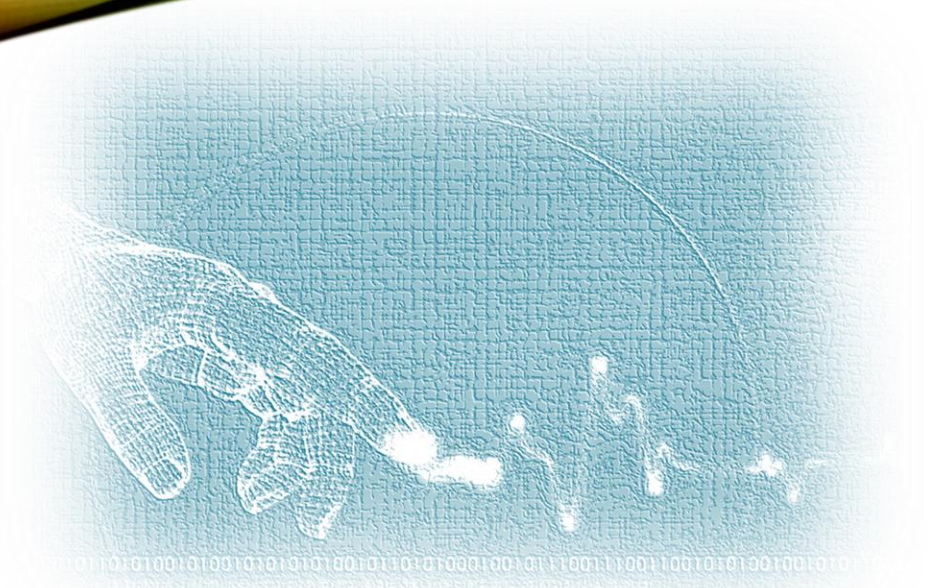


CLINICAL TRIAL APPLICATION MANAGEMENT

PRESENTED BY AMIT SRIVASTAVA

SCHEME OF PRESENTATION

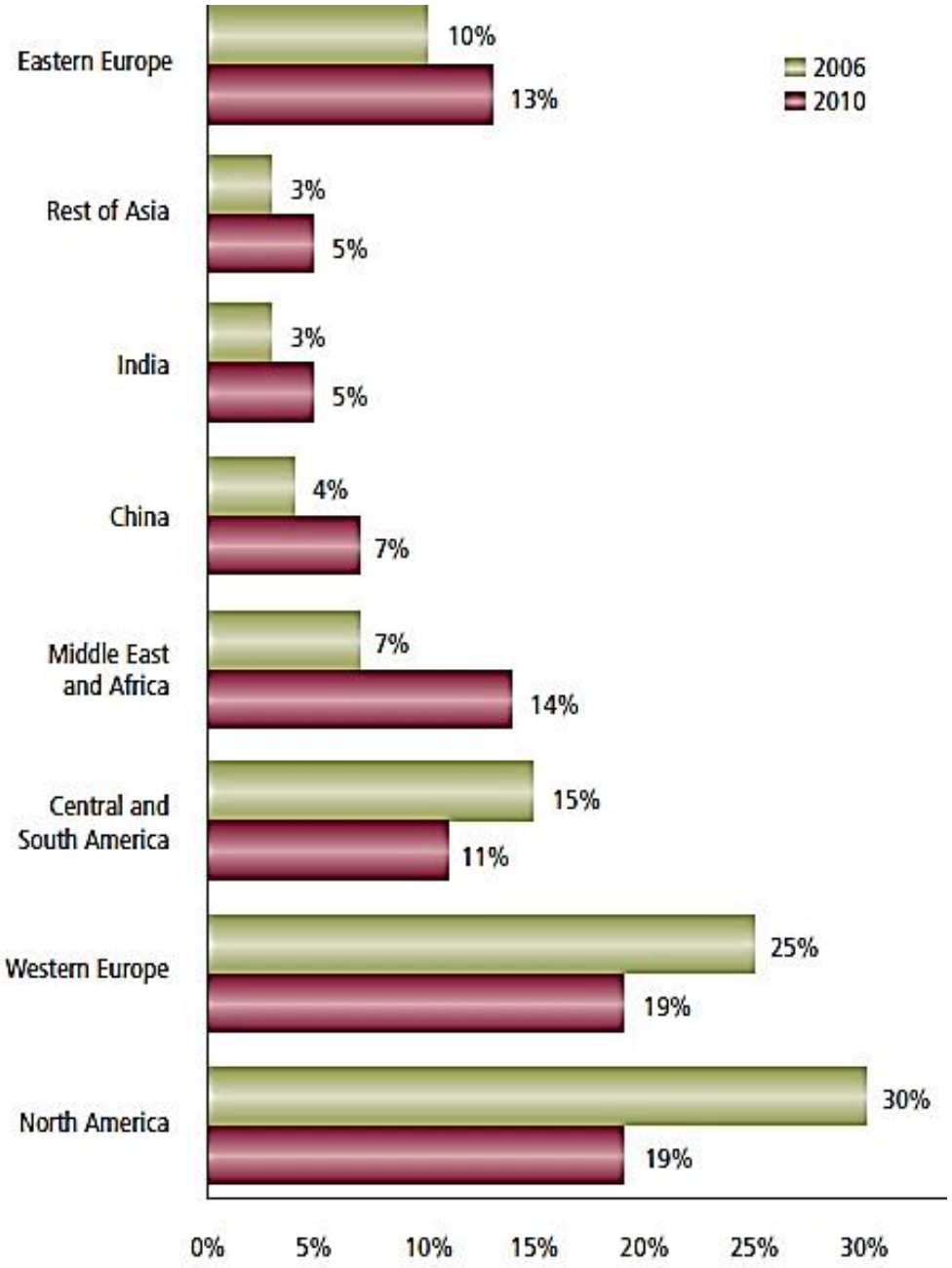
- What is Clinical Trial ?
- Role of Information Technology in Clinical Trail Management
- CTMS/CDMS
- Market Landscape

CLINICAL TRIALS

''Any investigational study that prospectively commissions **human participants** or groups of individuals to one or more **health associated interventions** to measure the result on **health outcomes**''

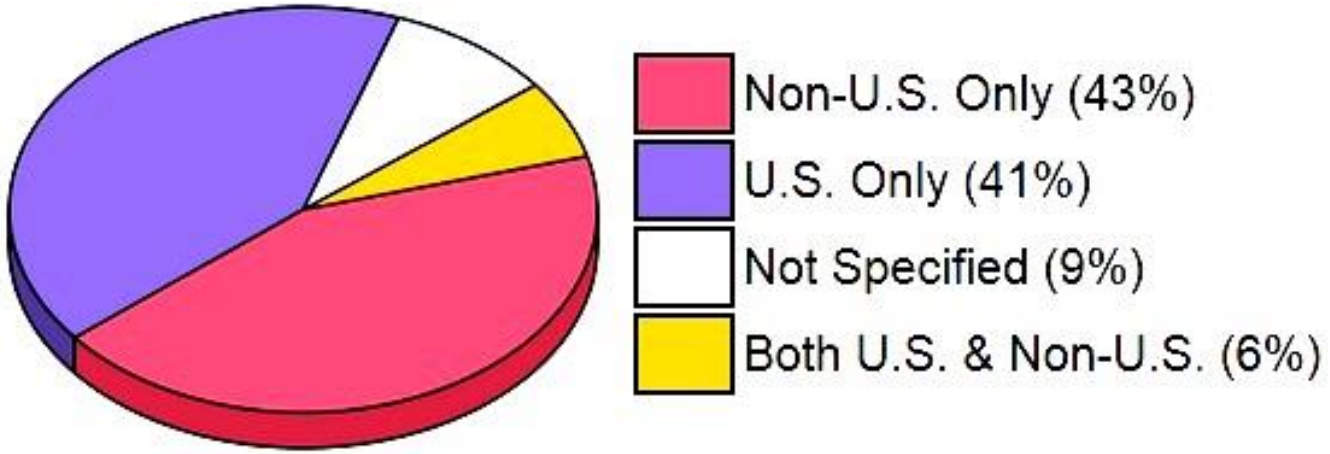
-WHO

GEOGRAPHICAL DISTRIBUTION OF CLINICAL TRIALS



Adapted from McDonnell & Mooraj, AMR Research.[1]

LOCATIONS OF REGISTERED STUDIES



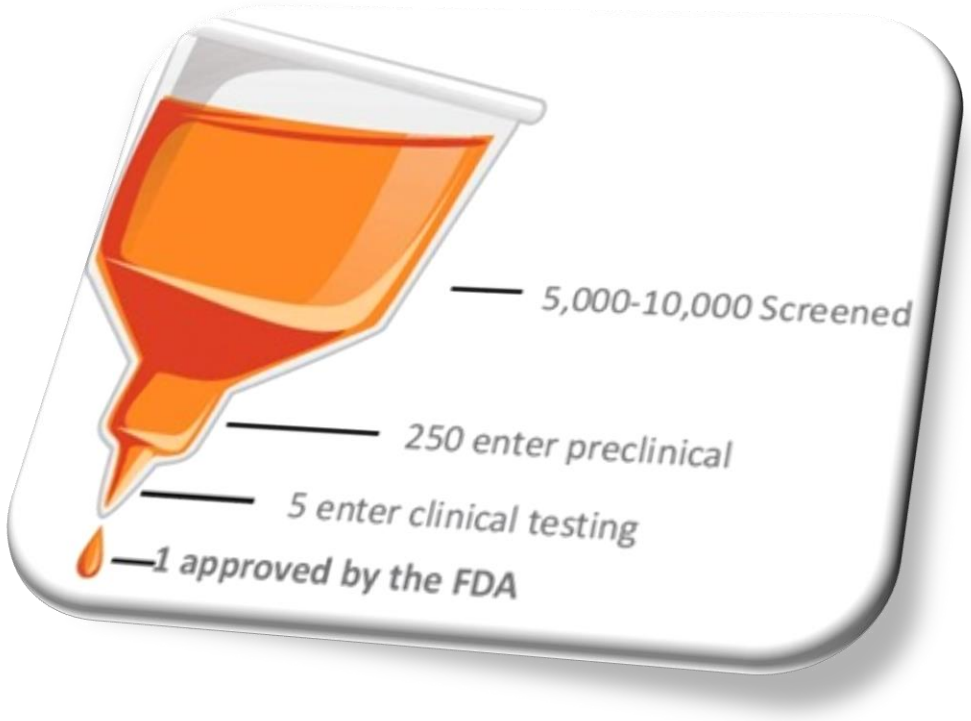
Location	Number of Registered Studies and Percentage of Total
Non-U.S. Only	61,819 (43%)
U.S. Only	58,925 (41%)
Not Specified*	13,241 (9%)
Both U.S. & Non-U.S.	9,103 (6%)
Total	143,088

* Not Specified: The location of the study was not provided by the Sponsor.

(Data as of April 05, 2013)

Reference: ClinicalTrials.gov currently lists 143,088 studies with locations in all 50 states and in 182 countries.

DRUG DEVELOPMENT



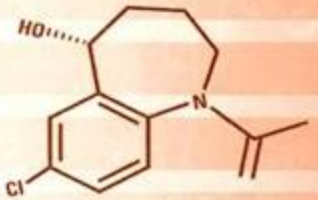
"**Drug development** is used to define the process of bringing a new drug to the market once a lead compound has been identified through the process of **drug discovery**"

- **Pre-clinical** research (microorganisms / animals
- **Clinical** trials (on humans)
- Step of obtaining **regulatory approval** to market the drug

FDA Drug Development Timeline

$1000 x Million Dollars

$900
$800
$700
$600
$500
$400
$300
$200
$100



Preclinical Research → Preclinical Development → Pivotal Trials → Clinical Research → Post-Approval Studies

5000-10000 Screened → 250 Drugs → 25 Drugs → NDA Filed → 5 Drugs → 1 Approved by FDA

Average Development Time: 13 Years

Average Cost: $ 500 Million-1.5 Billion

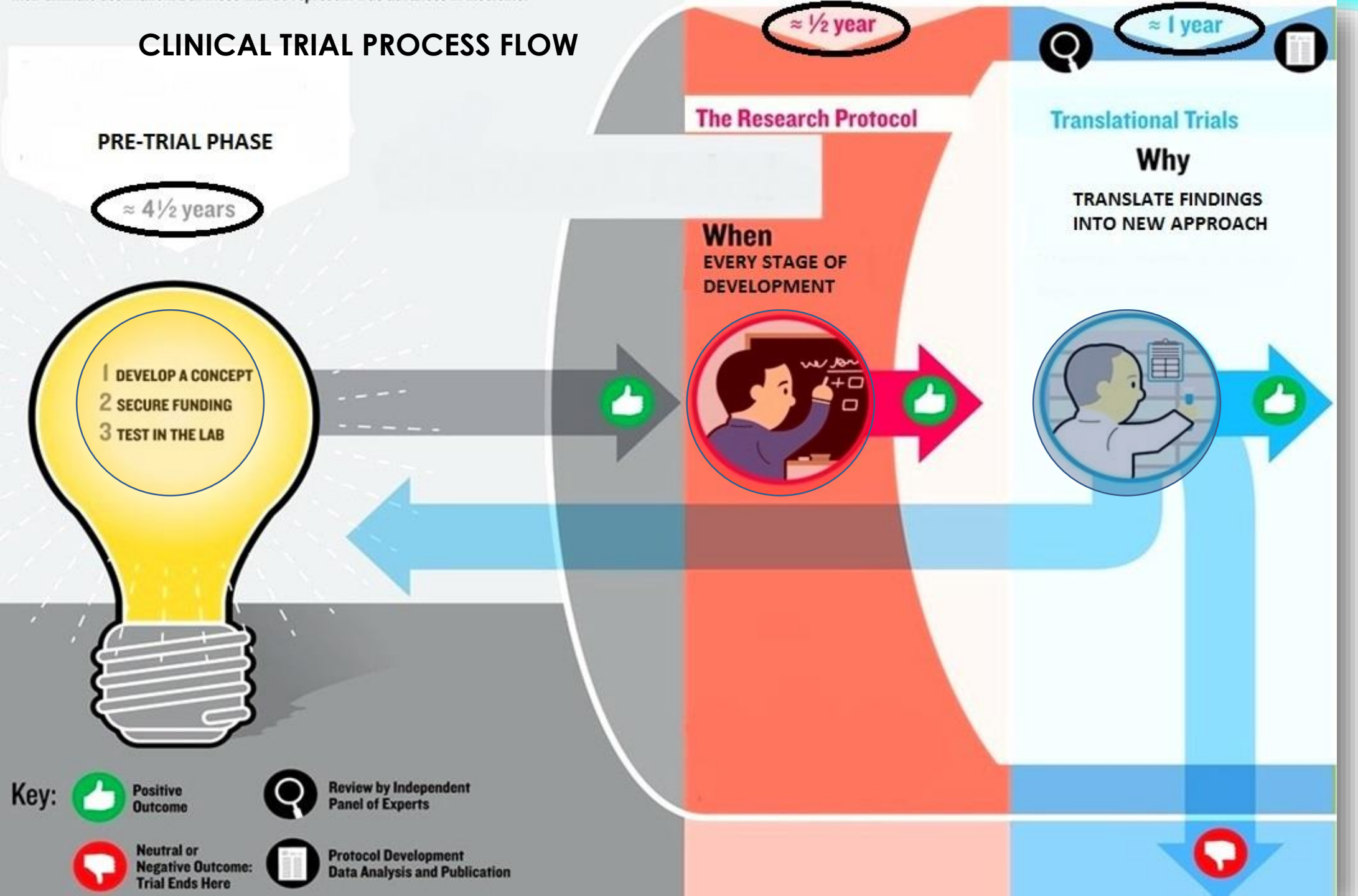
Phases of a Clinical Trial

New Drug Clinical Trials

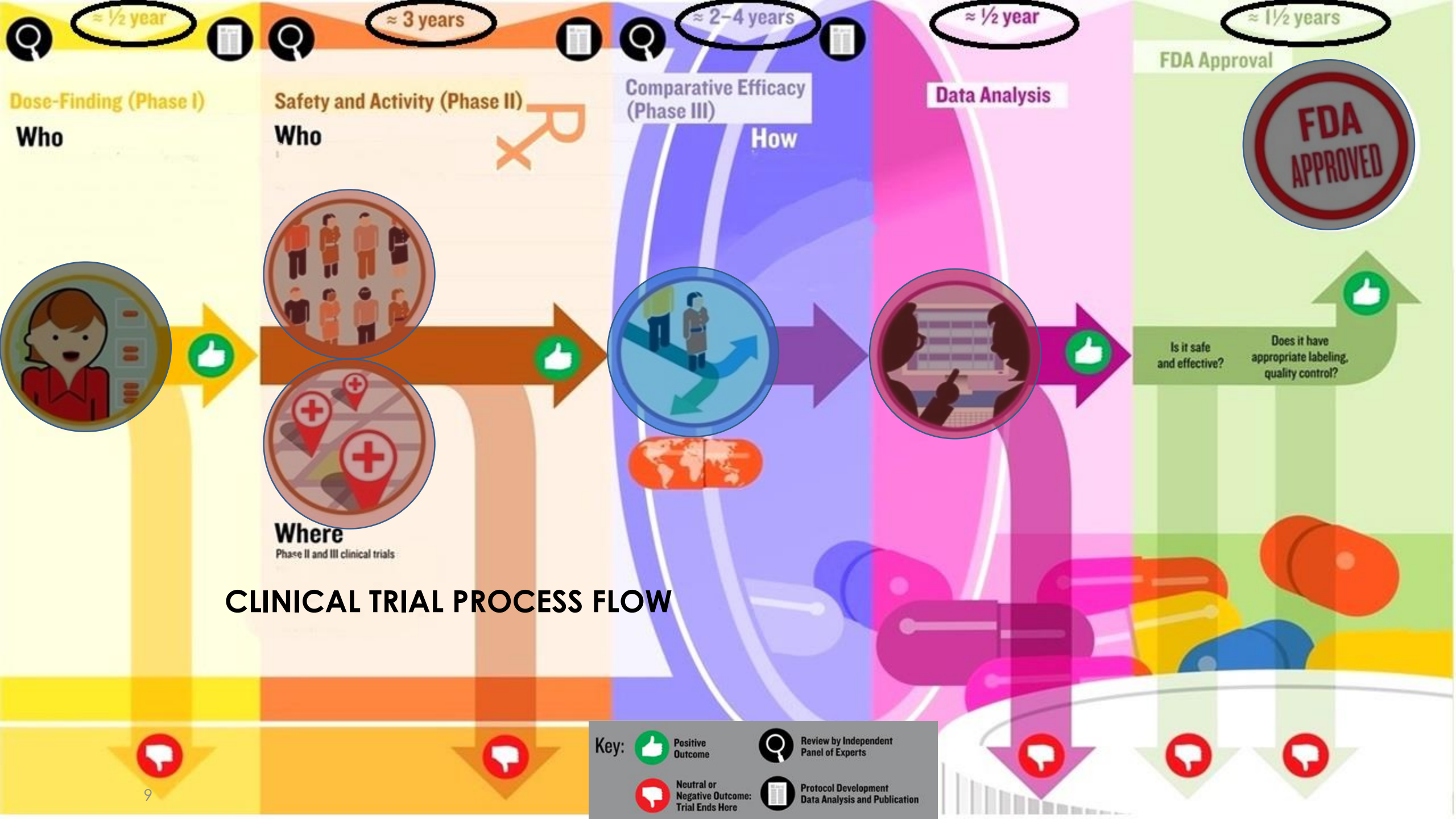
Downward Trend: Only 16 out of every 100 drugs that enter Phase 1 will make it to FDA approval.

Phase 1 Checking for Safety	$ Phase 2 Checking for Efficacy	$$ Phase 3 Confirm results	FDA Review / Phase 4 trials
20-100 volunteers *1st state of testing in humans*	**100 - 500 patients** *How well does the drug work?*	**1,000 – 5,000 patients** *- Drug MUST be safe - Comparison with current 'gold standard' treatment*	**Safety surveillance** in *'Real-life'* patients

CLINICAL TRIAL PROCESS FLOW



Clinical Trials



CLINICAL TRIAL PROCESS FLOW

STANDARDS

ICH-GCP Guidelines
GUIDELINE FOR GOOD CLINICAL PRACTICE E6(R1)

INTERNATIONAL CONFERENCE ON HARMONISATION OF TECHNICAL REQUIREMENTS FOR REGISTRATION OF PHARMACEUTICALS FOR HUMAN USE

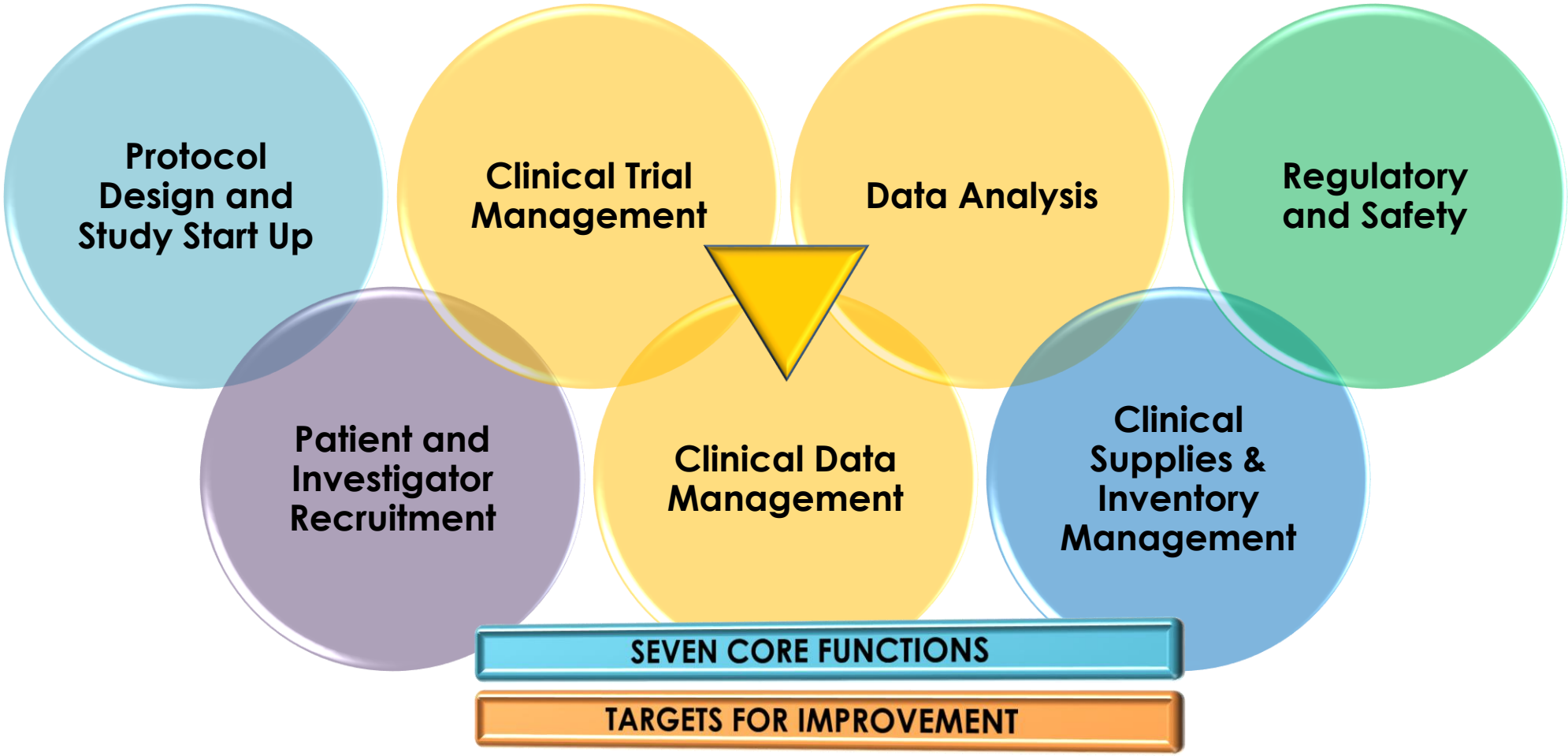
Code Of Federal Regulations
(CRF), 21 CRF Part 11

GCDMP
Good Clinical Data Management Practices Guidelines

SDTMIG
Study Data Tabulation Model Implementation Guide for Human Clinical Trials

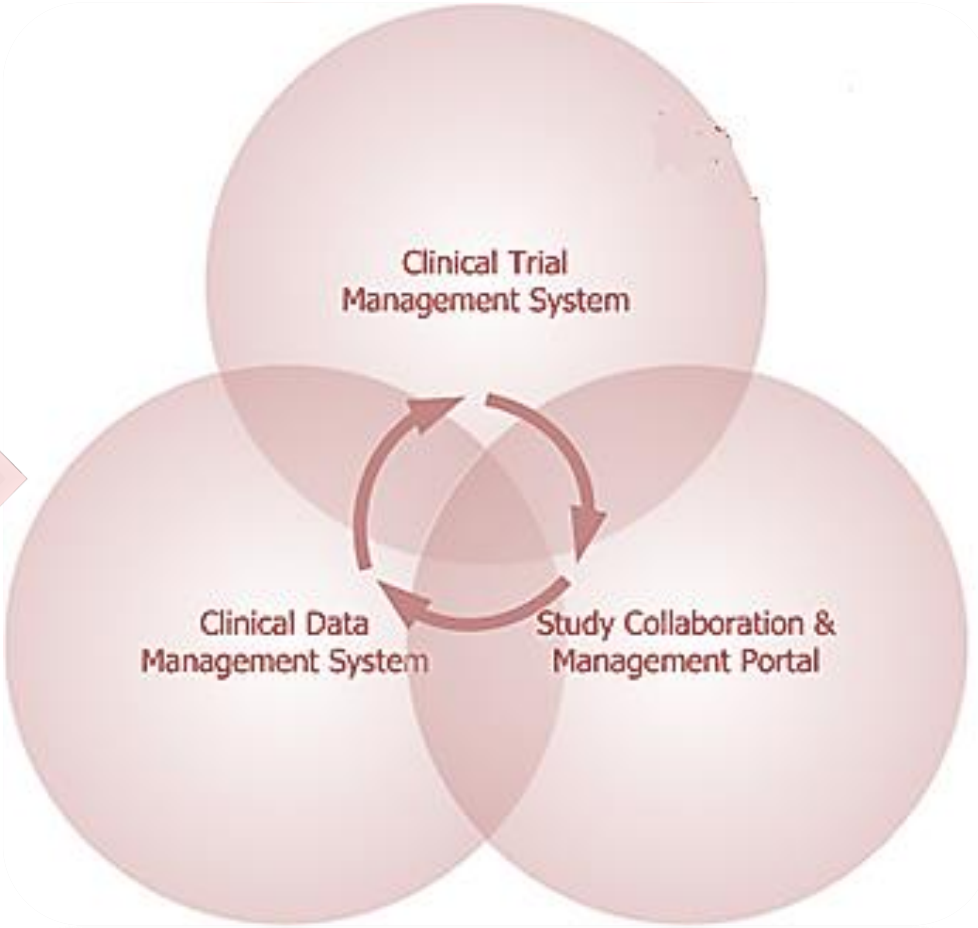
CDASH
Clinical Data Acquisition Standards Harmonization

IMPROVING CLINICAL TRIALS BY IMPLEMENTING INFORMATION TECHNOLOGY (IT)



DRIVING FORCES ACCELERATING INFORMATION TECHNOLOGY

- Increased Adoption of Electronic Health Records (EHRs) in US & Europe
- Increased Use of Adaptive Trial Design
- Continued Government & Sponsor Pressure for Cost & Cycle time Reduction
- Acceptance of Digitized Form by Regulatory Bodies



CLINICAL TRIAL MANAGEMENT SYSTEMS(CTMS)

"CTMS is Clinical Trial Management System which is used for larger utilization in development, planning, preparation, overall management and reporting of clinical trials"

CLINICAL DATA MANAGEMENT SYSTEMS(CDMS)

"CDMS is Clinical Data Management System which is used to gather, manage, handle, incorporate, process and submit clinical trial data"

KEY FEATURES

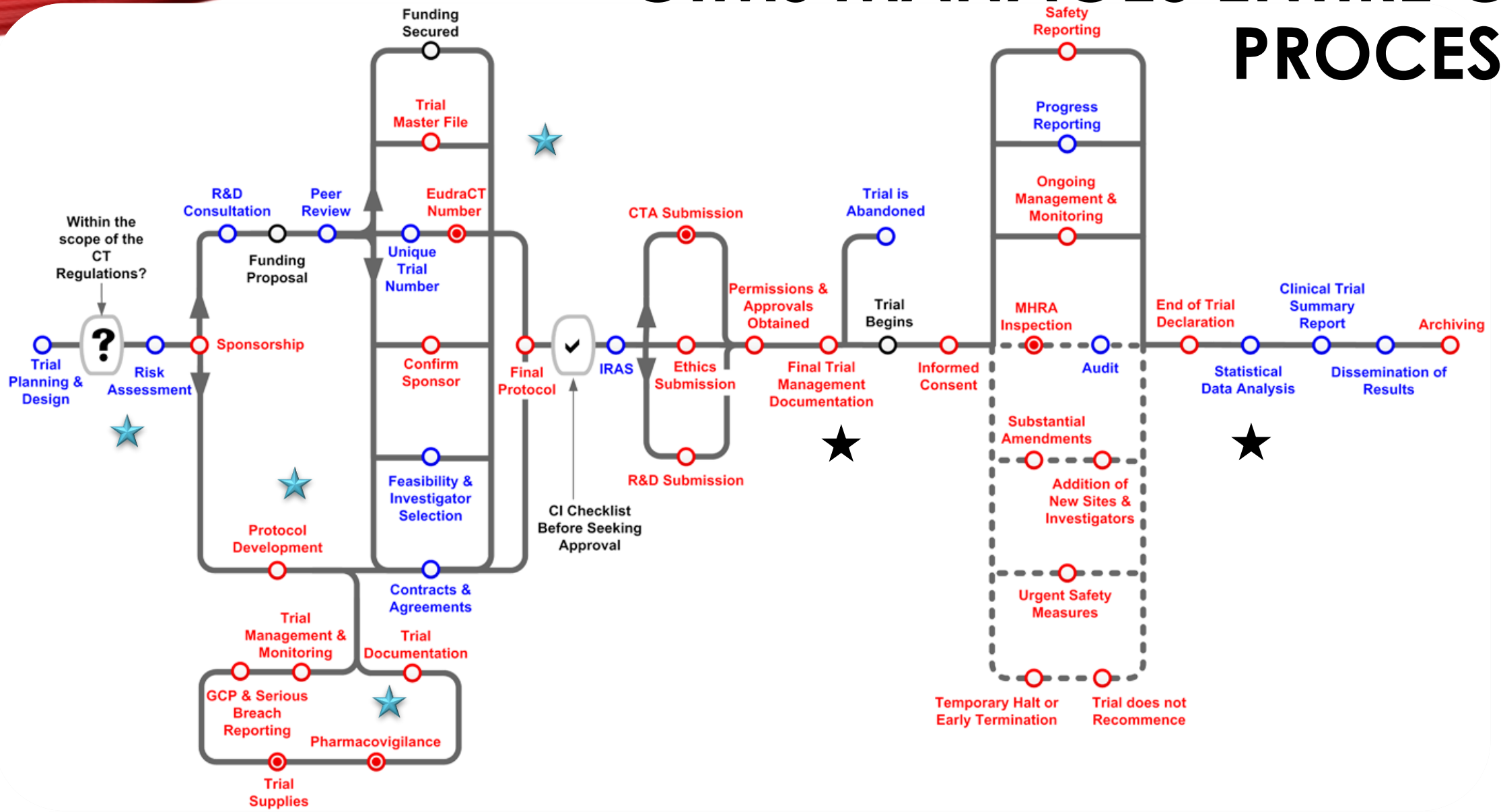
CTMS

- Site management
- Patient screening status tracking
- Patient enrolment status tracking
- Site monitoring
- Regulatory document tracking
- CRF, visit, and deviation tracking
- Inventory management
- Financial management
- Contact management

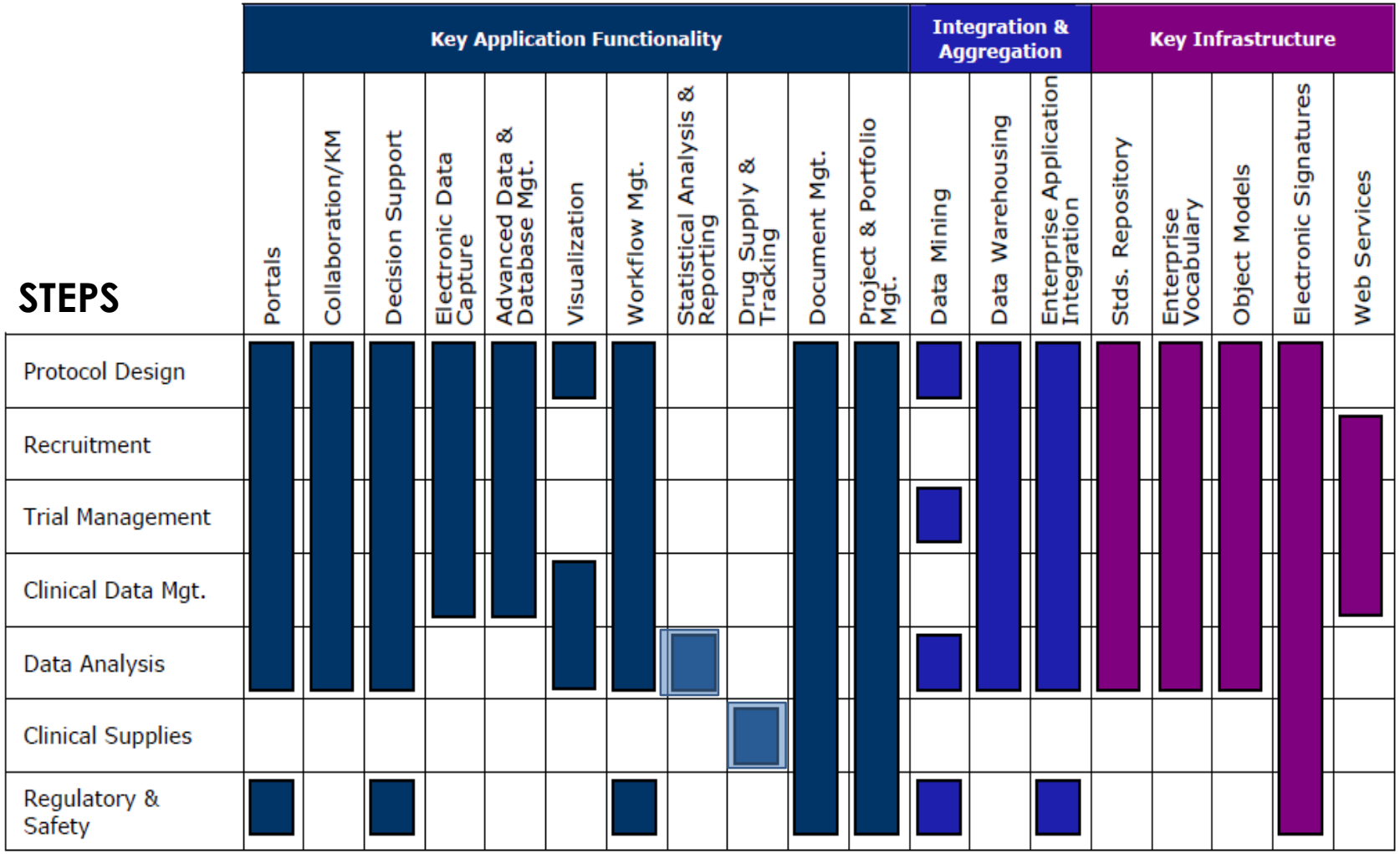
CDMS

- Data collection
- CRF Tracking
- CRF annotation
- Database Design
- Data Entry
- Medical Coding
- Data Validation
- Discrepancy Management
- Database Lock

CTMS MANAGES ENTIRE CT PROCESS



TECHNOLOGY MAP FOR CLINICAL TRIALS



Source: SAIC

MARKET PLAYERS

Pharmaceutical Companies	Contract Research Organisations (CROs)	IT/ITES Companies
Johnson & Johnson	Quintiles	Accenture
Pfizer	Covance	Wipro
GlaxoSmithKline	Pharmaceutical Product Development (PPD)	Intel
Roche	Charles River Laboratories (CRL)	Satyam
Sanofi-Aventis	ICON Clinical (ICON)	Cognizant
Novartis	Parexel	IBM
AstraZeneca	MDS	Oracle
Abbott Laboratories	Kendle	TCS
Merck	PharmaNet Development (PharmaNet)	Infosys
Wyeth	PRA International	Medidata
Bristol-Myers Squibb		BioClinica
Eli Lilly		

CTMS/CDMS TOOLS

Clinical Trial Management System	Clinical Data Management System
• Siebel Clinical(Oracle) • BioClinica CTMS (BioClinica, Inc.,) • Medidata CTMS (Medidata Solutions,) **Other Companies Providing CTMS** • Aris Global, LLC • Bio-Optronics, Inc. • DSG, Inc. • eClinForce, Inc. • eResearch Technology, Inc. • Integrated Clinical Solutions, Inc. • MedNet Solutions • Merge eClinical, Inc. • Nextrials, Inc. • Perceptive Informatics, Inc.	• Oracle Clinical • CLINTRIAL • MACRO™ • RAVE • eClinical Suite • Capture System™, • eResearch Network™ • CleanWeb™ • GCP Base™ • SAS™ • **OPEN SOURCE Tools** • OpenClinica • openCDMS • TrialDB • PhOSCo

CTMS MARKET

Global eClinical Solutions Market worth $4.8 Billion by 2017

Growing at a **CAGR of 14.53%**

http://www.marketsandmarkets.com/Market-Reports/clinical-trial-management-systems-market-470.html

OVERALL BENEFITS OF CTMS/CDMS IN CLINICAL TRIALS

REDUCING TURN-AROUND TIME	REDUCING COST	FLEXIBILITY	ACCURACY -Error free data
CONTROL -Quality	COMPLIANCE -Regulatory Standards	COMMUNICATIONS AND ALERTS	RESOURCE(MANPOWER) OPTIMIZATION

CASE STUDY

Comparative Study of Paper Medical Records & Electronic Medical Records

❖ **OBJECTIVE :**

TO DO A COMPARATIVE STUDY OF THE PAPER MEDICAL RECORDS AND THE ELECTRONIC MEDICAL RECORDS

❖ **METHODOLOGY:**

- Observational & Discussion method
- The information is collected primarily by observation of the software and making a comparison between paper medical records & electronic medical records.
- Focus points of discussion are:

- Disadvantages of PMR
- Advantages & EMR over PMR
- Disadvantages of EMR
- Also some information is collected using secondary data sources

OBSERVATION: PMR VS EMR

PMR

- Patient is identified by name, medical record number & other identifier
- Progress notes might be produced by dictation, free handwriting or form completion
- Consists of office or **progress notes in chronological sequence**. These are browsed by literally flipping through pages, until the desired entry is located
- Prescription is **written on paper**. It is manually checked for interactions & allergies. It is then taken by the patient to the pharmacy .It takes time & can also result in errors

EMR

- Patient can be identified by any identifier
- Progress notes are produced as the visit is produced
- Stores progress notes and provides quick access by date of visit, provider and the ability to browse by diagnosis and prescription
- Prescription is **written in the system.** It is checked for interactions & allergies by the system & then it is sent to the pharmacy by the system directly where it is verified & drug is dispensed. There are rare chances of errors.

❖DISADVANTAGES OF PMR

1. Needs lot of space for storage
2. No centralization of records & collection of records is a tedious task
3. More chances of medical errors caused by poor legibility on paper forms
4. Less in efficiency as compared to EMR
5. Data cannot be easily exchanged or transferred
6. They are not eco-friendly

❖ADVANTAGES OF EMR

1. Increasing storage capabilities
2. Accessible from remote sites
3. Retrieval of the information immediate
4. Continuously updated
5. Immediately accessible
6. Provides Medical alerts and reminders
7. Assist in decision making
8. Allows for customized views
9. Improve risk management and assessment outcomes

❖DISADVANTAGES OF EMR

1. Start-up cost is high
2. Lack of Technical knowledge
3. Inability of the provider to adapt
4. Usability is a major issue
5. Placement of hardware is an issue
6. Crashing of computer & loss of data
7. Change in workflow of the department after the implementation of an EMR
8. Lack of standardized terminology, system architecture, and indexing
9. Lack of flexibility and lack of capacity for the diverse requirements of the different healthcare disciplines

❖ RECOMMENDATIONS

- The robust back up methods, sophisticated protection mechanisms & advanced data recovery methods should be developed
- Decisions regarding the portability of the equipment must also be considered
- Documentation forms must be revised in order to accommodate the changes in the workflow
- Development of standard language is required
- A unique health identifier must also be developed
- Well planned training must be given to the end users

THANK YOU