ThermoFisher SCIENTIFIC

DEFENSE IN DEPTH

OFF-SITE STORAGE OF BIOLOGICAL SPECIMENS AND BIOPHARMACEUTICALS FOR RISK MITIGATION

By Bruce C. Simpson, Director of Commercial Operations, Thermo Fisher Scientific

- API
- BIOLOGICS
- VIRAL VECTOR SERVICES
- EARLY & LATE PHASE DEVELOPMENT
- CLINICAL TRIAL SOLUTIONS
- LOGISTICS SERVICES
- COMMERCIAL MANUFACTURING

patheon

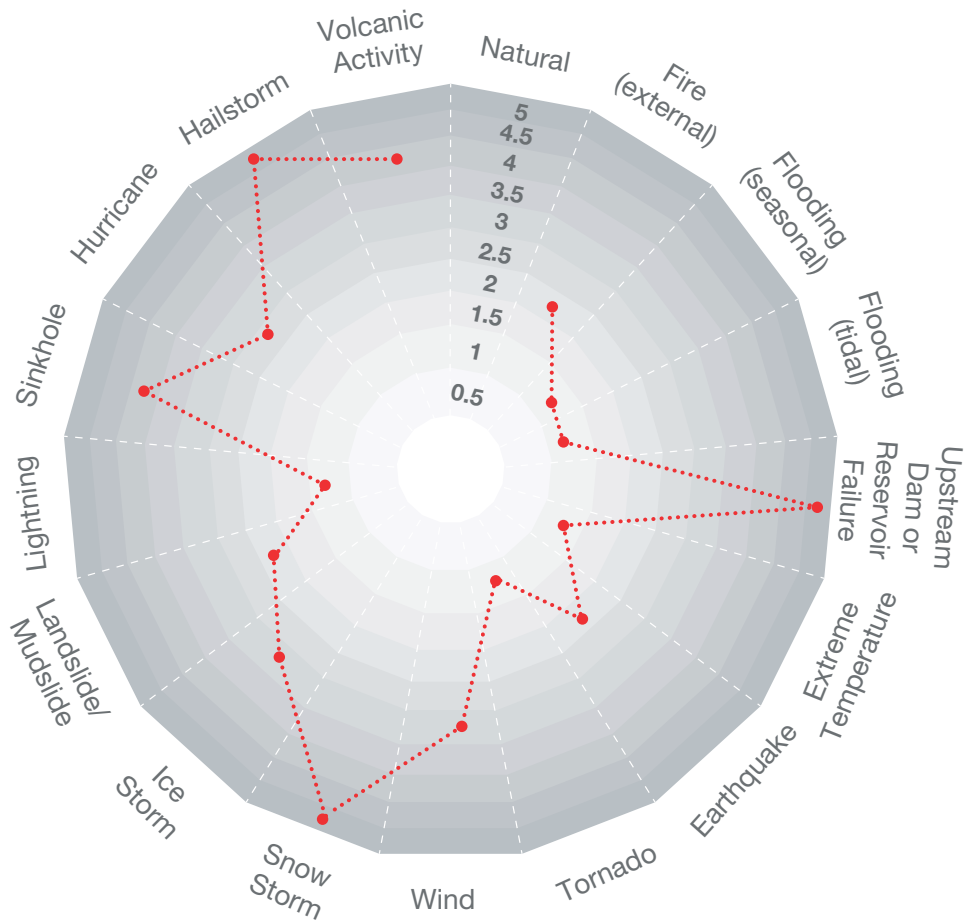
TABLE OF CONTENTS

Introduction	3
7 Key Tips Overview	4
Threat Assessments	5
The Emergency Action Plan	7
Location, Location, Location	8
Risk Mitigation Infrastructure	9
Biorepository Building Design	10
Protect Your Data	11
Do You Have the Time to Build?	12
Additional Resources	13

INTRODUCTION

The management of risk is part of all business operations, but to commercial biobanks, clinical research institutes, biotech, and pharmaceutical companies, risk mitigation is a critical element of day-to-day operations. The costly nature of irreplaceable samples/cell lines and high value products such as cell-based drugs, and biological active pharmaceutical ingredient (Bio-API) dictates planning for the full continuum of risk. The best solution is frequently off-site storage.

Choosing an offsite storage facility means asking the right questions, to determine if the storage provider has the appropriate risk mitigation infra-structure in place, beginning with a realistic threat assessment for the location.



7 KEY TIPS OVERVIEW

1 Threat Assessments

2 The Emergency Action Plan (EAP)

3 Location, Location, Location

4 Risk Mitigation Infrastructure

5 Biorepository Building Design

6 Protect Your Data

7 Defense in Depth

THREAT ASSESSMENTS

To Threat Assessments evaluate the probability of events such as:

- Tornadoes
- Earthquakes
- Floods
- Hurricanes
- High winds
- Airplane crashes
- Biological terrorism
- Chemical terrorism
- Radiological (nuclear) terrorism
- Hazardous material spills
- Arson
- Explosions (bombs, accidents), and other
- Local hazards (communication outages, power and other utility failures, internal flooding).

THREAT ASSESSMENTS

Risk/threat assessments are necessarily somewhat subjective. Most threats are of a low probability; long periods of mild weather are normal, and terrorism may be of minor concern as well, except for sites that are near potential targets, such as government buildings and major airports.

In addition to assessing the probability of a threat, the potential severity should be considered. A hurricane may be unlikely, but could leave serious damage behind, including extended power outages.

If an offsite storage provider has not performed a realistic, well-researched threat assessment, then the risk mitigation strategy is based on guesswork.

THE EMERGENCY ACTION PLAN

Ask potential off-site storage providers if an EAP is in force. Is there a plan for ensuring the safety of the employees, for securing the facility, for addressing the media, and notifying the relevant authorities following a disaster? Is there a plan for restoring normal operations as quickly as possible? These plans should be written, reviewed at regular intervals in case changes are warranted, tested via walk-through or table-top exercises to the extent possible, and the employees trained on the procedures. Ideally, this training is also documented, reviewed, and repeated annually as well as whenever changes are made.

Contact information for needed emergency supplies, such as providers of trailer-mounted generators, dry ice, liquid nitrogen.

Alternative locations for conducting critical business activities.

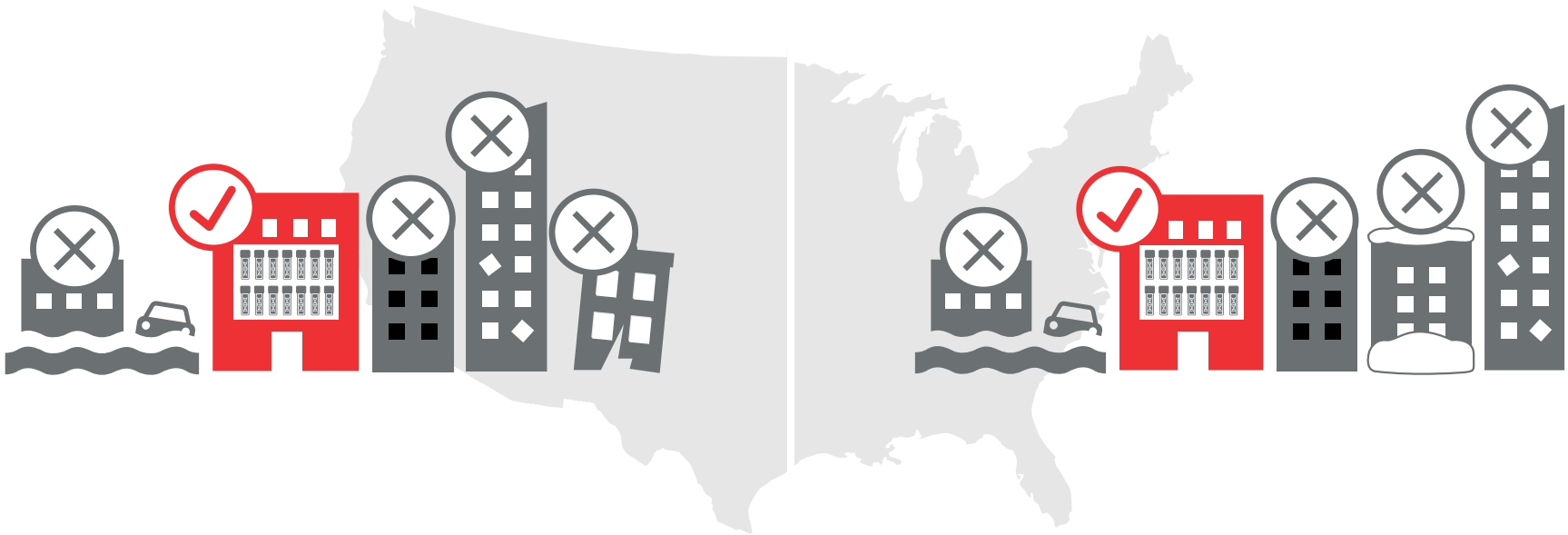
The local, State, and Federal agencies (and their contact information) that must be informed of environmental disasters.

Telephone numbers for reporting natural gas leaks and downed power lines.

Contact information for contractors for clean-up of hazardous spills.

Other resources and information.

LOCATION, LOCATION, LOCATION

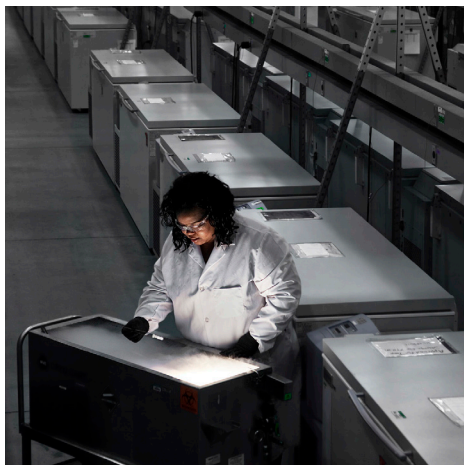


On the West Coast, proximity to the fault and compliance with local building code is a key consideration. Choosing an off-site storage facility may involve close examination of whether or not the facility is constructed not only to meet minimum code requirements, but to provide the specific protection needed for your valuable materials under worst case scenario conditions.

On the East Coast, is the location susceptible to tornadoes, hurricanes, or severe snowfall? How well does the off-site storage provider prepare for such events? Is the facility prepared for the once-every-fifty-years event as well as the more normal level of severity?

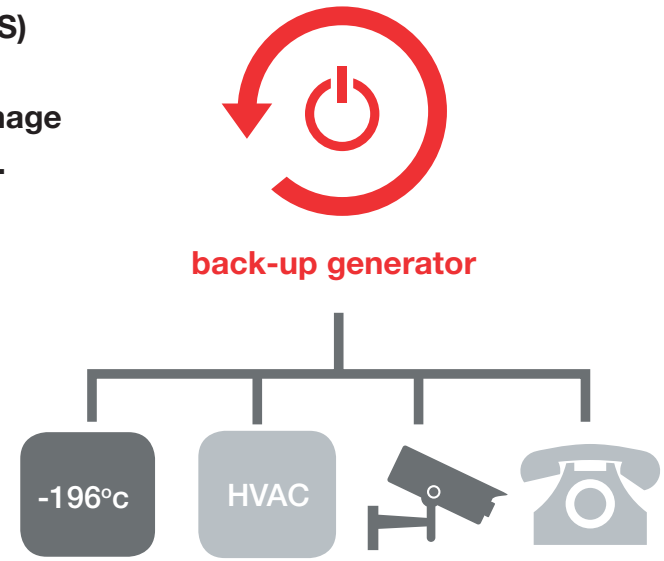
RISK MITIGATION INFRASTRUCTURE

Storage facilities should have back-up capacity well in excess of the minimum requirements. For instance, this may mean 100 percent redundant HVAC capacity. Mechanical freezers expel large amounts of heat that must be removed to keep the units running efficiently, reliably, and for a maximum lifespan. Fully redundant HVAC allows one unit to maintain correct facility temperatures while the other is serviced or repaired, as well as provide extra cooling capacity for summer heat waves.



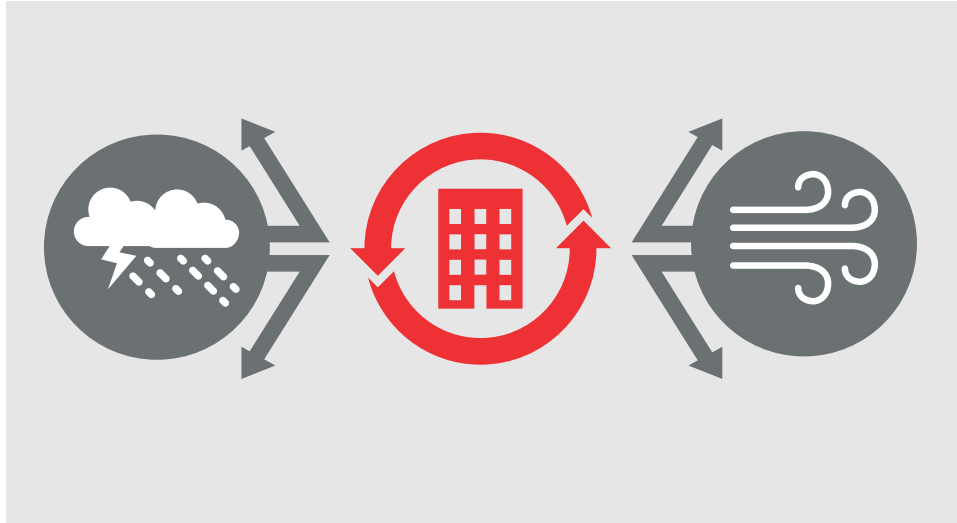
The same is true of back-up generators and their fuel supply. If the bulk tank holds only enough fuel for 72 hours, is there a possibility that the supplier, following a disaster, will not be able to reach the facility within that time frame? Do the back-up generators support the temperature monitoring systems, security systems, the telephones, and HVAC system?

A uninterruptible power supply (UPS) should be installed parallel to the back-up generators to prevent damage to electronics during power surges.



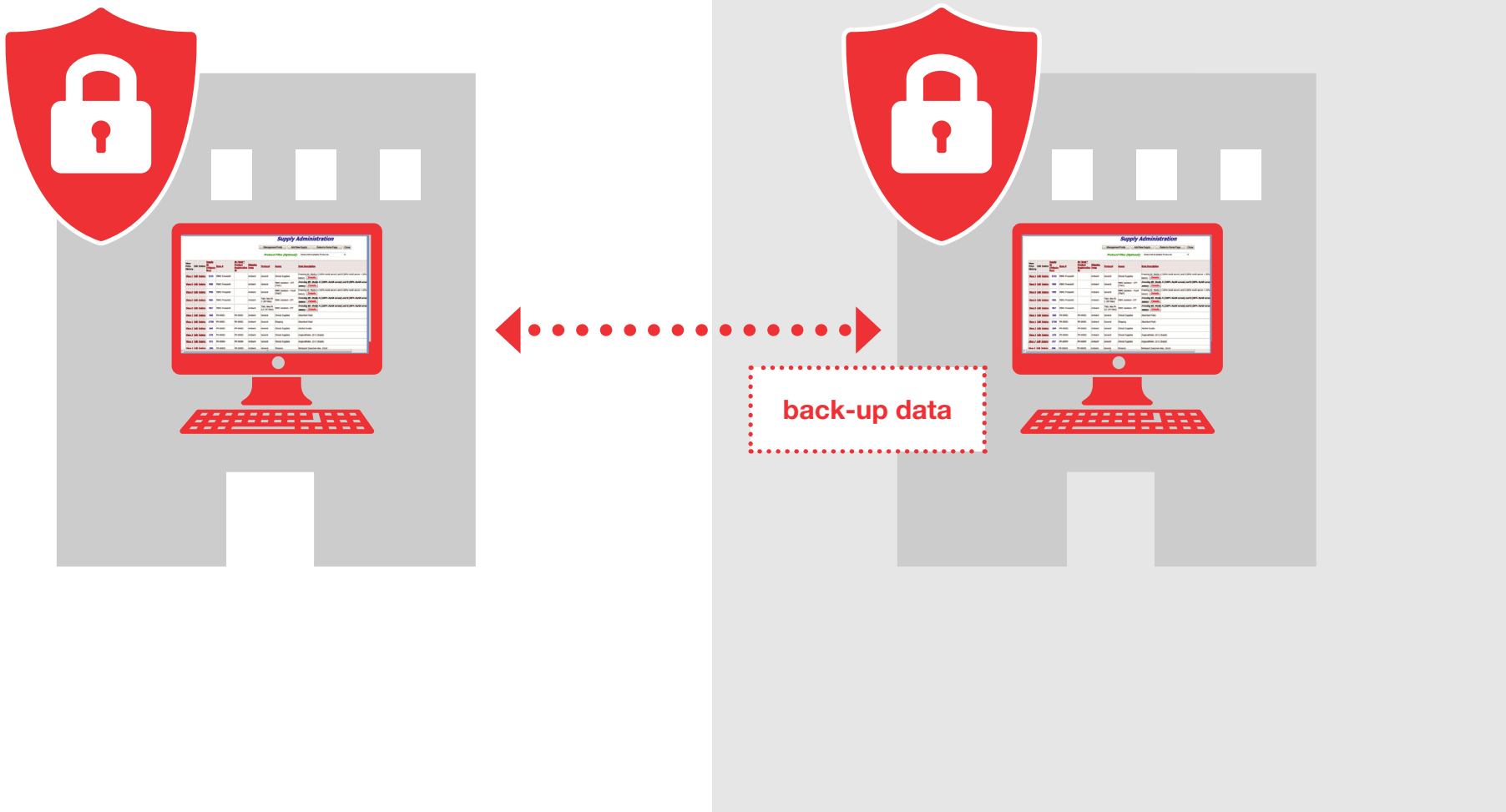
BIOREPOSITORY BUILDING DESIGN

Is the off-site storage building designed to protect against wind and water? Will the roof withstand the weight of a severe snowfall? Are the lower levels protected from flooding? The design should prevent water from entering the facility as well as minimize damage to the power distribution and back-up generators. A number of repository disasters occurred in the wake of Tropical Storm Sandy in 2012; these were in facilities where the electrical switchgear and generators (and in some cases, the biospecimens and laboratory animals) were located in basements that were prone to flooding.



PROTECT YOUR DATA

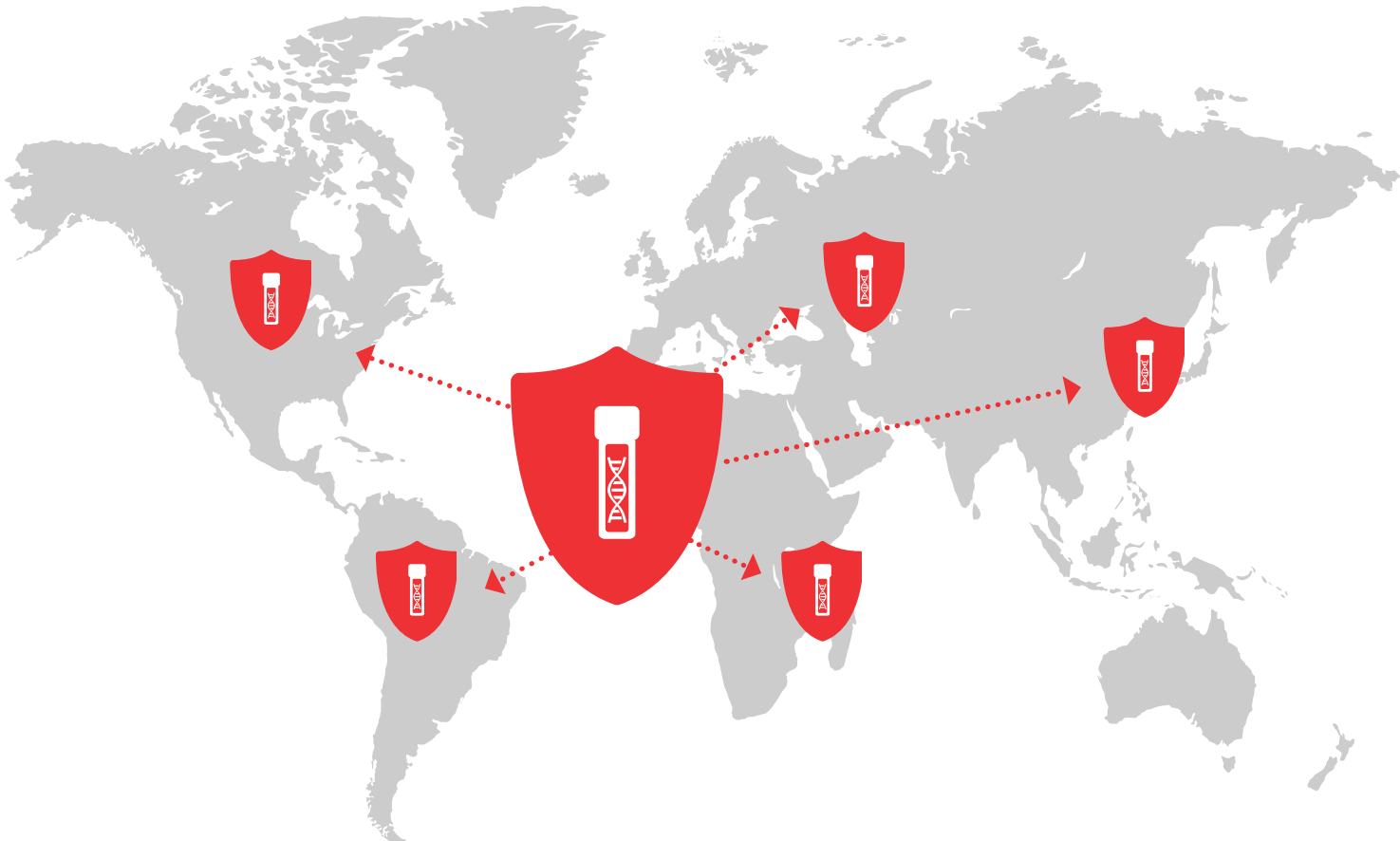
The off-site storage provider should manage your inventory data as carefully as your specimens, including back-up of the data on a preset schedule, testing the data for recoverability, and storing it at an offsite, fireproof, well protected location.



DO YOU HAVE THE TIME TO BUILD?

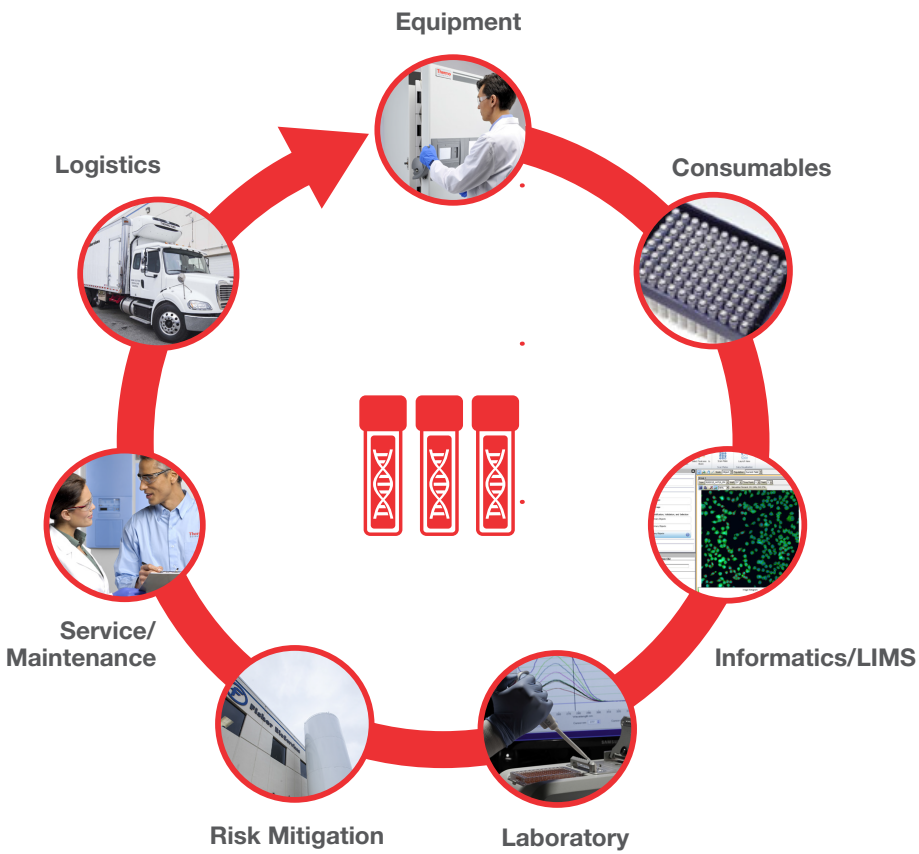
Risk mitigation occurs at all levels of operations. Additional options include dividing inventory into mirrored collections and storing them in multiple geographically separate biorepositories.

The question of risk mitigation is never fully answered. The nature of the biotech industry is one of constant change, and we must keep asking: If a disaster happens, will your research and materials be safe?



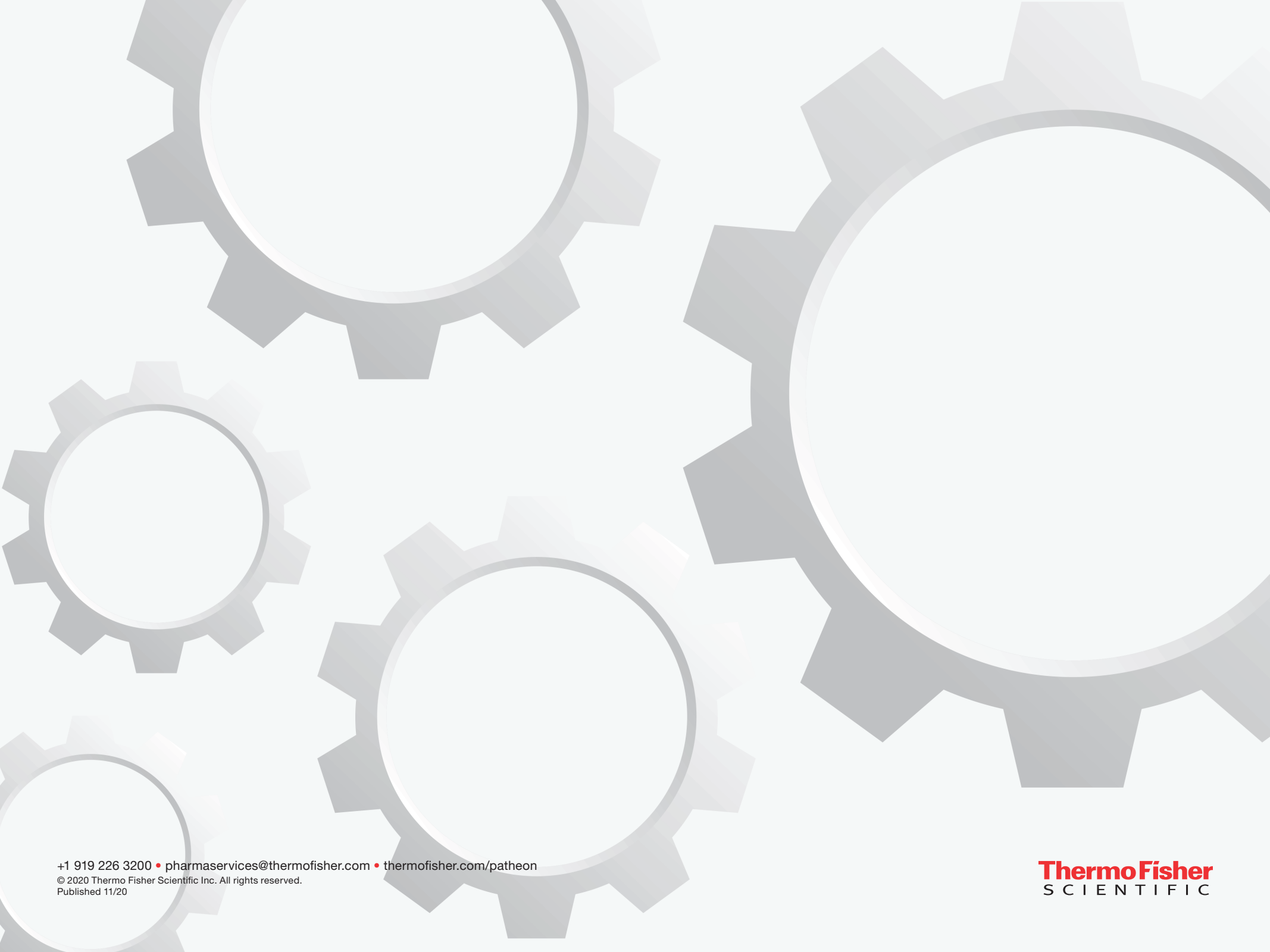
ADDITIONAL RESOURCES

Every phase of your sample lifecycle is critical to your risk mitigation strategy. Explore additional resources to learn how you can support every step of your biobanking workflow.



You can also consider using a biobank service provider to manage your on-site biobank as well as to provide off-site storage of your samples for risk mitigation.

- **Professional Staffing Services**
- **Information Technology Systems**
- **Biobank Equipment & Maintenance**



+1 919 226 3200 • pharmaservices@thermofisher.com • thermofisher.com/patheon
© 2020 Thermo Fisher Scientific Inc. All rights reserved.
Published 11/20

ThermoFisher
SCIENTIFIC