Disease and Health Outcome Registry

Ali Khorshidi

نظام مراقبت:

جمع آوری، آنالیز و تفسیر مستمر و سیستماتیک

داده های مرتبط با سلامت

اهداف نظام مراقبت:

بررسی روند بیماری ها

پیش بینی و کنترل اپیدمی ها

طراحی مداخلات

گسترش تحقیقات

نظام مراقبت

منابع داده ها:

Laboratories **Individuals** **Medical records**

Police records **Administrative records** **Birth/death certificates**

Environmental **Monitoring systems**

روش های مراقبت:

Notifiable diseases Laboratory specimens Vital records Surveys

Sentinel surveillance Administrative data systems **Registries**

ثبت بیماری ها و پیامدهای سلامت:

سیستمی سازمان یافته برای جمع آوری، ذخیره سازی، *بازیابی، تجزیه و تحلیل و انتشار*

اطلاعات افراد مبتلا به یک بیماری خاص

و یا

در مواجهه با مواد شناخته شده یا مشکوک به اثرات نامطلوب

در یک جمعیت و گستره جغرافیایی مشخص

اهداف ثبت:

بررسی ***بار*** بیماری (بروز و شیوع)

ارزیابی ***کیفیت*** خدمات و مراقبت بیماران

ارزیابی ***تغییرات*** زمانی و مکانی

اندازه گیری/پایش ***ایمنی*** و ***آسیب*** مواجهات

توسعه و ارتقاء تحقیقات

پژوهش های مبتنی بر ثبت:

مطالعات ***علت شناسی*** (اثر مواجهات و ...)

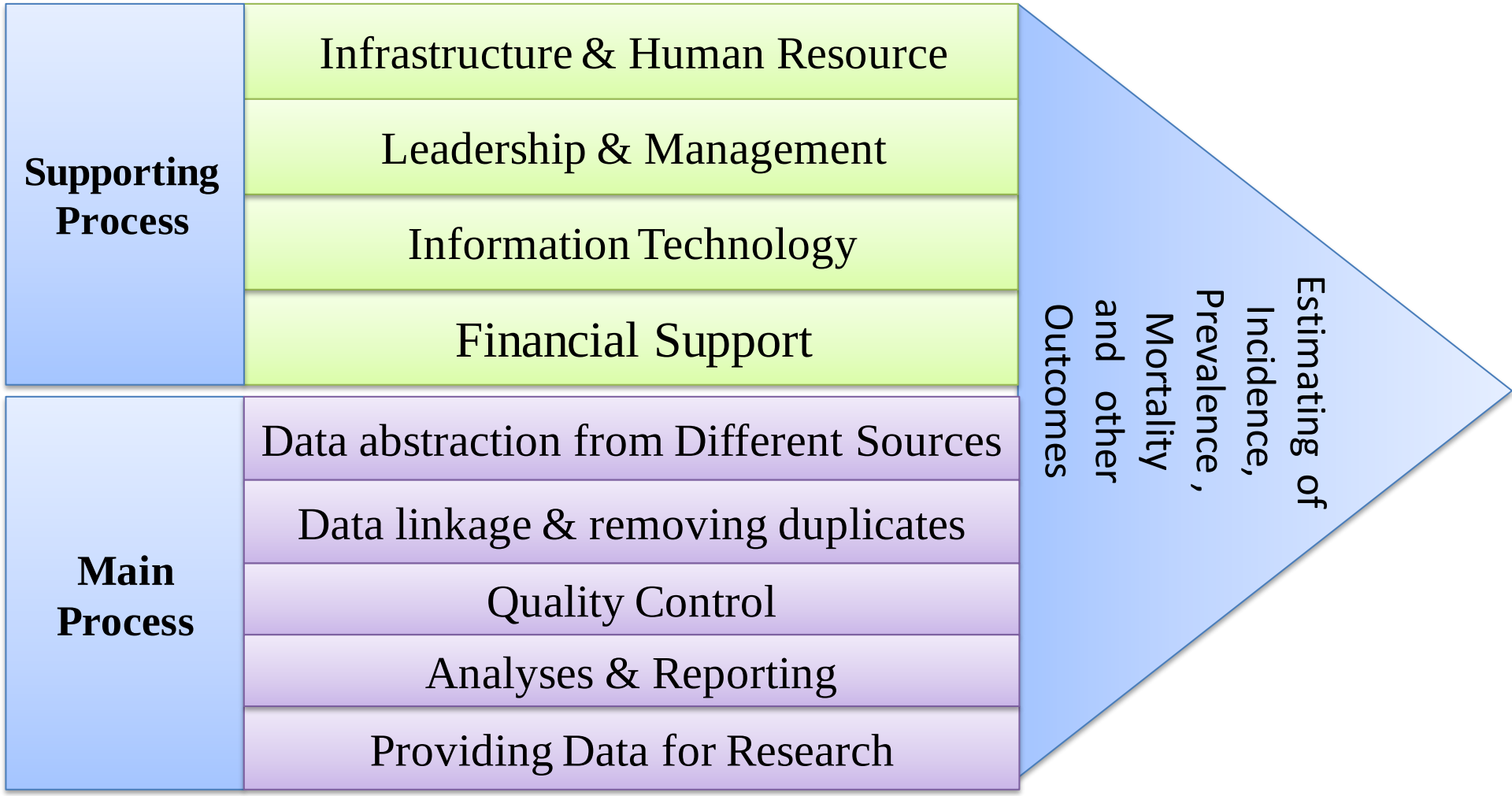
آنالیز بقا و ارزیابی ***پیامد مراقبت های بالینی***

تحلیل های اقتصادی و مدیریتی

تولید اطلاعات ***توصیفی*** (بروز، شیوع و مرگ ومیر)

منبع نمونه برای مطالعات کارآزمایی بالینی، مورد-شاهدی و کوهورت

Registry is a system



First-class quality registry fulfill six requirements

1 Strong core team

- **One team responsible**
  - Clear process leadership
  - Personal dedication
  - Sense of ownership
- **Strong support from specialists**
  - Data collection is team effort
- **Entrepreneurial "can-do" spirit**
  - creating winners

2 Committed specialists

- **Atmosphere of cooperation**
  - Evidence-based discussion
  - Mutual respect and team spirit
  - Peer pressure in joint efforts
- **Evidence-based approach**
  - Strong foundation in research
  - Willingness to measure

3 Valid & reliable metrics

- **Strong foundation in research**
  - Internationally tested metrics
  - Proven causality
  - Possible to benchmark
- **In touch with clinical practice**
  - Practicality filter
- **Risk adjustment possibilities**
  - Collect relevant patient data

4 Systematic feedback

- **Fast feedback of results**
  - To allow comparisons over time for own results
- **Learnings linked to feedback**
  - Learn from others
  - Workshops and seminars
  - Organized best-practice sharing

5 Easy-to-use IT interface

- **Easy to enter data**
  - Only collect what is needed
  - Easy-to-use IT interface
  - Move towards integration with EMR systems
- **Easy to receive feedback**
  - Fast feedback of own results
  - Decision-support tools

6 Stable financing

- **Access to stable financing**
  - Backing from institutions
  - Clearly delineated budget for registry admin, maintenance
- **Arms-length relationships with private financiers**
  - Access to funding without compromising data integrity

Current Uses for Patient Registries

a powerful tool to;

Observe the *course of disease*;

Understand *variations* in *treatment* & *outcomes*;

Examine factors that influence *prognosis* and *quality of life*;

Describe *care patterns*, appropriateness of care and disparities in the delivery of care;

Assess *effectiveness*;

Monitor safety & harm;

Measure quality of care

Who benefits from Registries

Clinicians

producing a *real-world* ***picture of disease***, ***current treatment*** practices, and ***outcomes***

Physician organization,

Assessing the degree to which ***clinicians are managing a disease*** in accordance with ***evidence-based guidelines***,

to focus attention on ***specific aspects*** of a particular disease that might be overlooked

compare clinicians with their ***peers***

Patients and patient advocacy organizations

increase understanding of ***natural history*** of a disease,

contribute to ***development*** of treatment ***guidelines***,

facilitate research on ***treatment***

Registry & Clinical Trial

Registries focus on specific diseases or conditions,
collect data from people with those conditions

Clinical Trial; study of new ways to
prevent
detect
treat diseases or conditions

Co-morbidities often excluded
Very homogeneous group of patients
Generalizability!!!

Taxonomy for Patient Registries

Product Registries;

*Patient is exposed to a **health care product**, such as a drug or a device*

Health Services Registries;

Individual clinical encounters;

Office visits or hospitalizations, procedures, full episodes of care

Disease or Condition Registries;

*Use the **state** of a particular **disease** or **condition** as inclusion criterion*

Combinations ;

National Program for Disease Registries Objectives:

To promote *quality of care*

To prepare an ***appropriate framework*** for ***evidence-based*** *health care* and *clinical* ***practice***

To expand required *infrastructure* for establishment of *disease registries*

To build and develop *international communications*

To acquire technical and administrative *knowledge* and *skills* for implementing *registry-based research*

To create an appropriate infrastructure for *generating high-quality data* to develop *medical* and *public health research*

To build and develop *research networks*

Creating a Registry

Planning

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Creating a Registry

Planning

Design

Data Elements

Data Sources

Software

Ethical and Legal Issues

Registries may be;

Large or small,

Target *rare* or *common* conditions & exposures

Require *limmited* or *extensive* amounts of data

Operate for *short* or *long* periods

Funded *generously* or *limited* financial support

Focus on or expand to different geographical regions

Registries require
good planning in order to be successful

Steps in planning a registry

Articulate the *Registry's Purpose*

makes it easier to evaluate,

helps clarify need for certain data

Is a registry *appropriate means to* achieve purpose?

Consider;

state of ***current knowledge*** and ***gaps*** in evidence;

breadth of ***target population***;

length of an ***period needed*** to achieve objective;

scope and variety of ***treatments*** used;

amount of ***funding*** available to address objectives

Steps in planning a registry

Identify Key Stakeholders

Public health or regulatory authorities;

Product manufacturers;

Health care service providers;

Patients and/or advocacy groups;

Clinician groups;

Academic institutions

Steps in planning a registry

Assess Feasibility

Funding;

Scope of registry, rigor of data collection;

Number of sites & patients;

Scope & method of data collected

Projected life of the registry

Life cycle for a registry

Establishment

Continuation

Extension / Transition

Ending (???)

Not fulfil the objectives

Inability to address the objective

Staffing and funding shortage

Other…..

Steps in planning a registry

Build a Registry Team

Different kinds of knowledge, expertise, and skills are needed

Depending on size, scope, and purpose of registry;

Build a Registry Team

Project management,

Needed to ***coordinate components*** of registry:

Subject matter,

A registry must be contains ***appropriate data***
to meet ***its goals*** and ***needs of its stakeholders***

e.g. ***experts*** in treatment of clinical disease to be studied, ***are also familiar*** with potential *toxicities of treatment(s)* to be studied (critical to success of registry)

Build a Registry Team

Registry science:

Epidemiology & biostatistics:

Design, implementation, analysis of registry data

Health outcomes and economics ***researchers***

Subject matter experts (clinicians)

Build a Registry Team

Data collection & database management:,

Decision to include data elements (*consultation with experts*)

Final determination of ***what is workable*** for ***data collection*** tools should be approved by ***members of team***

Experts **may need** to *write specific programs*, generate *reports*,

Responsible for implementing and maintaining firewalls to protect data

Build a Registry Team

Legal issues / patient privacy:

Quality assurance:

The goals for quality assurance should be established,

Efforts made and the results achieved should be described

Data elements for registries

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Data Elements for Registries

Selection of data elements requires balancing competing considerations;

importance *of data elements to integrity of registry,*

their ***reliability****,*

their ***necessity*** *for analysis of primary outcomes,*

their ***contribution*** *to the overall response burden,*

the ***incremental*** *costs associated with their collection*

Data Elements for Registries

Identifying Domains;

Registries generally *include*;

personal, exposure, and ***outcomes information***

Measuring ***potential confounding*** *factors should be taken into account*

Data Elements for Registries

Selecting data elements;

Each data element should

support purpose of registry

answer an explicit *scientific question*

The *most effective* way to select data elements;

start with study *purpose* and *objective*,

decide what types of groupings, measurements, or calculations will be needed to *analyze objective*

Selecting data elements;

Use of established data standards;

Improve efficiency *in establishing registries;*

promote more effective *sharing, combining, or* ***linking*** *of data sets from different sources*

to allow ***comparisons*** *between studies*

Data Elements needed for ***specific types*** of Registries;

Registries ***examining safety*** for drugs, vaccines, procedures, devices;

History of exposure & Potential confounding factors;

Data on use (start & stop)

comorbidities,

socioeconomic status,

ethnicity,

environmental and social factors

Table 4–1. Standard terminologies

Standard	Acronym	Description and Web Site	Developer
Billing-related			
Current Procedural Terminology	CPT®	Medical service and procedure codes commonly used in public and private health insurance plans and claims processing. Web site: http://www.ama-assn.org/ama/pub/category/3113.html	American Medical Association
International Classification of Diseases	ICD, ICD-O, ICECI, ICF, ICPC	International standard for classifying diseases and other health problems recorded on health and vital records. ICD-9-CM, a modified version of the ICD-9 standard, is used for billing and claims data in the United States, which will transition to ICD-10-CM in 2014. The ICD is also used to code and classify mortality data from death certificates in the United States. ICD adaptations include ICD-O (oncology), ICECI (External Causes of Injury), ICF (Functioning, Disability and Health), and ICPC-2 (Primary Care, Second Edition). Web site: http://www.who.int/classifications/icd/en	World Health Organization

Clinical			
Systemized Nomenclature of Medicine	SNOMED CT	Clinical health care terminology that maps clinical concepts with standard descriptive terms. Formerly SNOMED RT and SNOP. Web site: http://www.ihtsdo.org/snomed-ct	International Health Terminology Standards Development Organization
Unified Medical Language System	UMLS	Database of 100 medical terminologies with concept mapping tools.[19] Web site: http://www.nlm.nih.gov/research/umls/	National Library of Medicine
Classification of Interventions and Procedures	OPCS-4	Code for operations, surgical procedures, and interventions. Mandatory for use in National Health Service (England). Web site: http://www.datadictionary.nhs.uk/web_site_content/supporting_information/clinical_coding/opcs_classification_of_interventions_and_procedures.asp	Office of Population, Censuses, and Surveys
Diagnostic and Statistical Manual	DSM	The standard classification of mental disorders used in the United States by a wide range of health and mental health professionals. The version currently in use is the DSM-IV. Web site: http://www.psych.org/MainMenu/Research/DSMIV.aspx	American Psychiatric Association
Drugs			
Medical Dictionary for Regulatory Activities	MedDRA	Terminology covering all phases of drug development, excluding animal toxicology. Also covers health effects and malfunctions of devices. Replaced COSTART (Coding Symbols for a Thesaurus of Adverse Reaction Terms). Web site: http://www.meddramsso.com	International Conference on Harmonisation (ICH)

Table 4–2. Examples of possible baseline data elements

Enrollee contact information	• Enrollee contact information for registries with direct-to-enrollee contact • Another individual who can be reached for followup (address, telephone, email)
Enrollment data elements	• Patient identifiers (e.g., name [last, first, middle initial], date of birth, place of birth, Social Security number) • Permission/consent • Source of enrollment (e.g., provider, institution, phone number, address, contact information) • Enrollment criteria • Sociodemographic characteristics, including race, gender, and age or date of birth • Education and/or economic status, insurance, etc. • Preferred language • Place of birth • Location of residence at enrollment • Source of information • Country, State, city, county, ZIP Code of residence

Table 4–3. Examples of possible additional enrollee, provider, and environmental data elements	
Pre-Enrollment History	
Medical history	• Morbidities/conditions • Onset/duration • Severity • Treatment history • Medications • Adherence • Health care resource utilization • Diagnostic tests and results • Procedures and outcomes • Emergency room visits, hospitalizations (including length of stay), long-term care, or stays in skilled nursing facilities • Genetic information • Comorbidities • Development (pediatric/adolescent)
Environmental exposures	• Places of residence

Patient characteristics	• Functional status (including ability to perform tasks related to daily living), quality of life, symptoms • Health behaviors (alcohol, tobacco use, physical activity, diet) • Social history • Marital status • Family history • Work history • Employment, industry, job category • Social support networks • Economic status, income, living situation • Sexual history • Foreign travel, citizenship • Legal characteristics (e.g., incarceration, legal status) • Reproductive history • Health literacy • Individual understanding of medical conditions and the risks and benefits of interventions • Social environment (e.g., community services) • Enrollment in clinical trials (if patients enrolled in clinical trials are eligible for the registry)
Provider/system characteristics	• Geographical coverage • Access barriers • Quality improvement programs • Disease management, case management • Compliance programs • Information technology use (e.g., computerized physician order entry, e-prescribing, electronic medical records)

Data Elements for Registries

Data Definitions

Explicit data definitions is essential to process of selecting data elements

Important to ensure ***internal validity***

History of exposure & Potential confounding factors;

Should include the ranges and acceptable values for each individual data element

Determine which data elements are ***required*** *or may be* ***optional***

Data Elements for Registries

Patient-Reported Outcomes

It is important to use patient-reported outcomes;

valid, reliable, responsive, interpretable, and translatable

Reflect patients' perceptions of their status

Data Elements for Registries

Pilot Testing

*To determine **time needed** to complete the form and the resulting subject / abstractor burden*

*May **uncover problems** in registry logistics*

*Evaluation of **accuracy** and **completeness** of registry questions*

***Comprehensiveness** of both **instructional** materials and **training** in addressing these potential issues*

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Registry Design

Questions for Registries

Descriptive questions;

Understanding characteristics cases

How disease generally progresses

Analytic questions;

Clinical effectiveness,

Assessing safety or harm

Evaluating effects of specific treatments on patient

Research questions should address ***registry's purposes***

Research Questions in Registries

Natural history studies; *observe* ***clinical practice & patient experience***

Measures of *clinical effectiveness*;

Followup for long-term *benefits* or *harm*

Surveillance for rare events

Evaluations of standard medical practice

Research Questions in Registries

Studies;

for treatments in which *randomization is unethical or not necessary*

for which *blinding* is challenging or unethical

of conditions with *complex treatment*

of health care *access* and *barriers* to care

of heterogeneous patient populations;

of effectiveness and safety

Registry Design

Translating *clinical questions* into *measurable exposures* & *outcomes*

Clinical questions in registry will guide *definitions* of;

Study subjects,

exposure,

outcome measures,

study design,

data collection,

analysis

Registry Design

Finding necessary data

Identification of key outcomes, exposures & patients, ***drive strategy*** for data collection

Generally, ***not possible*** to collect all desired data (key challenge to registries)

Data collection should be both ***parsimonious*** & ***broadly applicable***

Registries should focus on collecting ***relevant data***

Registry data can be obtained from;

patients, clinicians, medical records, linkage with other sources

Registry Design

Study Designs for Registries

Case Series Design;

Commparison case series

Self-controlled case series, controls for all confounders that do ***not vary over followup time***

Registry Design

Study Designs for Registries

Cohort Design ;

follow over time, to see particular ***endpoint*** or ***outcome***

is used for *descriptive studies*

to evaluate *comparative effectiveness* and/or safety or quality of care

may include *only people with exposures* ***(a particular drug)***

may include *one or more comparison groups*

Registry Design

Study Designs for Registries

Case - Control Design;

Gathers patients who have a ***particular*** *outcome / an adverse event* (cases) & who have not (controls)

Representative of source population **(from which cases arise)**

Employed for etiology of ***rare diseases***

Cases & **controls** may be ***identifiable*** within a ***single registry***

Note; controls from **outside** registry must be **comparable** with cases

Registry Design

Study Designs for Registries

Nested case - control Design;

a variant of case-control study

controls are selected via ***risk-set*** sampling,

each person in source population has a probability

of being selected ***as a control***; (in proportion to

person-time contribution to cohort)

Registry Design

Study Designs for Registries

Case - Cohort Design;

a variant of case-control study

each control has ***an equal probability*** of being sampled

from source population

This allows *for collection of data* for ***cases*** and a ***sample***

of full cohort, instead of ***whole cohort***

Choosing Patients for Study;

Target Population

population to which the findings are meant to apply,
(all patients with a disease or a common exposure)

registries will enroll all, or nearly all, of target population,
most, enroll only a sample of target population

Study population

subset of those who can ***actually be identified*** & ***agree to participate***

rarely possible study groups ***fully representative***

clear definitions *of inclusion /exclusion criteria*
registries typically have few *inclusion / exclusion criteria*

Choosing Patients for Study;
Comparison Groups

To collect data on ***comparators*** (parallel cohorts)??

Depending on purpose of registry*, internal, external, or historical groups can be used*

*Comparison groups are most **useful**;*

*to strengthen understanding of whether observed effects are **real***

to distinguish between alternative decisions

to assess differences, magnitude of differences, and strength of associations between groups

Challenges*;*

Comparison groups may yield significant complexity, time, cost;

Multiple comparisons: dificulties in interpretation of registry results

Registry Design

Choosing Patients for Study;

Sampling *(in terms of patients and sites)*

Representativeness of sample affects generalizability

Probability sampling;

Simple random sampling

Stratified random sampling

Systematic sampling

Cluster (area) sampling

Multistage sampling

Nonprobability sampling:

Selection is not random

Registry Design

Registry Size and Duration;

Precision in measurement and estimation

corresponds to ***reduction of random error;***

improved by ***increasing size*** of study

Duration of registry *enrollment and follow up determined by*

required ***sample size*** *&*

time-related considerations

Sample size & Duration

Aims of a registry,
Desired **precision** of information sought,
Hypotheses to be tested**,**

determine

process and inputs for arriving at a *target sample size* and specifying *duration of follow up*

Registry Design

Internal validity*;*

extent to which;

study results are free from bias,

and reported ***association*** *between exposure and outcome is not due to* ***unmeasured or uncontrolled-for*** *variables*

External validity *(generalizability);*

refers to utility of the inferences for broader population that the study subjects are intended to represent

Registry Design

Internal and External Validity;

Registries, usually focus on ***generalizability***

include more heterogeneous populations

Registries have more opportunities to ***introduce bias***

Registry Design

Information Bias;

Selection Bias;

Loss to Followup;

attrition of patients and sites

Bias from study of Existing rather than New Product Users

incidence/prevalence bias, survivorship bias, and followup bias

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