



Navigating Excursion Management in Clinical Trial Settings

Strategies for Prevention, Improving Detectability and Decreasing Response Times

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Agenda

- Minimizing risk – preventative actions
- What to consider when defining an excursion management process:
 - Data
 - People
 - Technology
- Case study: What happens when Sponsors lose sight of alarms
- Innovations in the excursion management process



Fundamentals of Minimizing the Risk of a Temperature Excursion



Identifying Risk – What are the Risks?

Drug will be exposed to
adverse temperature conditions

Reported

- Excursion is reported
- Drug is rejected
- Patient is not able to be dosed
- Patient lost from the trial

Unreported

- Excursion is not reported
- Drug is not rejected
- Patient is dosed
- Adverse reaction

Identifying Risk – When Can Excursions Occur?

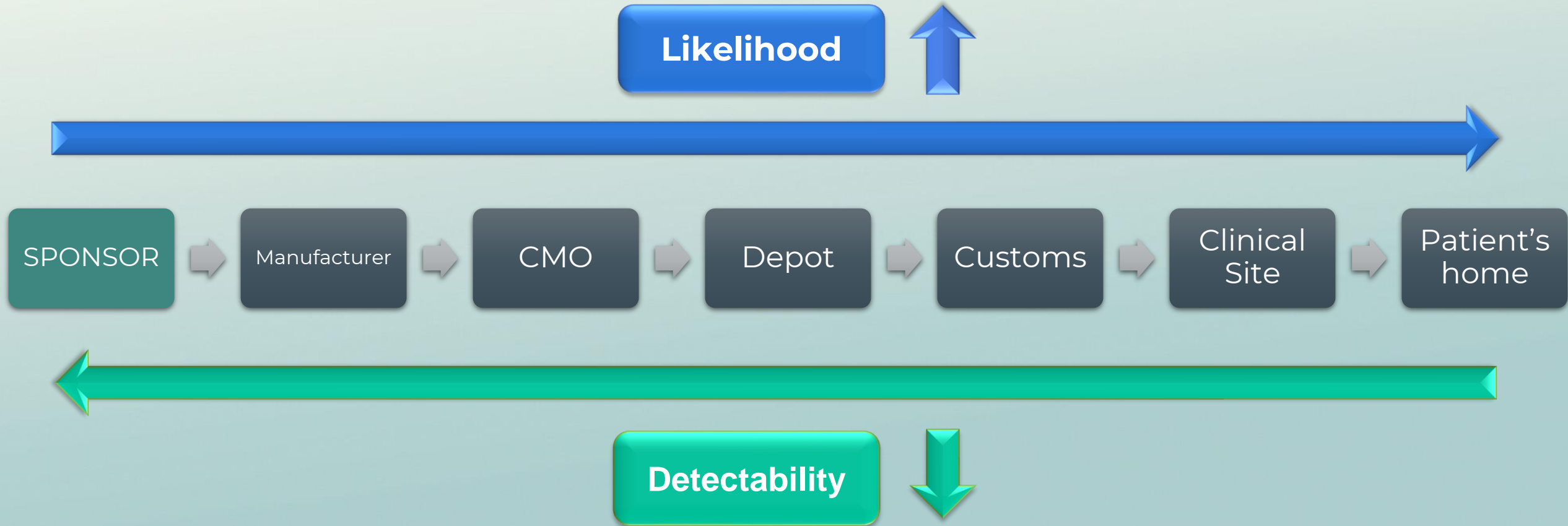
When the drug is stored

- Manufacturer
- CMO
- Depots
- Customers
- Clinical site
- Patient's home

When the drug is moving

- Manufacturer to CMO
- CMO to Depot
- CMO/Depot to customs
- CMO/Depot to clinical site
- CMO/Depot to patient's home
- Clinical site to patient's home

Identifying Risk – Risk Assessment



Decreasing the Likelihood of Excursions - Prevention



- Phase change shippers



- Experienced distribution staff at CMOs and Depots



- Reliable courier services



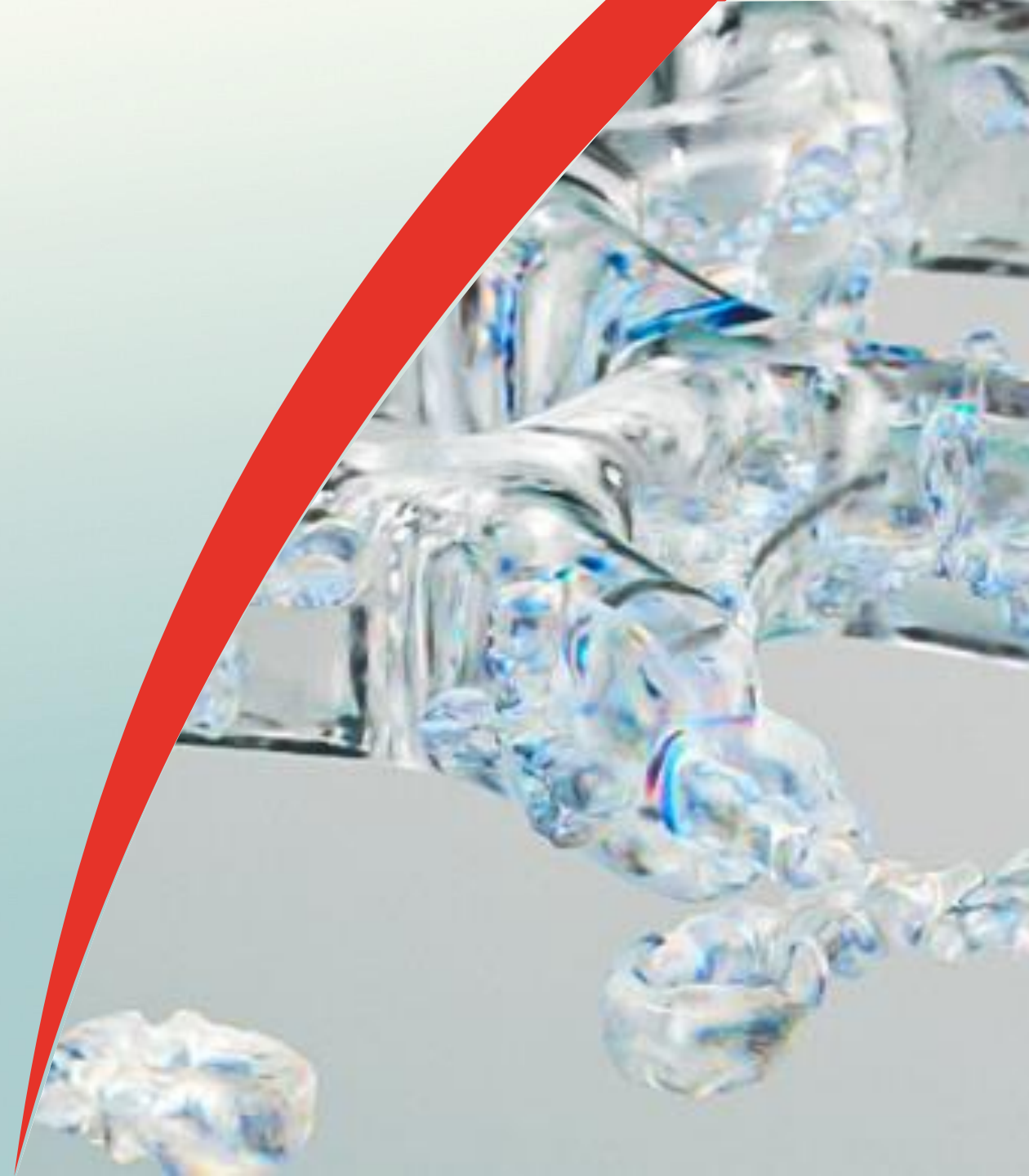
- Establishing robust processes with sites on handling drug/temp monitors



- Real time temperature devices during transit – cost vs. gain



Defining an Excursion Management Process



Key Areas to Consider



Excursion Management - Data

What data?

- What do you need for **regulatory** purposes?
- What do you need to adjudicate an **excursion**?

When do you need the data?

- When do you want temperature monitor **data** from **shipments**?
- When do you expect **excursions** to be notified?
- How are you going to manage data at the **clinical site storage facilities**?

How to get/manage the data?

- Can you **collate and locate** the information easily?
- Will you know when there are **gaps** with your data?
- How are you going to manage **stability updates**?
- How are you going to **cumulatively track** excursions?

Excursion Management - People

What can you ask clinical sites to do?

- Processes need to be **easy**
- Sites need **direction and clarity**
- What can aid **compliance**?

What can your team manage?

- What are you expecting your **resources** to manage?
Experience?
- What **size** is the study? What is the workload going to look like?
- How are resources getting **centralised access** to data?

When do you need help from external parties?

- Excursion management – **time zone** considerations
- Compliance of sites – what has **shipped** vs. data **returned**?
- **Collation** of data

When does it make sense to bring in technology?

- Where do you need **help**?
- What **companies** are you dealing with in your **supply chain**?
- Who is it going to **impact** daily?
- System **support & roll-out considerations**

What technology can you bring into the mix?

- Temperature management solution system?
- IRT?
- What level of **validation** do these systems have?

What about the cost?

- Value vs. investment
- Justification?

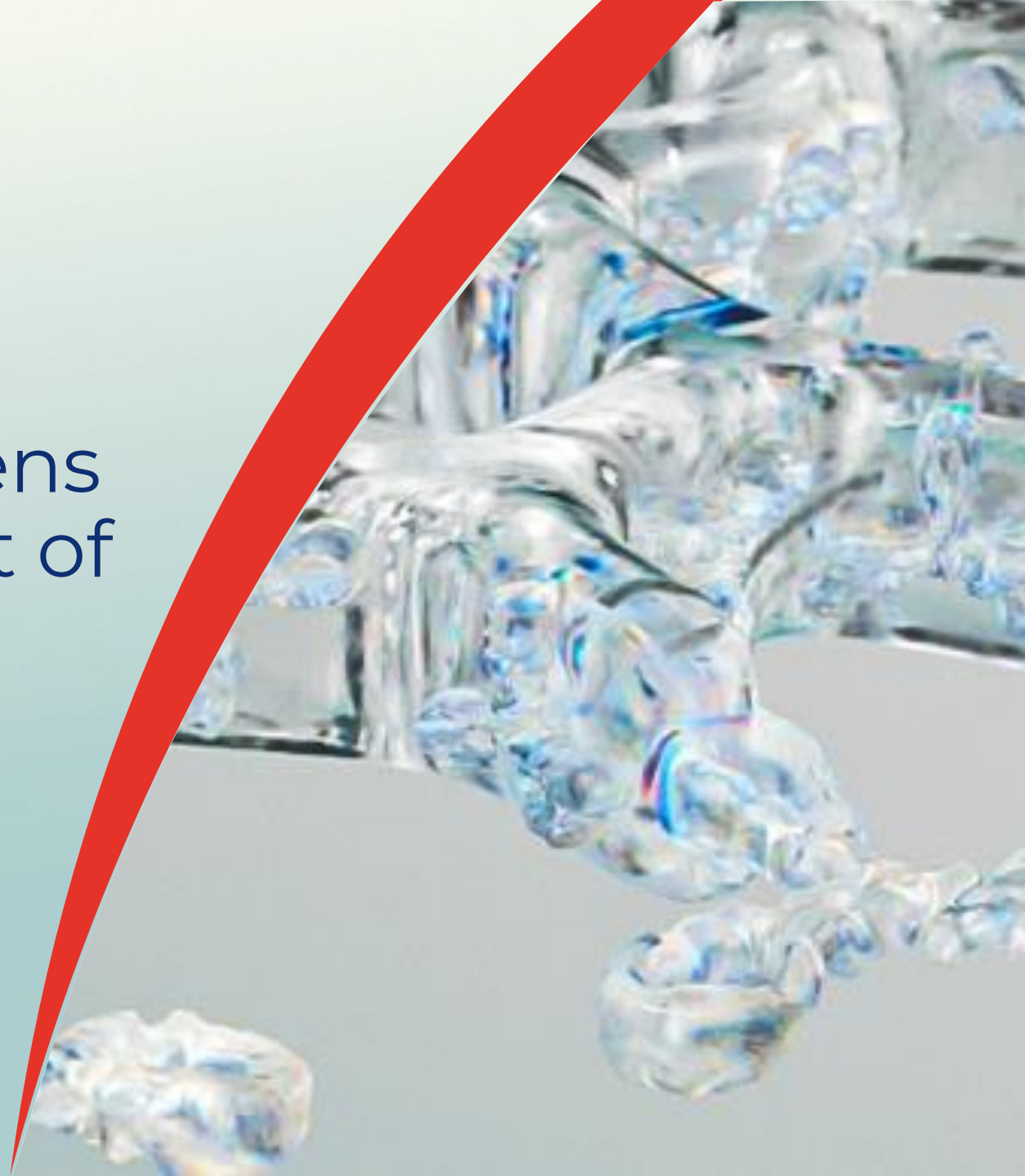
Don't Forget About the Patient!

Improving your excursion management processes means:

- Patients get dosed safely
- Patients get dosed quickly
- Patients get the care they need
- Trials can continue to run smoothly and successfully, ultimately benefiting patients coming down the track



Case Study: What happens when Sponsors lose sight of alarms



Case Study: Losing Sight of Alarms

Background

- Current Almac TS customer
- Adjudicating transit & site excursions
- CRO responsible for site compliance

Issue

- FDA auditor discovered 12 unreported site storage excursion
- Over a 2 year period, drug had been administered to patients

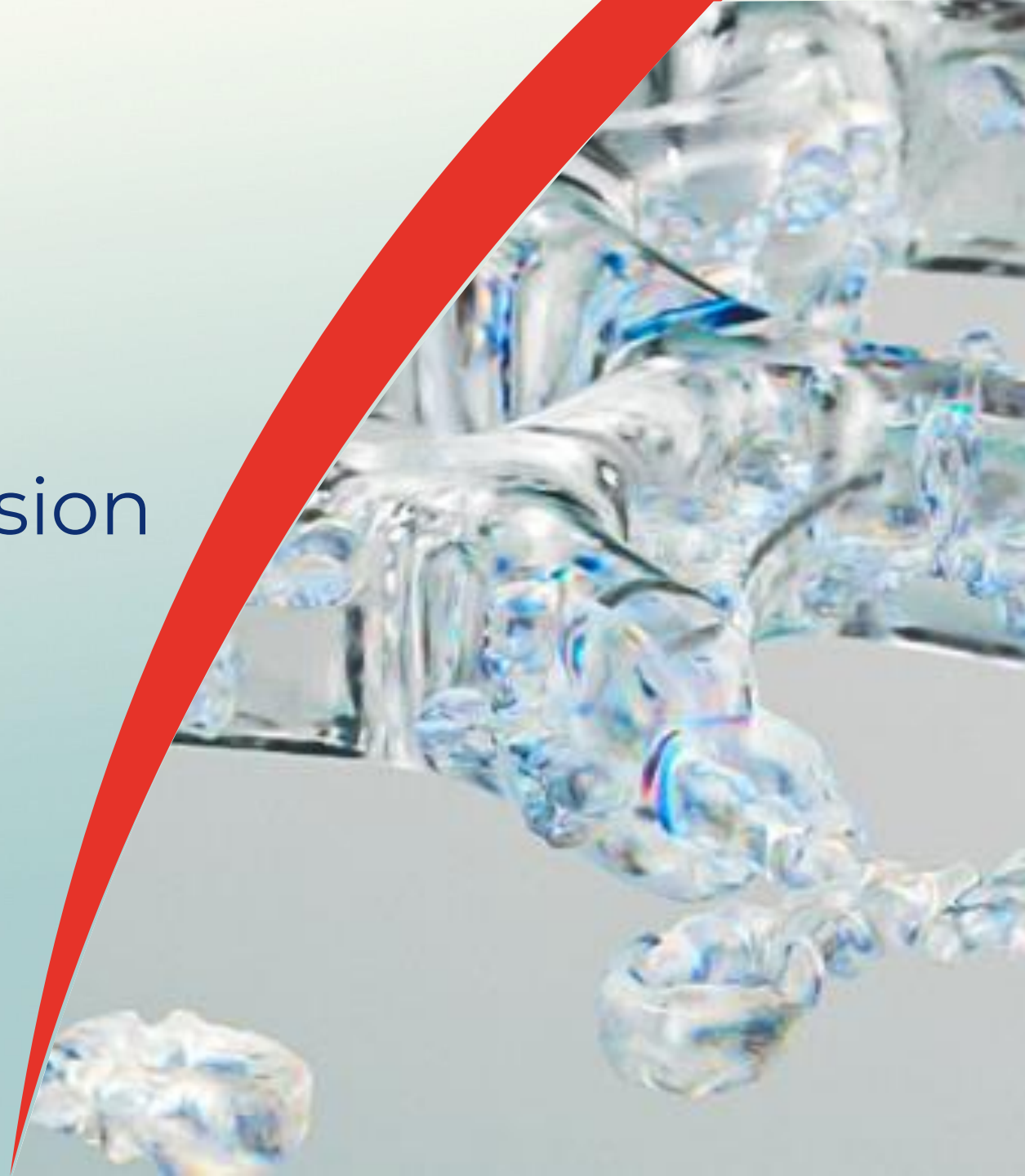
Action

- CRA had been visiting site but had not noticed excursions
- Almac supported the expedited review
- No unacceptable material

Next Steps

- Almac supporting Sponsor on site storage compliance
- Proactively collecting and reviewing site storage temperature logs on a monthly basis

Innovations within Excursion Management



What is coming next?

Automatic Adjudications

- Using stability profile data to get clinical sites decisions on excursions quickly
- Considerations:
 - System validations
 - Cumulative tracking of excursions – true end to end?

Use of Real Time Monitors

- Ensuring compliance and notification of excursions
- Considerations:
 - Cost
 - Management
 - Integrations & reliance on IRTs

What & where is the risk?

- Decreasing likelihood - mitigations
- Increasing detectability - process

Define a process - key considerations

- **Data**
 - What information do you need?
- **People**
 - Who is going to need the information?
- **Technology**
 - How are you going to get the information to them?

Don't forget the patient!

Thank you!

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