

Brighton 2011



OPEN STANDARDS AND GLOBAL COLLABORATION

Hilton Metropole, Brighton. 9th – 12th October 2011

An Introduction to the Pharmaceutical Industry?

By James McDermott



Brighton 2011

Contents

OPEN STANDARDS AND GLOBAL COLLABORATION

Hilton Metropole, Brighton. 9th – 12th October 2011

- Introduction
- Drug Development Lifecycle
 - “The Patent Clock”
- The Clinical Trial
- Drug Regulation
- The Global Industry
- The Clinical Development Process
- Final Thoughts



Brighton 2011

Introduction

OPEN STANDARDS AND GLOBAL COLLABORATION

Hilton Metropole, Brighton. 9th – 12th October 2011

- Overview of the Industry
- Necessarily broad subject
- References are detailed in the paper
- Slides will be available from PhUSE website



Brighton 2011

Drug Development Lifecycle

OPEN STANDARDS AND GLOBAL COLLABORATION

Hilton Metropole, Brighton. 9th – 12th October 2011

Discovery

Pre-Clinical

Clinical

Review/
Approval

Post Marketing

Patent
Application
Milestone



Registration
Milestone

20 years ----->|

< 1.1 years >

<----- 8 years ----->





Brighton 2011

Phases of Clinical Trials

OPEN STANDARDS AND GLOBAL COLLABORATION

Hilton Metropole, Brighton. 9th – 12th October 2011

Discovery

Pre-Clinical

Clinical

Review/
Approval

Post Marketing

- Pre-Clinical (in vivo, in vitro)
- Apply to regulatory authority for permission to use compound in man
 - *Phase I - First time in humans*
 - *Phase II - Exploratory*
 - *Phase III - Confirmatory*
- Apply to regulatory authority for permission to market compound in Region
 - *Phase IV - Post Marketing*

Brighton 2011



OPEN STANDARDS AND GLOBAL COLLABORATION

Hilton Metropole, Brighton. 9th – 12th October 2011

Clinical Trial Definition

“...any form of planned experiment which involves patients and is designed to elucidate the most appropriate treatment of future patients with a given medical condition.”

Pocock, from Clinical Trials: A Practical Approach (1984)

1747

1747 Lind Experiment with untreated control group (Lind, 1753)
 Haygarth Use of sham procedure (Haygarth, 1800)
 Waterhouse U.S.-based smallpox trial (Waterhouse, 1800, 1802)
 Gull Use of placebo treatment (Sutton, 1865)
 Fisher Application of randomisation to experimentation

(Fisher and MacKenzie, 1923)

Special committee on clinical trial created by the

Medical Research Council of Great Britain

(Medical Research Council, 1931)

Random allocation of treatment to groups of patients (Amberson *et al.*, 1931)

Start of NIH grant support with creation of the National Cancer Institute (National Institutes of Health, 1981b)

Publication of multicenter trial on treatment for common cold (Patulin Clinical Trials Committee, 1944)

Promulgation of Nuremberg Code for Human Experimentation (Curran and Shapiro, 1970)

Publication of book on clinical trials (Hill, 1962)

Amendments to the Food, Drug and Cosmetic Act of 1938 (United States Congress, 1962)

Publication of U.S. Public Health Service regulations leading to creation of Institutional

Review Boards for research involving humans (Levine, 1981)

Structure for separating the treatment monitoring and treatment administration process

(Coronary Drug Project Research Group, 1973a)

Establishment of Society for Clinical Trials

(Society for Clinical Trials, Inc., 1980)

First issue of *Controlled Clinical Trials*

1980

1967 Chalmers

1962

1960



Brighton 2011

Clinical Trials in Industry

OPEN STANDARDS AND GLOBAL COLLABORATION

Hilton Metropole, Brighton. 9th – 12th October 2011

- Clinical Trials are performed in
 - Pharmaceutical Products (synthetic medicinal drugs)
 - (<http://www.fda.gov/Drugs/default.htm>)
 - Biotechnology Products (from human cells/tissues for example, such as vaccines, blood products)
 - (<http://www.fda.gov/BiologicsBloodVaccines/default.htm>)
 - Devices (e.g., cardiac stents, pacemakers)
 - (<http://www.fda.gov/MedicalDevices/default.htm>)

**Drugs**[Home](#) > [Drugs](#)
[+ Share](#)
[✉ Email this Page](#)
[🖨 Print this page](#)
[🔍 Change Font Size](#)
**The Past, Present, and Future of FDA Human Drug Regulation**

A free Continuing Education activity.

**Medication Health Fraud**

Health scams can lead patients to delay proper treatment and cause injuries.

**FDA Drug Info Rounds**

A series of training videos for practicing clinical and community pharmacists

Spotlight

- [Influenza \(Flu\) Antiviral Drugs and Related Information](#)
- [Access to Investigational Drugs](#)
- [Drugs@FDA](#)
- [Approved Drug Products with Therapeutic Equivalence Evaluations \(Orange Book\)](#)
- [National Drug Code Directory](#)

Recalls & Alerts

- [MedWatch: The FDA Safety Information and Adverse Event Reporting Program](#)
- [Recalls, Market Withdrawals, & Safety Alerts](#)

Approvals & Clearances

- [New and Generic Drug Approvals](#)
- [Drug and Biologic Approval Reports](#)
- [Drug Approval Reports by Month](#)

Stay Informed

- [What's New \(Drugs\)](#)
- [E-mail Alerts, News Feeds, and Podcasts on Drug Topics](#)
- [FDA Drug Information Widgets](#)

Emergency Preparedness

Bioterrorism, drug preparedness and natural disaster response

Drug Approvals and Databases

Drug-Related Databases from FDA; Information on Drug Approvals

Drug Safety and Availability

Medication Guides, Drug Shortages, Public Health Advisories and Other Safety Announcements

Development & Approval Process (Drugs)

Conducting Clinical Trials, Types of Drug Applications, Forms and Submissions Requirements, Labeling Initiatives

Guidance, Compliance & Regulatory Information

Guidance for Industry, Warning Letters, Postmarket Surveillance Programs

News & Events

What's New on This Site, Drug Approval Listing, Meetings and Conferences

Science & Research (Drugs)

Research by FDA Staff to Evaluate and Enhance the Safety of Drug Products

Resources for You

For Consumers, Health Professionals, Industry

Resources for You

- [About the Center for Drug](#)

Search Drugs

**Contact Us**



▼ Human medicines

[Pre-authorisation](#)[Post-opinion](#)[Post-authorisation](#)[Product information](#)[Scientific advice and protocol assistance](#)[Scientific guidelines](#)[Innovation Task Force](#)[Regulatory and procedural guidance](#)[SME office](#)[Paediatric medicine](#)[Orphan designation](#)[Herbal products](#)[Referral procedures](#)[Article 58 applications](#)[Compassionate use](#)[Pharmacovigilance](#)[Advanced therapies](#)[Inspections](#)[Product defects and recalls](#)[Parallel distribution](#)[▶ Home ▶ Regulatory ▶ Human medicines](#)

Human medicines

[✉ Email a friend](#)[Print page](#)[Help](#)

This section of the website provides information for companies and individuals involved in developing and marketing medicines for use in the European Union.

For further information on EU legislation and procedures for the regulation of medicines, see also Volumes 1-4 and 9-10 of [The Rules Governing Medicinal Products in the European Union](#).

Important note on document formats: All Microsoft Office documents submitted to the European Medicines Agency must be in a format compatible with MS Office 2003. Office 2007 and Office 2010 formats cannot currently be accepted.

In this section you will find the following topics, click on a link to go to the page:

- ▶ [Pre-authorisation](#)
- ▶ [Post-opinion](#)
- ▶ [Post-authorisation](#)
- ▶ [Product information](#)
- ▶ [Scientific advice and protocol assistance](#)
- ▶ [Scientific guidelines](#)
- ▶ [Innovation Task Force](#)
- ▶ [Regulatory and procedural guidance](#)
- ▶ [SME office](#)
- ▶ [Paediatric medicine](#)
- ▶ [Orphan designation](#)
- ▶ [Herbal products](#)
- ▶ [Referral procedures](#)
- ▶ [Article 58 applications](#)
- ▶ [Compassionate use](#)
- ▶ [Pharmacovigilance](#)
- ▶ [Advanced therapies](#)
- ▶ [Inspections](#)
- ▶ [Product defects and recalls](#)
- ▶ [Parallel distribution](#)
- ▶ [Non-pharmaceutical products](#)
- ▶ [New countries/EFTA](#)
- ▶ [Fees](#)

Brighton 2011



OPEN STANDARDS AND GLOBAL COLLABORATION

Hilton Metropole, Brighton. 9th – 12th October 2011

Drug Regulation

Comprehensive Review in
International Textbook on Clinical Pharmacology
By
Rago & Santoso

- Since Ancient times remedies have been sold Caveat Emptor
- 1937 >100 people in the US died of diethylene glycol poisoning following the use of a sulfanilamide Elixir
 - This triggered the introduction of The Federal Food, Drug and Cosmetic Act with the premarket notification requirement for new drugs in 1938.
- Between 1958 and 1960 Thalidomide was introduced in 46 different countries worldwide resulting in an estimated 10,000 babies being born with deformities.
 - In the UK, the Committee on the Safety of Drugs (CSD) was started in 1963
 - Followed by a voluntary adverse drug reaction reporting system (Yellow Card Scheme) in 1964



Brighton 2011

The Regulatory Landscape

OPEN STANDARDS AND GLOBAL COLLABORATION

Hilton Metropole, Brighton. 9th – 12th October 2011



Brighton 2011



OPEN STANDARDS AND GLOBAL COLLABORATION

Hilton Metropole, Brighton. 9th – 12th October 2011

A Global Industry

A Review of the
Companies and Markets



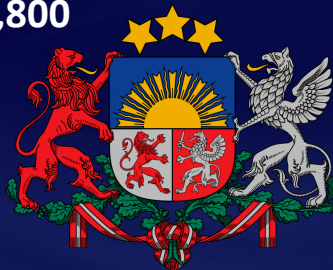
Brighton 2011

The Largest Companies

OPEN STANDARDS AND GLOBAL COLLABORATION

Hilton Metropole, Brighton. 9th – 12th October 2011

Republic of Latvia, a country in the Baltic region of Northern Europe, Popn: 2,218,800



In its purest form, the term "biotechnology" refers to the use of living organisms or their products to modify human health and the human environment.

Pharmaceutical

Biotechnology

CRO

Wall Mart
\$421,800Mn
2,100,000

Pfizer
\$67,800Mn
110,600

Amgen
\$15,100Mn
17,000

Covance
\$2,108Mn
10,528



Brighton 2011

The Forbes 2000 Top 10 Pharmaceutical Companies in April 2011

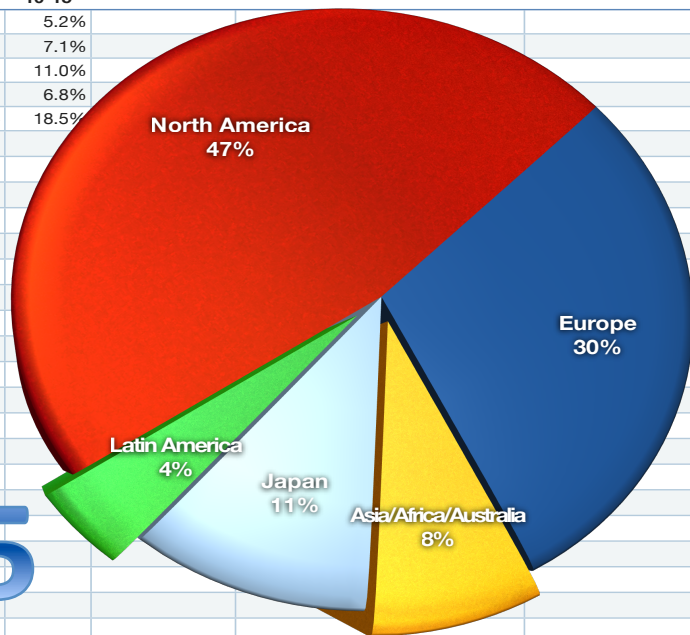
OPEN STANDARDS AND GLOBAL COLLABORATION

Hilton Metropole, Brighton. 9th – 12th October 2011

Rank ▲	Company	Country	Sales	Profits	Assets	Market Value
36	 Pfizer	United States	\$67.8 B	\$8.3 B	\$195 B	\$155.7 B
6			\$9.6 B	\$9.8 B	\$123.3 B	\$125.2 B
				\$7.3 B	\$110.3 B	\$89.2 B
				\$9.3 B	\$62.9 B	\$120.9 B
				\$4.6 B	\$59.5 B	\$75 B
				\$8.1 B	\$54.8 B	\$65.6 B
				\$2.5 B	\$62.1 B	\$99.2 B
				\$861 M	\$105.8 B	\$100.9 B
				\$5.1 B	\$31 B	\$40.4 B
				\$3.5 B	\$37.9 B	\$46.8 B

Source: http://www.forbes.com/global2000/#p_1_s_acompanyRankOverall_Pharmaceuticals_All_All

	10-15	
North America	265.7	5.2%
Europe	169.5	7.1%
Asia/Africa/Australia	46.4	11.0%
Japan	60.3	6.8%
Latin America	24	18.5%
	565.9	



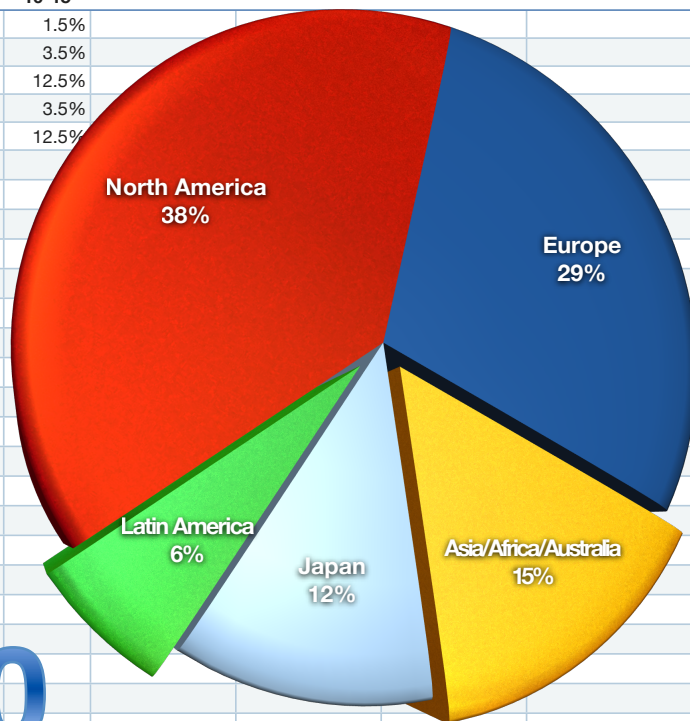
2005

The Industry Segmented by Geographic Region

Pharmaceutical Market By Region

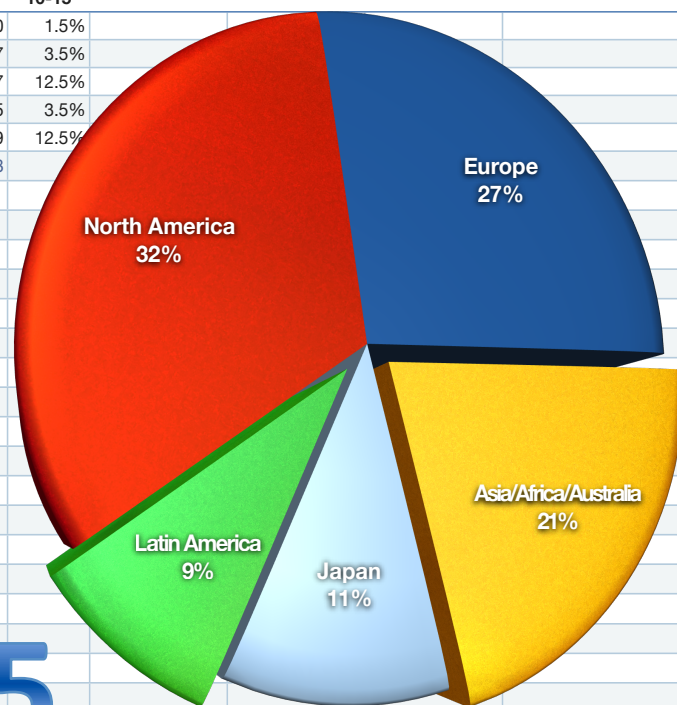
2009	2006-2010	2011	2011-2015
% Growth	CAGR %	Forecast % Growth	CAGR %

	10-15	
North America	335.1	1.5%
Europe	253.2	3.5%
Asia/Africa/Australia	129.7	12.5%
Japan	102.3	3.5%
Latin America	54.3	12.5%
	874.6	



2010

Region	Mkt Size US\$bn	GAGR 10-15	Market Size in US\$bn
North America	361.0	1.5%	
Europe	300.7	3.5%	
Asia/Africa/Australia	233.7	12.5%	
Japan	121.5	3.5%	
Latin America	97.9	12.5%	
	1114.8		



2015

Brighton 2011



OPEN STANDARDS AND GLOBAL COLLABORATION

Hilton Metropole, Brighton. 9th – 12th October 2011

The Clinical Development Process

An Overview



Brighton 2011

A Process Flow Diagram

OPEN STANDARDS AND GLOBAL COLLABORATION

Hilton Metropole, Brighton. 9th – 12th October 2011

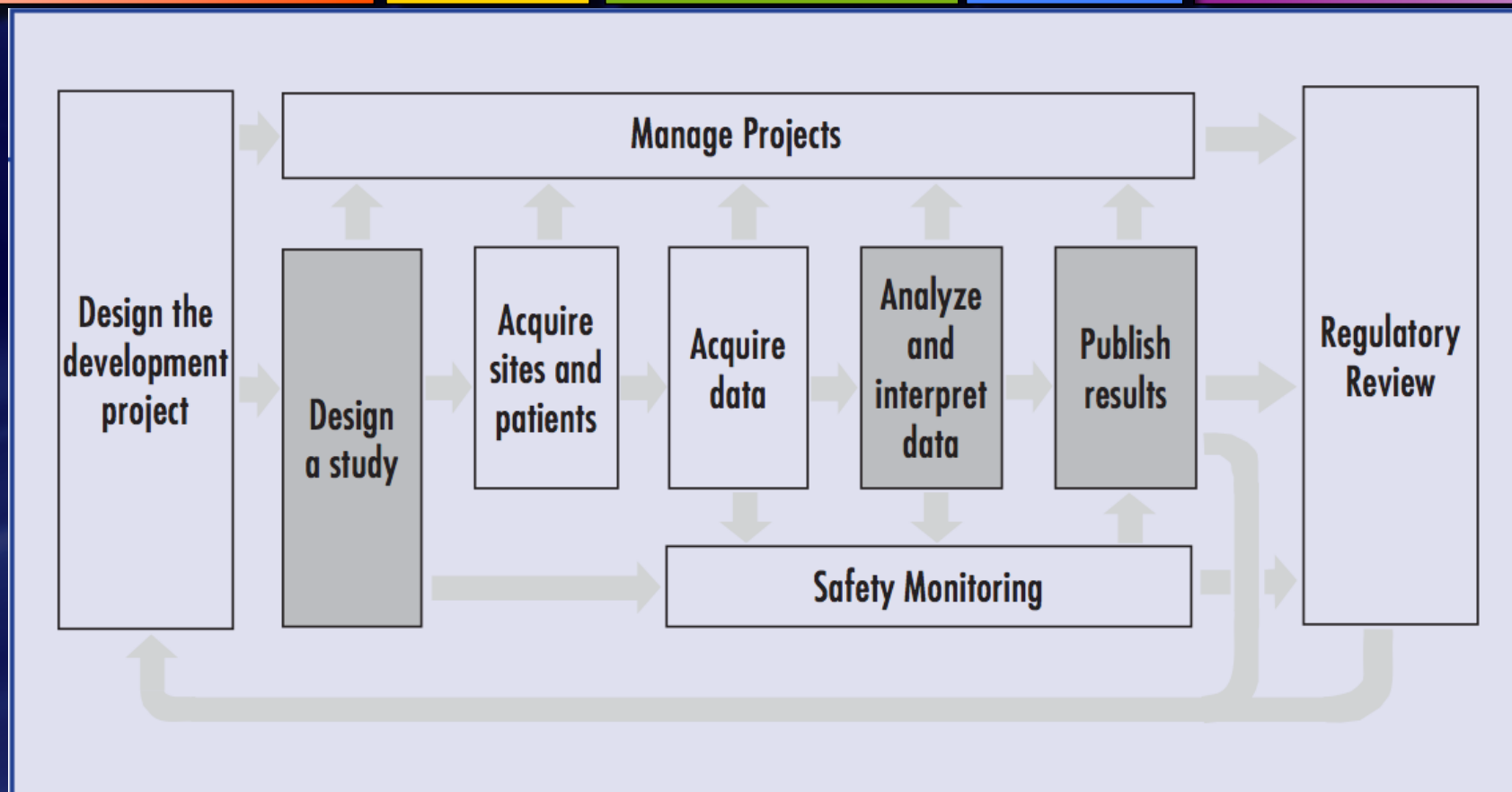
Discovery

Pre-Clinical

Clinical

Review/
Approval

Post Marketing





Brighton 2011

Roles and Responsibilities

OPEN STANDARDS AND GLOBAL COLLABORATION

Hilton Metropole, Brighton. 9th – 12th October 2011

Discovery

Pre-Clinical

Clinical

Review/
Approval

Post Marketing

Functional Roles	Protocol	CRF	Analysis Plan	Study Report	ISS, ISE, etc	Label	Re-Use
Clinical Dev	x	x	x	x	x	x	?
Monitoring	x	x		?			
Data Mgmt	x	x	?				
Statistics	x	x	x	x	x	x	x
Medical Writing	?			x	x	?	?
Regulatory	x	?	?	x	x	x	



Brighton 2011

A Typical Organisational Structure

OPEN STANDARDS AND GLOBAL COLLABORATION

Hilton Metropole, Brighton. 9th – 12th October 2011

Discovery

Pre-
Clinical

Clinical

Review/
Approval

Post Marketing

Research &
Development

Clinical Dev.
Ops

Medical
Affairs

Reg. Affairs

QA

Clinical Dev.
Ops.

Clinical Prog.
Man.

Statistics

Programming

Data
Management

Medical
Writing



Brighton 2011

OPEN STANDARDS AND GLOBAL COLLABORATION

Hilton Metropole, Brighton. 9th – 12th October 2011

Final Thoughts

- An established and disciplined industry
- Worthwhile and rewarding place for a career
- Many opportunities for Information Scientists
- Pace of technological advancement accelerating
- Eastern Markets evolving from simply “low-cost”
- Truly Global Standards

Brighton 2011



OPEN STANDARDS AND GLOBAL COLLABORATION

Hilton Metropole, Brighton. 9th – 12th October 2011

Thank you for listening

Any Questions?