DESIGN, EXECUTION, AND MANAGEMENT OF MEDICAL DEVICE CLINICAL TRIALS

SALAH ABDEL-ALEEM

WILEY

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Published by John Wiley & Sons, Inc., Hoboken, New Jersey.
Published simultaneously in Canada.

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Library of Congress Cataloging-in-Publication Data:
Abdel-aleem, Salah.
Design, execution, and management of medical device clinical trials / Salah Abdel-aleem.
p. ; cm.
Includes bibliographical references and index.
ISBN 978-0-470-47426-6 (cloth)
1. Medical instruments and apparatus–Research. 2. Clinical trials. I. Title.
[DNLM: 1. Equipment and Supplies–standards. 2. Clinical Trials as Topic–methods.
3. Device Approval–standards. 4. Evaluation Studies as Topic. W 26 A135d 2009]
R856.4.A23 2009
610.28′4—dc22
2008049904

Printed in the United States of America.

10 9 8 7 6 5 4 3 2 1

Dedication

For my mother, Farha, my loving wife, Maro, and my sons Omar, Tarek, and Yussuf. Your support has been truly inspirational.

CONTENTS

LIST OF ABBREVIATIONS

AE	Adverse event
ACE	Angiotensin converting enzyme
ANDA	Abbreviated new drug application
ARR	Absolute risk reduction
BMS	Bare metal stent
CBER	Center for Biologics Evaluation and Research (FDA)
CDHR	Center for Devices and Radiological Health (FDA)
CDER	Center for Drug Evaluation and Research (FDA)
CE marking	A mandatory European marking for certain product groups to indicate conformity with the essential health and safety requirements set out in European directives
CFR	Code of federal regulation
CMS	Centers for Medicare and Medicaid Services
CRA	Clinical research associate
CRFs	Case report forms
CRPAC	Clinical research policy analysis and coordination
CRO	Clinical research organization
CLI	Critical limb ischemia
DCFs	Data correction forms
DES	Drug eluting stent
DOB	Date of birth

DOD	Date of death
DSMB	Data safety monitoring board
EC	Ethics committee
ELA	Excimer laser atherectomy
FDA	Food and Drug Administration
FWA	Federal wide assurance
LACI	Laser angioplasty for critical limb ischemia
LOI	Letter of intent
GCP	Good clinical practice
GMDN	Global medical device nomenclature
HDE	Humanitarian device exemption
HIPAA	Health Insurance Portability Accountability Act
HUD	Humanitarian use device
ICF	Informed consent form
IDE	Investigational device exemption
IND	Investigational new drug
IRB	Institutional review board
NDA	New drug application
NIH	National Institute of Health
NSR	Nonsignificant risk
MACE	Major adverse cardiac events
MI	Myocardial infarction
OHRP	Office of Human Research Protection
OPC	Objective performance criteria
PAD	Peripheral artery disease
PI	Principal investigator
PMA	Premarket approval
PTA	Percutaneous transluminal angioplasty
RAS	Renin-angiotensin system
RRR	Relative risk reduction
SAE	Serious adverse event
SAP	Statistical analysis plan
SFA	Superficial femoral artery
SR	Significant risk
SOP	Standard operating procedures

SSN	Social security number
TASC	TransAtlantic Inter-Societal Consensus
TLR	Target lesion revascularization
TVR	Target vessel revascularization
UADE	Unanticipated adverse device effect
WHC	Weighted historic control