

Life Sciences Clinical Trials Risk Map

5th Edition



Risk. Reinsurance. Human Resources.

Aon Life Sciences Group
One Liberty Place
1650 Market Street, Suite 1000
Philadelphia, PA 19103
t: +1-215-255-1857
e: lifesciences@aon.com

Aon Life Sciences Clinical Trials Risk Map

The globalization of clinical trials continues to be on the rise, leading to a plethora of regulatory and operational challenges for the Life Sciences industry. Aon's 5th edition Clinical Trials Risk Map highlights clinical trials insurance regulations and complexities for over 80 countries throughout the world leveraging Aon's global network and clinical trials expertise. Our global network is positioned to help life sciences companies efficiently and effectively secure international clinical trials coverage that complies with the regulatory requirements of individual countries, ultimately minimizing the risk of financial volatility.

Aon Life Sciences Group

The Aon Life Sciences Group has been assisting life sciences companies with securing international clinical trials insurance for over 30 years. We have the largest equity-owned global network in the world, housing clinical trials specialists who provide our life sciences clients with industry-leading expertise and accountability. Our experts constantly review country-by-country clinical trials regulations in order to provide our clients with industry-leading risk management advisory and brokerage services.

© Copyright Aon plc 2015. All rights reserved.
No part of this publication may be reproduced, stored in a retrieval system, or transmitted in any way or by any means, including photocopying or recording, without the written permission of the copyright holder. Application for which should be addressed to the copyright holder.

Published by Aon Global Corporate Marketing and Communications
#16641-02/2015

Risk. Reinsurance. Human Resources.



Compulsory Clinical Trials Insurance Requirements	Symbols Illustrating Clinical Trials Insurance Characteristics
No Compulsory Clinical Trials Requirements	Compulsory Limit of Liability
No Compulsory Requirements; However, Standard Practice Dictates Clinical Trials Coverage	High Compulsory Limit of Liability
Compulsory Clinical Trials Requirements	Medical Malpractice is a Standard Policy Extension
Compulsory Clinical Trials Requirements with Extended Reporting or Life-of-Trial Requirements	Foreign Entity may be Listed as Named on a Local Policy
No Data Available	Admitted Insurance Laws May Apply
	Coverage is Available on a No Fault Basis
	Standard Clinical Trials Insurance Coverage may not include Trial Participant Pre-Enrollment Screening
	Clinical Trials Insurance Policies allow Direct Reimbursements to Trial Participants
	Aon Office

Symbol Definitions:

Compulsory Clinical Trials Insurance Requirements: Government-mandated clinical trial liability insurance, evidence of which must be provided by sponsors to regulators before regulatory authorities will grant approval to commence the trial.

Extended Reporting or Life-of-Trial Requirements: Government-mandated insurance regulations requiring that clinical trials insurance include extended reporting or "tail" liability for a period of time following the completion of a clinical trial or Life-of-Trial coverage.

Compulsory Limit of Liability: Government-regulated clinical trial insurance with limit of liability requirements (in some countries limit requirements vary by trial size/number of human subjects).

High Compulsory Limit of Liability: Government-regulated clinical trial insurance with limit of liability requirements in excess of \$5 million (in some countries limit requirements vary by trial size/number of human subjects).

Medical Malpractice is a Standard Policy Extension: Professional liability coverage for trial investigators as part of their participation in the study is a standard coverage under the local clinical trials liability policy.

Coverage is Available on a No Fault Basis: A type of clinical trial liability policy under which insureds are indemnified for losses regardless of fault.

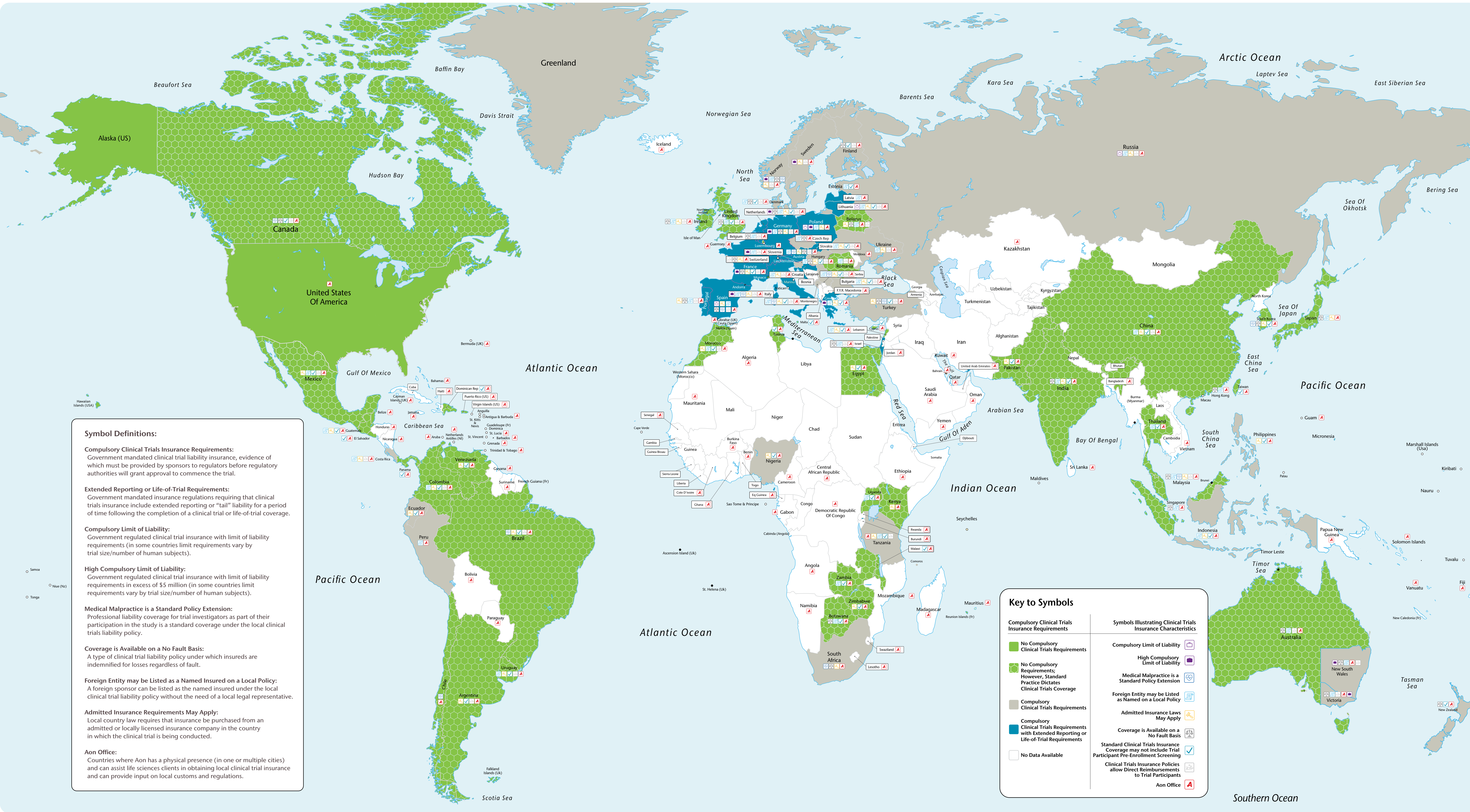
Foreign Entity may be Listed as a Named Insured on a Local Policy: A foreign sponsor can be listed as the named insured under the local clinical trial liability policy without the need of a local legal representative.

Admitted Insurance Requirements May Apply: Local country law requires that insurance be purchased from an admitted or locally licensed insurance company in the country in which the clinical trial is being conducted.

Aon Office: Countries where Aon has a physical presence (in one or multiple cities) and can assist life sciences clients in obtaining local clinical trial insurance and can provide input on local customs and regulations.

Aon Life Sciences Clinical Trials Risk Map

Aon Risk Solutions | Life Sciences Group
 tel: 1+215.255.1857
 e-mail: lifesciences@aon.com



Symbol Definitions:

Compulsory Clinical Trials Insurance Requirements:
 Government mandated clinical trial liability insurance, evidence of which must be provided by sponsors to regulators before regulatory authorities will grant approval to commence the trial.

Extended Reporting or Life-of-Trial Requirements:
 Government mandated insurance regulations requiring that clinical trials insurance include extended reporting or "tail" liability for a period of time following the completion of a clinical trial or life-of-trial coverage.

Compulsory Limit of Liability:
 Government regulated clinical trial insurance with limit of liability requirements (in some countries limit requirements vary by trial size/number of human subjects).

High Compulsory Limit of Liability:
 Government regulated clinical trial insurance with limit of liability requirements in excess of \$5 million (in some countries limit requirements vary by trial size/number of human subjects).

Medical Malpractice is a Standard Policy Extension:
 Professional liability coverage for trial investigators as part of their participation in the study is a standard coverage under the local clinical trials liability policy.

Coverage is Available on a No Fault Basis:
 A type of clinical trial liability policy under which insureds are indemnified for losses regardless of fault.

Foreign Entity may be Listed as a Named Insured on a Local Policy:
 A foreign sponsor can be listed as the named insured under the local clinical trial liability policy without the need of a local legal representative.

Admitted Insurance Requirements May Apply:
 Local country law requires that insurance be purchased from an admitted or locally licensed insurance company in the country in which the clinical trial is being conducted.

Aon Office:
 Countries where Aon has a physical presence (in one or multiple cities) and can assist life sciences clients in obtaining local clinical trial insurance and can provide input on local customs and regulations.

Key to Symbols

Compulsory Clinical Trials Insurance Requirements	Symbols Illustrating Clinical Trials Insurance Characteristics
No Compulsory Clinical Trials Requirements	Compulsory Limit of Liability
No Compulsory Requirements, However, Standard Practice Dictates Clinical Trials Coverage	High Compulsory Limit of Liability
Compulsory Clinical Trials Requirements	Medical Malpractice is a Standard Policy Extension
Compulsory Clinical Trials Requirements with Extended Reporting or Life-of-Trial Requirements	Foreign Entity may be Listed as Named on a Local Policy
No Data Available	Admitted Insurance Laws May Apply
	Coverage is Available on a No Fault Basis
	Standard Clinical Trials Insurance Coverage may not include Trial Participant Pre-Enrollment Screening
	Clinical Trials Insurance Policies allow Direct Reimbursements to Trial Participants
	Aon Office

© Copyright Aon plc 2015. All rights reserved. Published by Aon Global Corporate Marketing and Communications.

The information contained in this map is based on Aon experience as of the publishing date (05/1). The environment (both regulatory and practical) for clinical trials is constantly changing and this map should not be solely relied upon without further consultation from an Aon Life Sciences professional. In addition, ethics committees, regulatory authorities and published guidelines within individual countries can differ depending upon individual study requirements and the views of individual regulators and ethics committees.

Risk. Reinsurance. Human Resources.

