any protocol giving you complete control over sites' compliance with Good Clinical Practice

ART™ is not just a tool for supply management and monitoring. It is vital for sites to achieve compliance, essential for CRAs to streamline their operations, and key for Clinical Operations to

Identify data inconsistencies, protocol deviations, and data integrity issues through audit trail **reviews.** It's critical to be able to quickly see trends and issues and take necessary action. OVERSIGHT provides on demand visibility to the data history of Kits, Subjects, and Sites. It is a

critical control point given that in many instances the IXRS acts as an eCRF given it is the first point of entry and as such the source of data that is ultimately pushed to other systems (EDC, eCOA, CTMS) and can be used to investigate any potential discrepancies between systems or

The International Council for Harmonization of Technical Requirements for Pharmaceuticals for

performed oversight of the study. Three views for traceability include for events, summary and

Human Use (ICH) revised guidance requires documented evidence on how the sponsor

 $\mathsf{ART}^{\scriptscriptstyle\mathsf{TM}}$

Umbrella

With the most comprehensive and customizable delivery model available, we are able to tailor the IXRS platform configuration and workflow to sponsor-specific requirements, as well as integrate with

scratch.

Transparency

Prebuilt Integrations

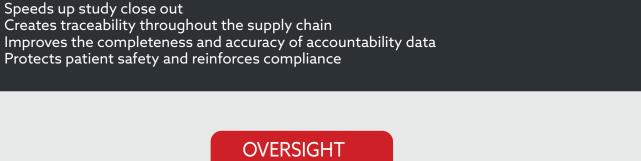
You can see how changes to platform configuration

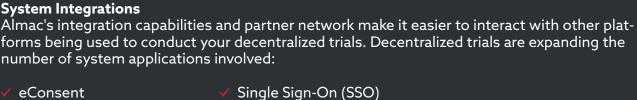
Simplify™ includes integrations with other common

eClinical systems removing the time required for

planning and starting a new EDC integration from

effect the cost and timelines in-real-time.





Remote Screening

Patient retention by lessening the burden of traveling to every dispensing site visit Preventing wasted investigational material at sites with low or no enrollment

IRT generates patient specific assignment and

drug order forms

Site sends PII

to Depot via Form

Provides the ability for a site to register a visit with home delivery of investigational material.

IXRS3

EDC ersonalised Medicine that a successful study is the result of a myriad of

600+ Studies

50+ Studies

200+ Studies

25+ Studies

US HQ

+1 215 660 8500

Durham, NC, USA

+1 (919) 479 8850

1200+ Studies 400+ Studies **Integration Experience**

(GCP).

monitor, audit, and produce records.

Streamline the reconciliation process

ongoing reconciliation activities during the trial.

transaction details.

System Integrations

Patient Recruitment

IXRS®3 Decentralized Trial Features

DTP (Direct To Patient)

workflow management

This type of protocol design can help with:

Agility in changing supply chain landscape

eConsent eCOA

A step ahead of the latest guidelines & regulations

Trial Data Integrity **Monitoring System**

DCT Support Package As sponsors embrace components of decentralized clinical trials (DCT), we're further expanding our capabilities in support of these trial designs.



includes many of the biggest and most innovative players in the industry.

Partnership Programs With our IRT focus and expertise, we understand

technologies, data solutions, and people - all working together to achieve a common goal. We built our IXRS®3 Solutions Suite to be

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EDC

CTMS

Clinical Supplies

Optimization

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Almac Clinical Technologies' IXRS®3 Solutions Suite can integrate with any system or vendor.