

Introduction to Biomarkers

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Introduction

- In this section we will discuss...
- What are biomarkers
- History
- What is a good biomarker
- Types of biomarkers
- Nature of biomarkers
- Biomarker validation
- Role of BMs in health care system

Introduction

- **Biomarker**
- Defined as a characteristic that can be objectively measured and evaluated as an indicator of a physiological or a pathological process or pharmacological response to a therapeutic intervention
- Classical biomarkers being blood pressure, glucose....

Introduction

- History

Table 1.1 Historical landmarks in discovery and development of biomarkers

Year	Landmark
1847	The first laboratory test for a protein cancer biomarker, the Bence Jones protein in urine
1954	Test for the measurement of transaminases in myocardial infarction (Karmen et al. 1954)
1960s	The term “biomarker” started to appear in the literature in connection with metabolites and biochemical abnormalities associated with several diseases
1967	An improved test for myocardial infarction based on a biomarker – serum creatine phosphokinase (Rosalki 1967)
1971	Report of carcinoembryonic antigen (CEA) as biomarker of cancer (Moore et al. 1971)
1987	Troponin I as a biomarker for myocardial infarction (Cummins et al. 1987)
Early 1990s	Accelerator mass spectrometry used for analysis of biological samples for biomarkers
1995	Applications of proteomics for discovery of biomarkers and use in molecular diagnostics
1999	Emergence of metabolomics for study of biomarkers
2000	Sequencing of the human genome completed opening the way for discovery of gene biomarkers
2005	Discovery and application of biomarkers becomes a major activity in biotechnology and biopharmaceutical industries

Introduction

- **What is a good BM**
- Ideal BM must be specifically associated with a particular disease or disease state and should be able to differentiate between similar physiological conditions
- Standard biological sources like serum or urine can be used for identification
- Should have an accurate, simple and cost effective measurement method
- Must have base line reference point

Introduction

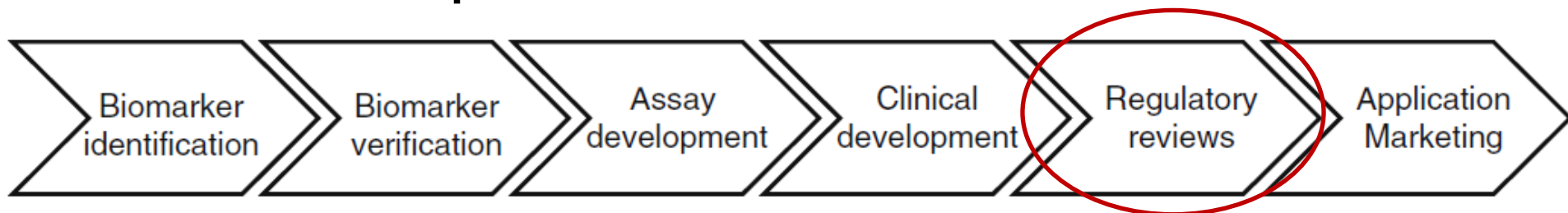
- **Types of biomarkers**
- **Predisposition BMs**
 - Helpful in identifying likeliness of getting disease
- **Screening BMs**
 - Helpful in screening who is suffering the disease
- **Staging BMs**
 - Helpful in categorizing disease severity
- **Prognostic BMs**
 - Helpful in assessing disease progression
- **Prediction BMs**
 - Helpful in predicting the course of the disease
- **Recurrence monitoring BMs**
 - Helpful in identifying recurrence of the disease

Introduction

- **Nature of Biomarkers**
- Nature of BMs can be as simple as metabolites like glucose, steroids, lipids... and also can be complex such as T cells, auto-antibodies....
- Classically they can be
 - A piece of DNA – gene – genomics
 - RNA – transcriptomics
 - Any protein – proteomics
 - Any metabolite – metabolomics
 - Protein interactions - interactome

Introduction

- **Biomarker validation**
 - Is the process of assessing the assay or measurement performance characteristics
- **Biomarker qualification**
 - Is the process of providing evidence to link a BM with biology and clinical end points

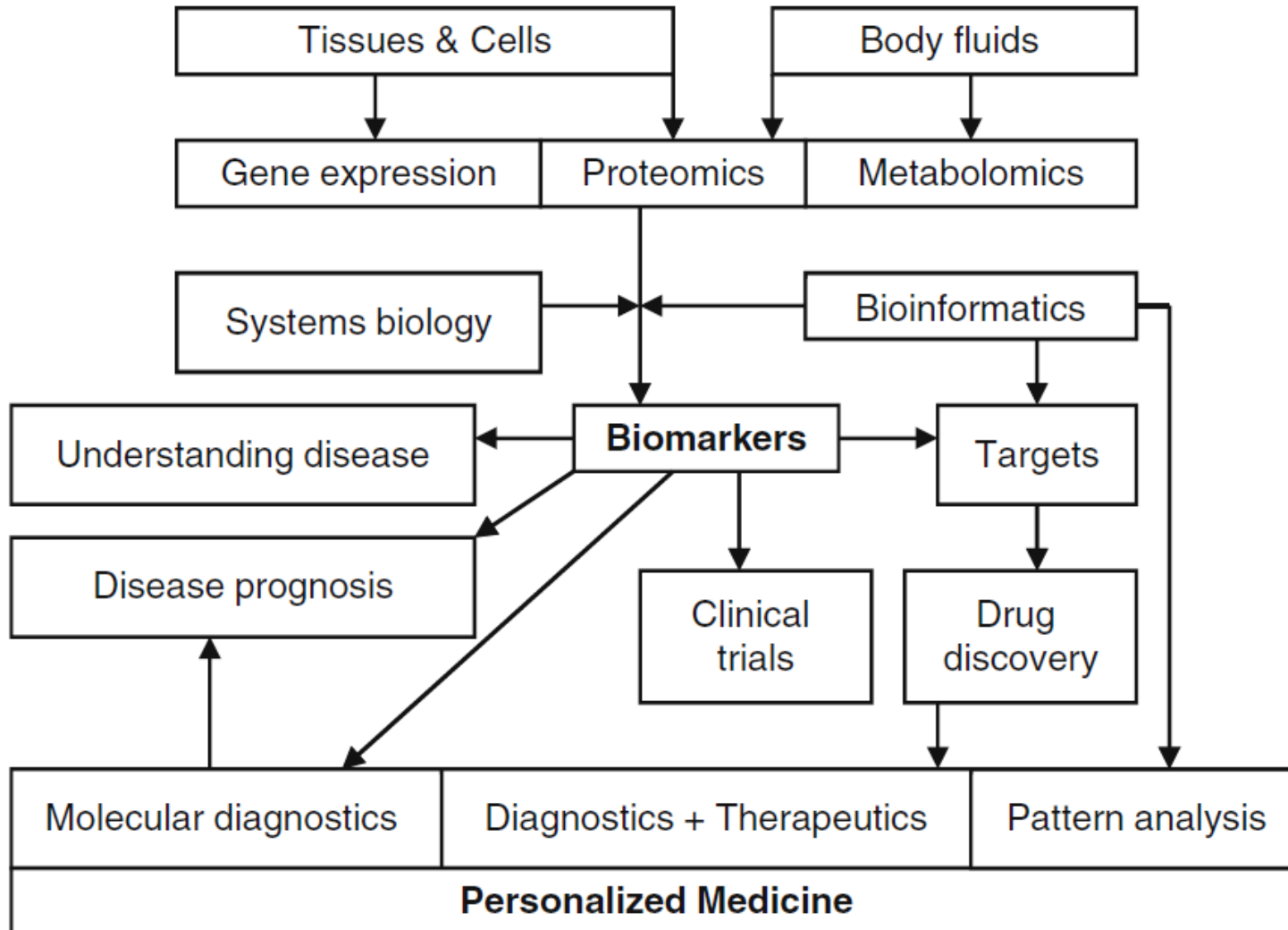


Introduction

- **Role of BMs in health care**
 - Knowledge of BMs can be used by translational medicine (transfer of research findings to clinical applications)
 - BMs play important role if not central
 - Helpful in inventing diagnostic kits ultimately leading to drug development
 - Aid in developing personalized medicine which is the future of health care
- **Limitations**

Introduction

- Relationship of BMs to health care



Introduction

- Next class.....
 - BMs of general tissue functions