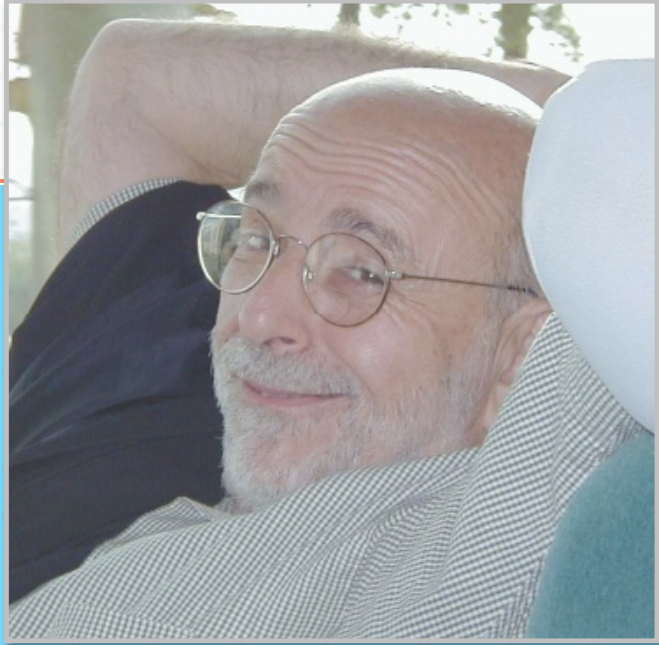
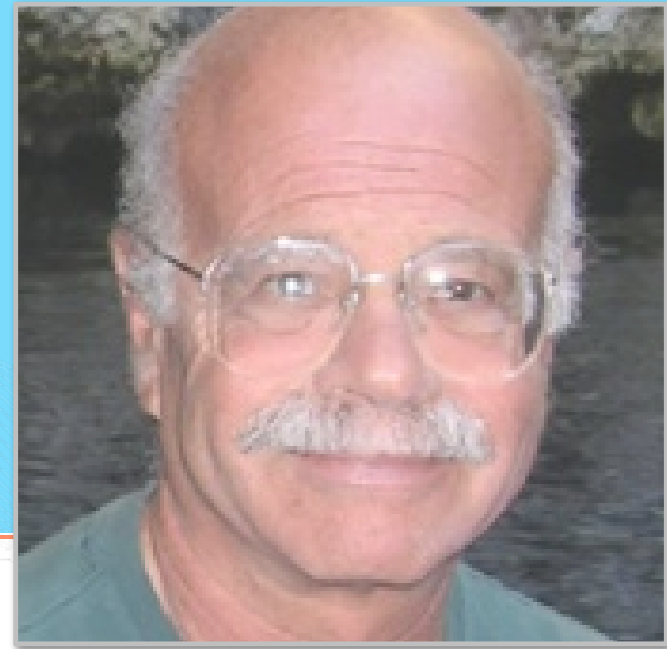


# Advancing Pharmacometrics

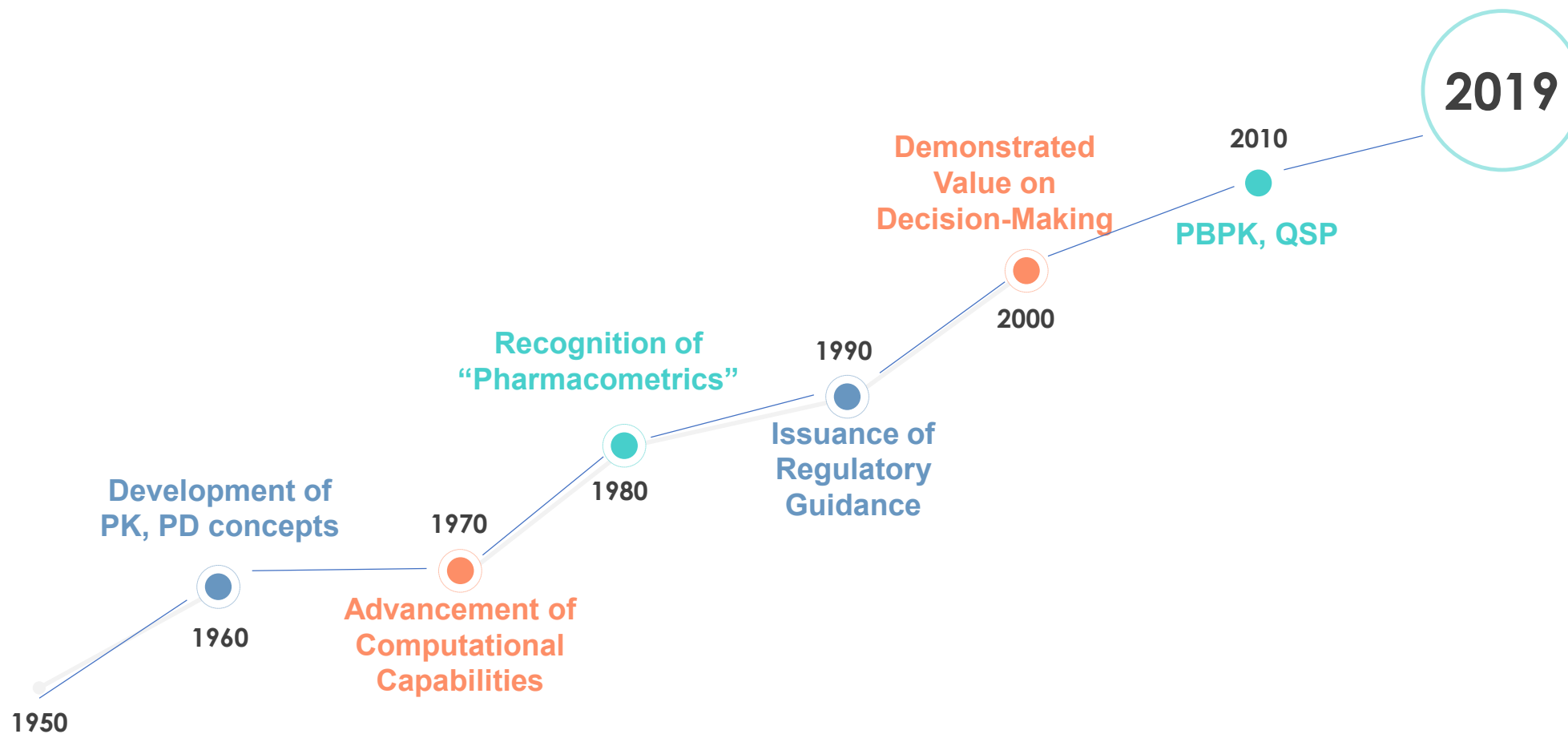


**Sheiner**



**Beal**

# Growth of Pharmacometrics



# Pharmacometrics 2.0



**Scientists**



**500**

**MIDD**



**100% Trials**

**Tools**



**Efficient  
Software**

**Stories**



**Share Case  
Studies**



Integrated Clinical Pharmacology

# Pharmacometrics 3.0: The Next Big Thing



RID:9456

RID:7032

RID:2668



A set of small icons representing a user interface, including a person icon, a list icon, and a grid icon, overlaid on a background of data points and lines.

# HealthCare Crisis

Low Quality, High Cost



TREATMENT

HEALTH

DNA

RID:9450

RID:7032

RID:2668

HS

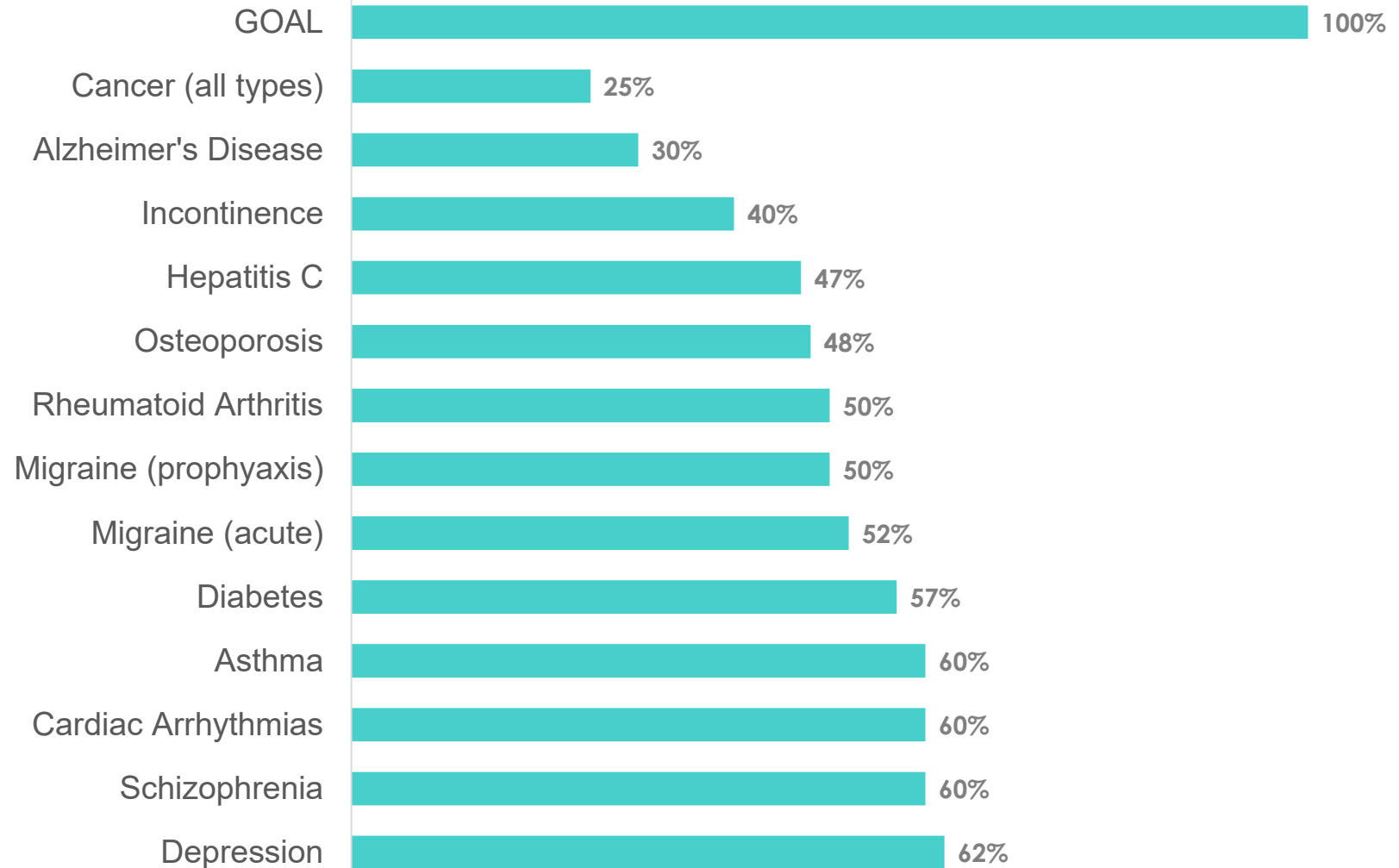
HN



# HealthCare Crisis



## Therapeutic Area



Rate of efficacy with standard drug treatment





## Individual Patient

- › Drugs are developed for an average patient
- › Hospitals treat individual patients



## Individual Benefit/Risk

- › CE assessment for a patient from trials unlikely
- › Patients are treated by trial and error



# Pharmacometrics-Driven Decision Support Systems

Disrupting HealthCare

## Pharmacometrics 3.0

RID:9450

RID:7032

RID:2668







## Database

- › Create real-time database of key patient data (EHR) and other external scientific information



## Prescribers

Real-time access to knowledge to make informed patient decisions



## Application

- › Develop front-end tools for enabling knowledge to guide prescriber decisions



## Analytics

- › Build analysis engines to analyze patient and other scientific data using Pharmacometric approaches

# New Rules of Engagement

## Past

### Pay for Service

Pay for Service has no motivation for quality



## Future

### Pay for Performance

Therapy should prove to be efficient: maximizes patient benefit and reduces health care costs



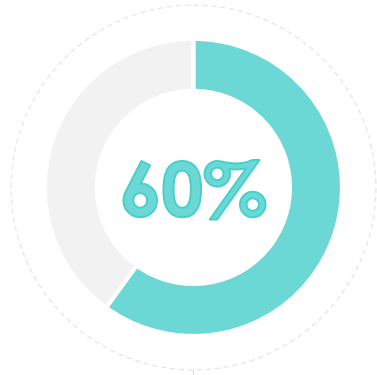
# CMS Incentive



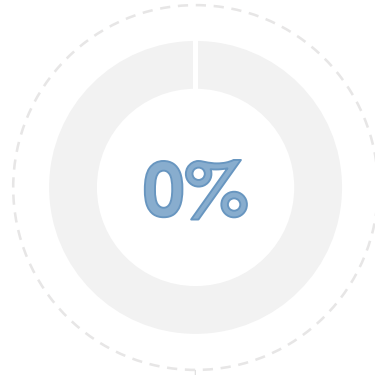
Under MIPS, there are 4 performance categories that will affect your Medicare payments



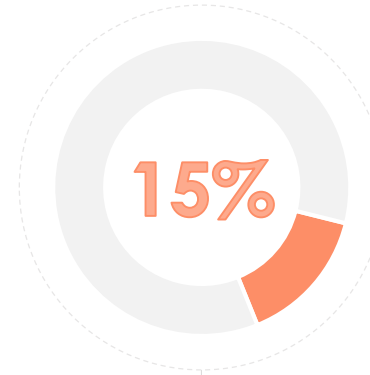
Quality



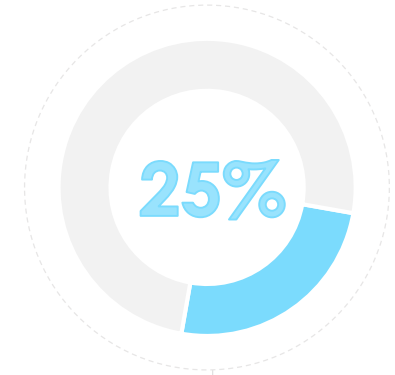
Cost



Improvement  
Activities



Advancing care  
information



Weight

*Merit-based Incentive Payment System*

# The Problem



## HCP Decisions



Upon diagnosis, HCP decides drug/dose for a patient



## HCP Challenges

Primary basis of treatment guidelines is average, not the patient

## New Law



EHRs



## No Existing Solution

Most HCPs make decisions based on their limited experience

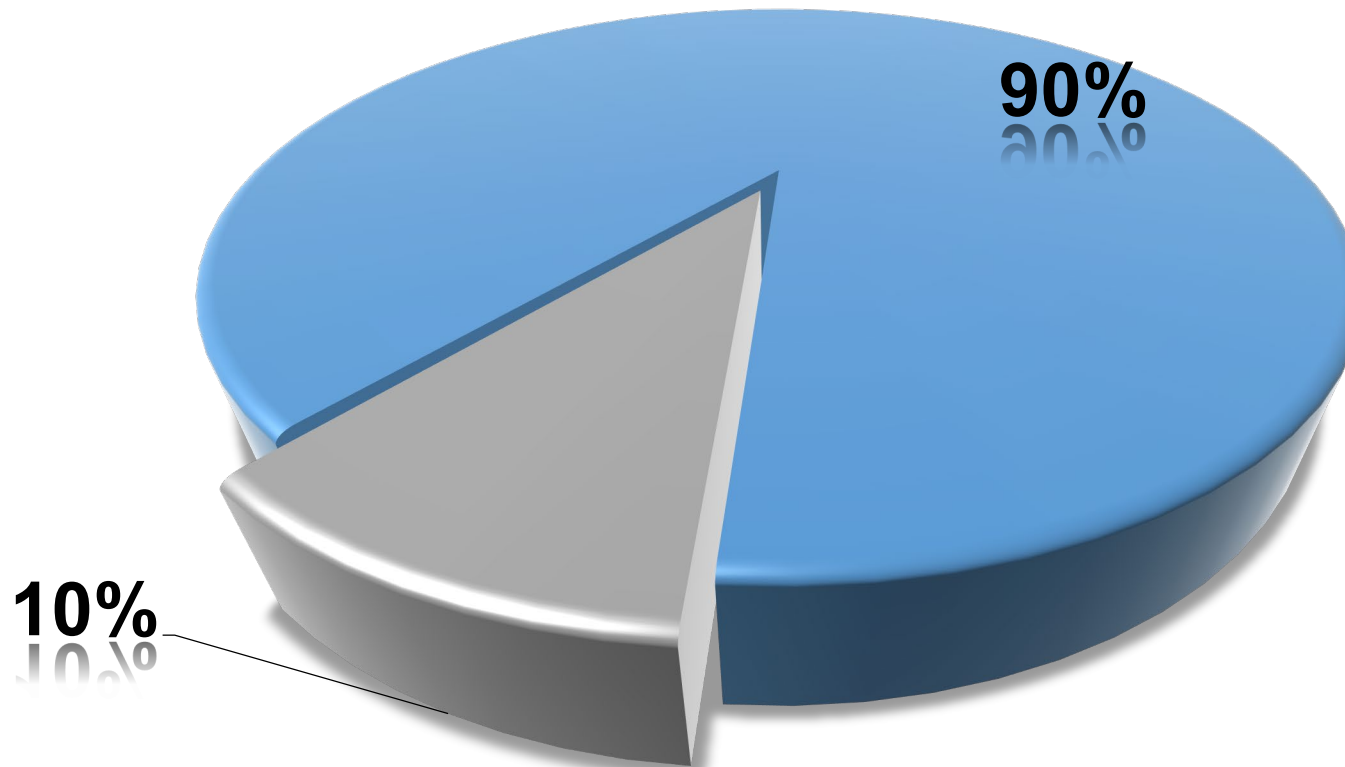


# Follow the Money



**\$3.5 Tr**

▣ Health Care    ▣ Prescription Rx



# Pharmacometrics-Driven Decision Support Systems



## Vision

To enhance the efficiency of healthcare by developing and implementing DSS



## Mission 1

To double the patient response by actively employing prior trial results and real time patient data to optimize the treatment or prevention options



## Mission 2

To half the healthcare costs by empowering prescribers with the latest intelligence on precision therapeutics

# Mean

New Mind Set





# Meax

New Mind Set

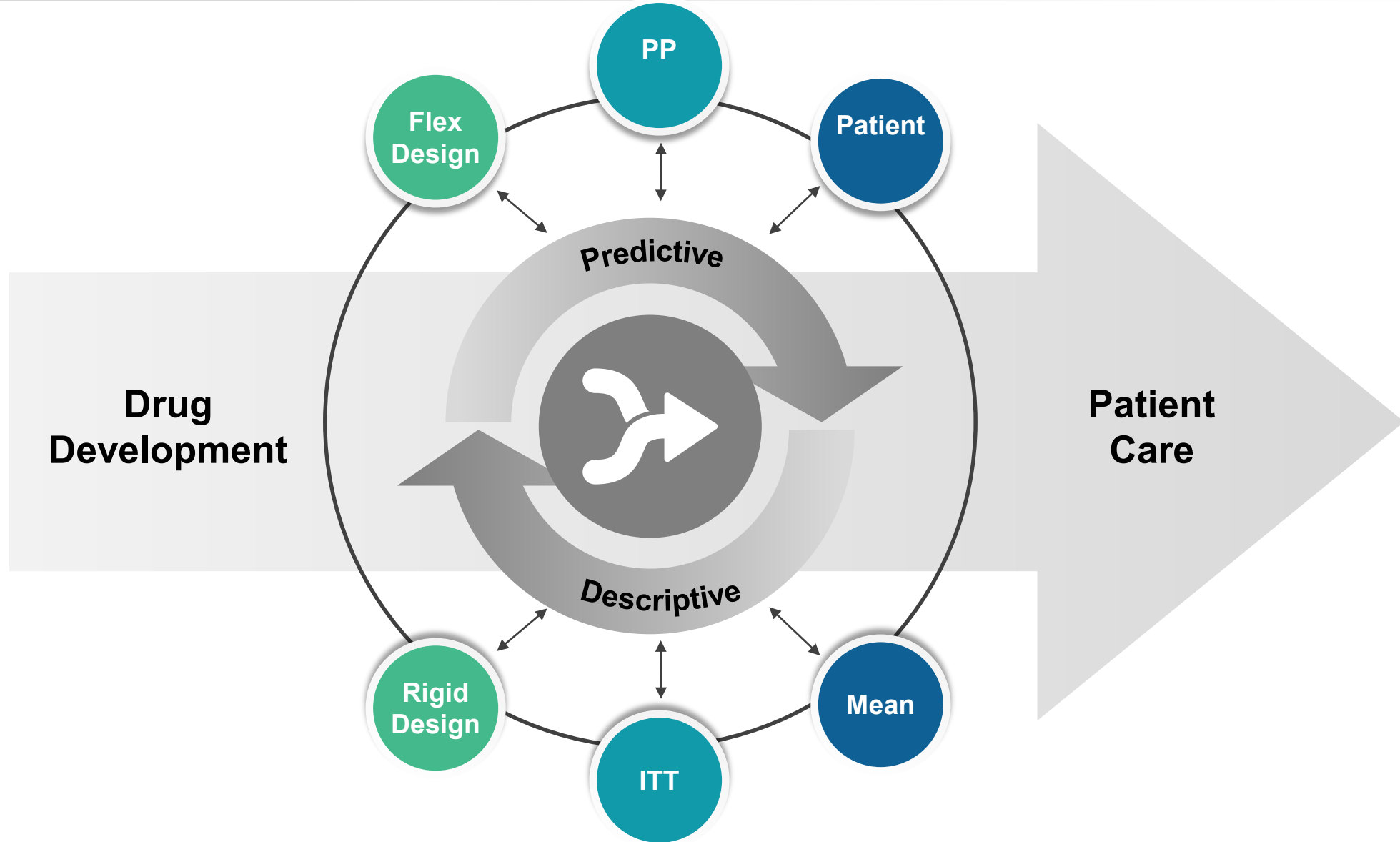


- ▶ RID:9450
- ▶ RID:7032
- ▶ RID:2668

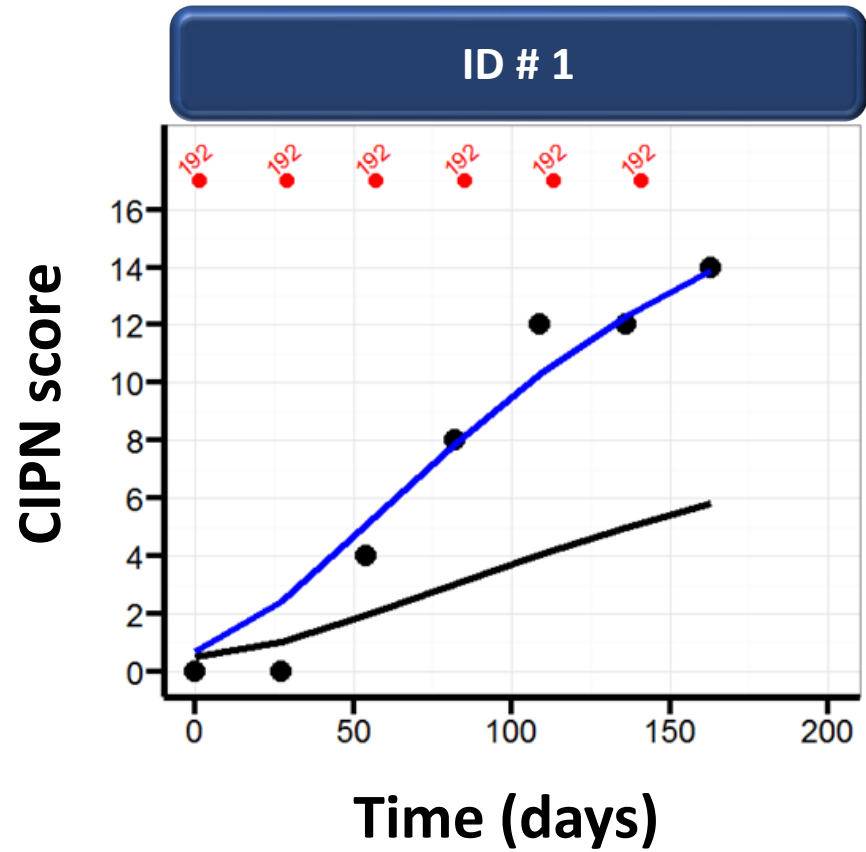




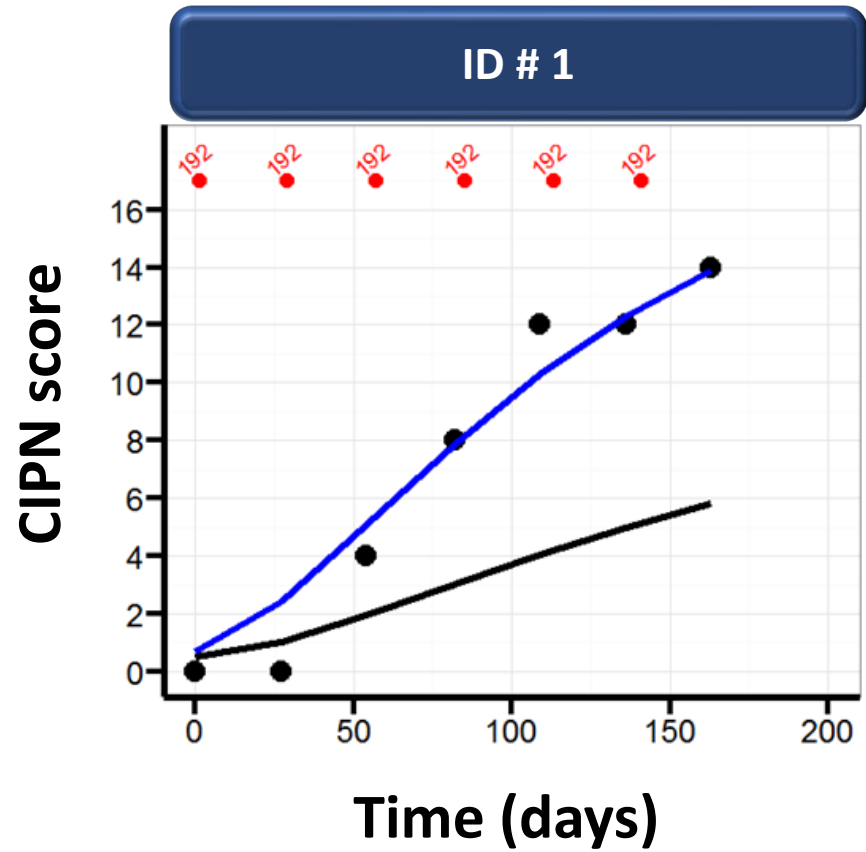
# Descriptive Analyses → Predictive Systems



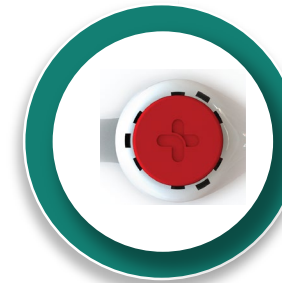
# Descriptive Analyses



# Descriptive Analyses



# Data Collection



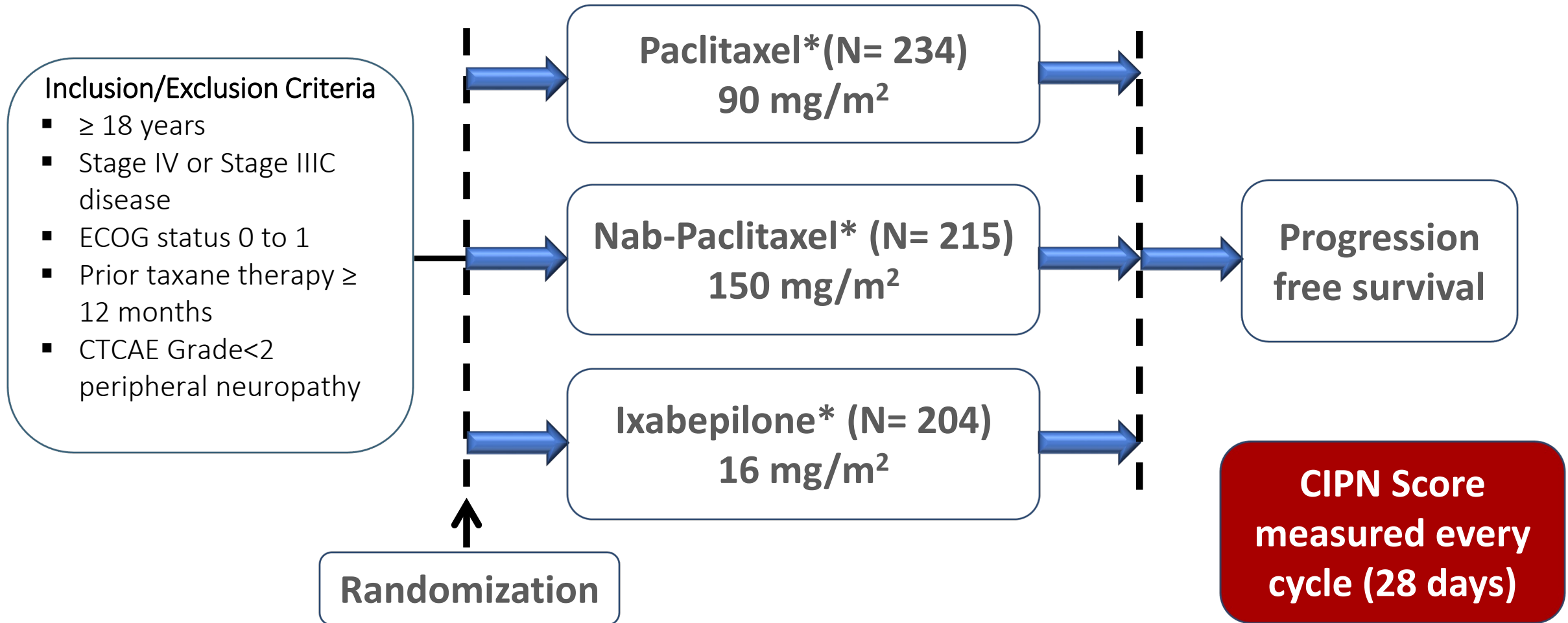
Ecological Momentary Assessment (EMA)

# Chemotherapy-Induced Peripheral Neuropathy (CIPN)

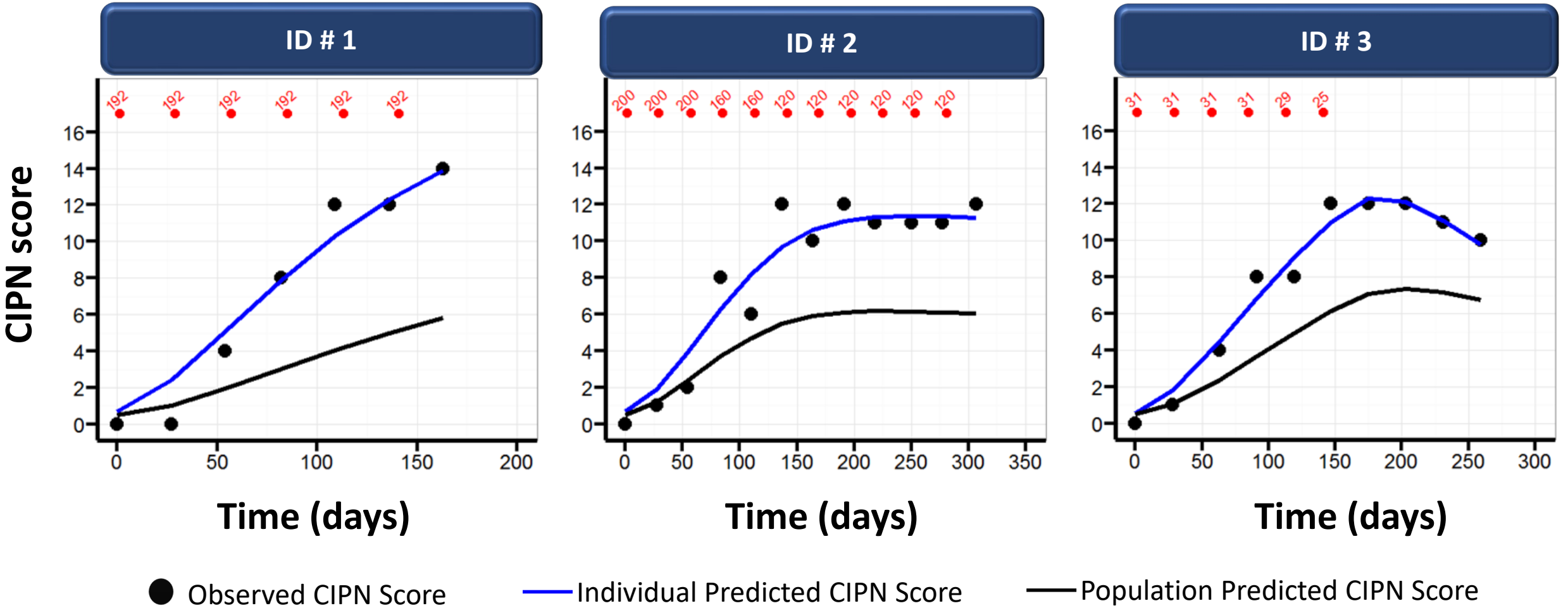
## Can Early Patient Data Predict Risk of CIPN?

Mehrotra S, Sharma MR, Gray E, Wu K, Barry WT, Hudis C, Winer EP, Lyss AP, Toppmeyer DL, Moreno-Aspitia A, Lad TE, Valasco M, Overmoyer B, Rugo H, Ratain MJ, Gobburu JV. Kinetic-Pharmacodynamic Model of Chemotherapy-Induced Peripheral Neuropathy in Patients with Metastatic Breast Cancer Treated with Paclitaxel, Nab-Paclitaxel, or Ixabepilone: CALGB 40502 (Alliance). AAPS J. 2017 Sep;19(5):1411-1423.

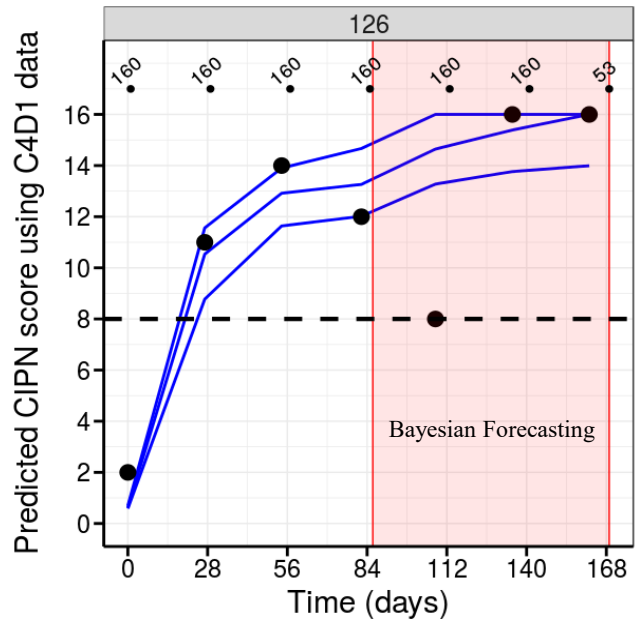
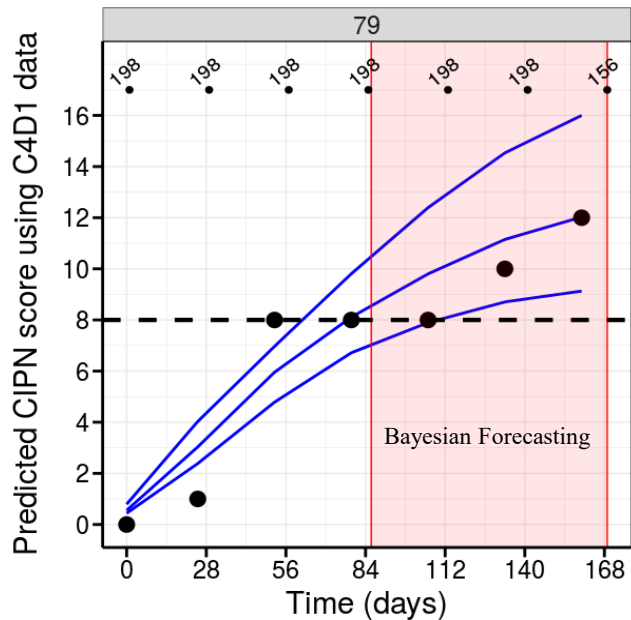
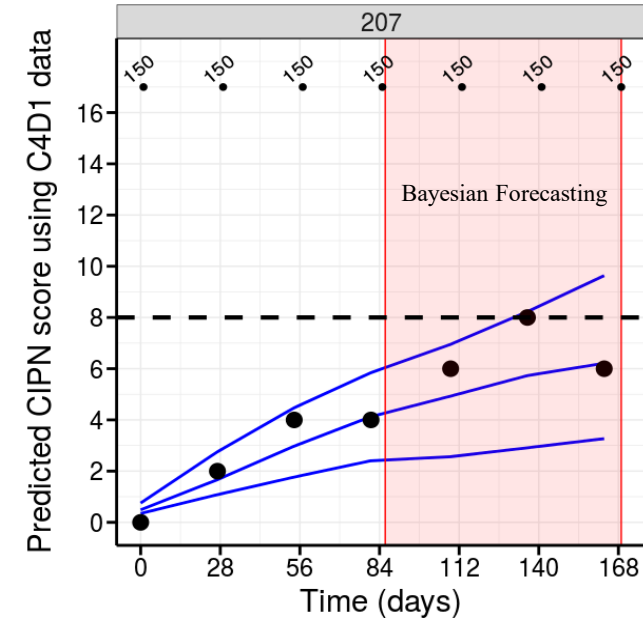
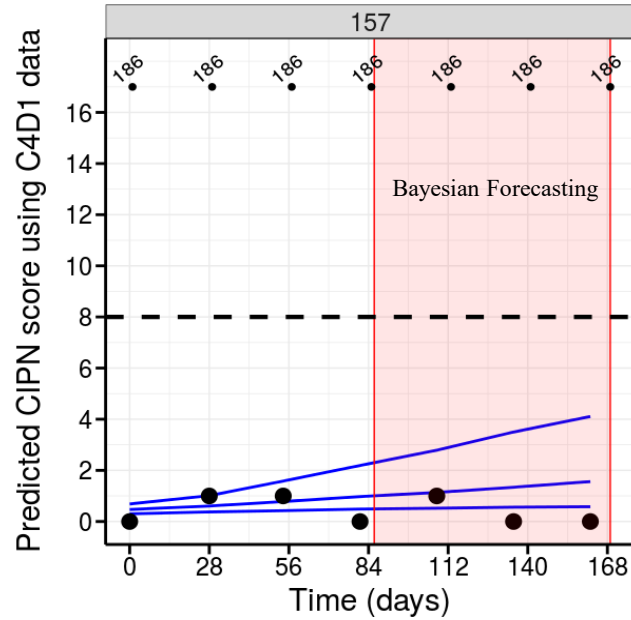




# Descriptive Model



# Bayesian Forecasting is the Brains behind DSS





# Strategic Requirements

For DSS to be Successful



# DSS – Strategic Requirements



**Integrated Tools**  
Seamless Analyses



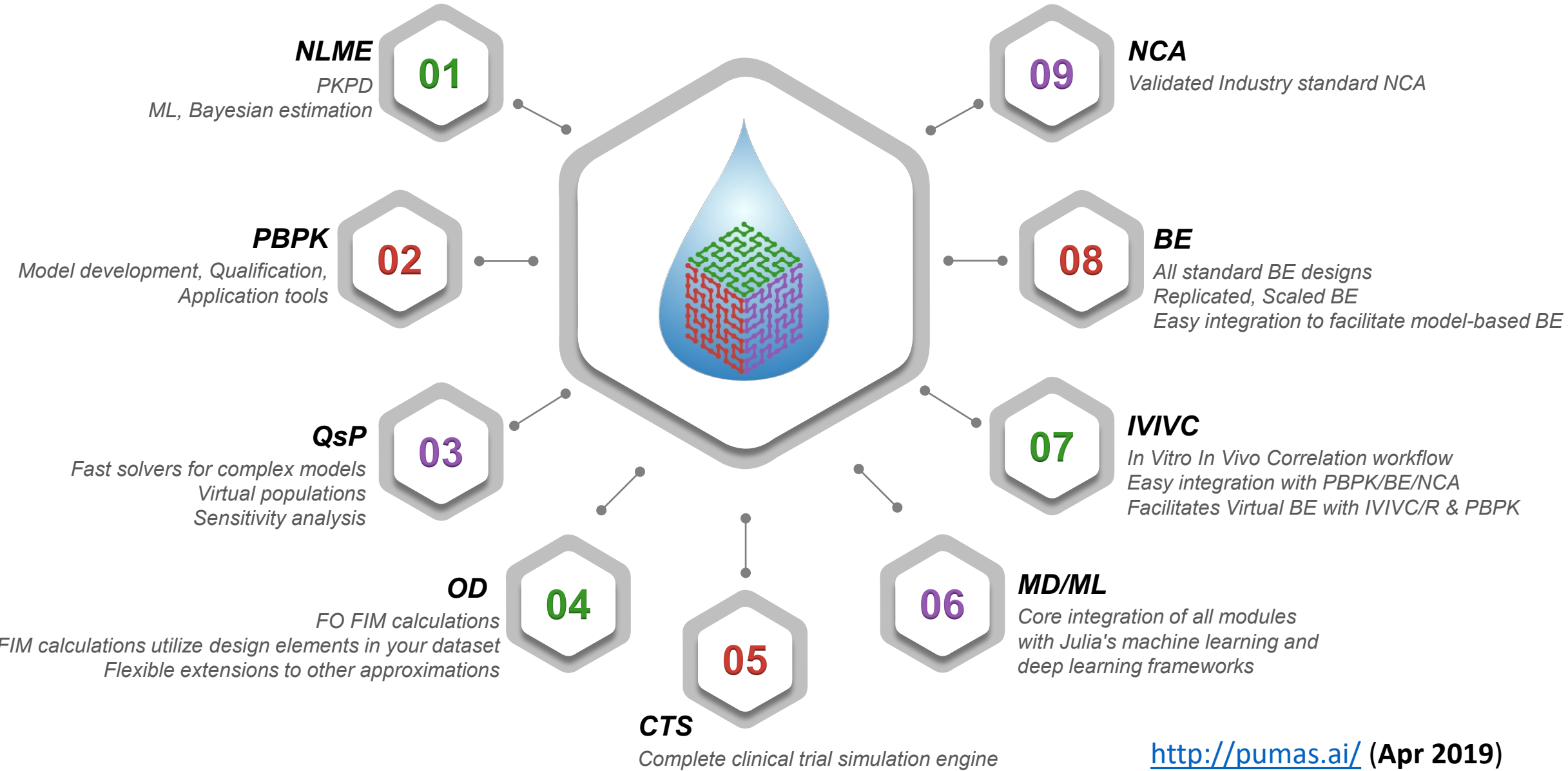
**Diverse Experts**  
Pharmacists, Academicians, Engineers



**Entrepreneurial Spirit**  
Sustainability

# Disjointed Tools





<http://pumas.ai/> (Apr 2019)

# Diverse Experts: Pharmacists



01

**Drive Workflows**

02

**Influence Practice Decisions**

03

**Appreciate Clinical Pharmacology**

04

**Professional Societies**

# Diverse Experts: Academicians, Engineers



W Craft, T Lewis, C Hendrix, S Vinks

01

Derive Treatment Algorithms

02

Validate DSS (RWE)

03

Novel Analyses Techniques

04

State-of-the-art Technology

# Entrepreneurial Spirit









RID:7032

RID:2668



## Pharmacometrics 3.0



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