

The evolution of clinical decision support tools that enable precision dosing at the point of care

FDA Precision Dosing Workshop

Sirj Goswami

August 12th, 2019

Agenda / Learning Objectives

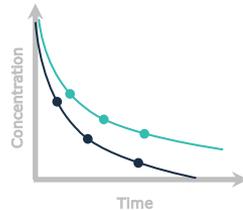
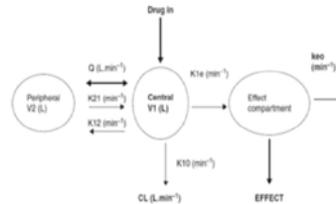
- (1) Describe the **current state of precision dosing tools** and highlight macro-level factors that enable broad adoption of CDS platforms
- (2) Highlight approaches to overcome **electronic health record integration** barriers and develop an **optimal user experience**
- (3) Highlight the importance of an **analytics framework and dashboard** to improve platform scalability and demonstrate value

An ideal CDS platform should be **user friendly, scalable, integrated into the clinical workflow and improve healthcare outcomes**

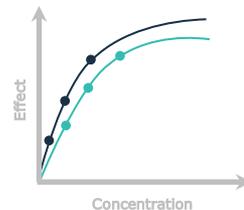
HISTORICAL CONTEXT

First model-informed precision dosing (MIPD) tool developed in 1969

PK/PD Models to support clinical decisions



Pharmacokinetics



Pharmacodynamics



Computers and Biomedical Research

Volume 2, Issue 6, December 1969, Pages 507-518

ELSEVIER

Computer-aided long-term anticoagulation therapy

Lewis B. Sheiner*

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[https://doi.org/10.1016/0010-4809\(69\)90030-5](https://doi.org/10.1016/0010-4809(69)90030-5)

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Abstract

A computer program is described which calculates a suggested daily anticoagulant dose schedule for a patient. The program requires previous prothrombin times and drug dosages as well as physician determined therapeutic goals and limits. A simple compartmental response model is used to predict prothrombin time responses from previous drug doses. Suitable future dose suggestions are calculated from these prothrombin time predictions. A retrospective study provided a test of the program's performance relative to that of resident physicians and three staff cardiologists at a large teaching hospital. The doses computed by the program were found to compare favorably with those of the pilot sample of physicians.

Current environment: Fragmented dosing calculators and spreadsheets that do not leverage the power of MIPD

- *Imprecise (not-model based)*
- *Difficult to use*
- *Fragmented*
- *Requires manual entry*
- *Lack of standardization*

Drug Parameters

Aminoglycoside: Gentamicin
Dosing Method: Extended / Conventional
Goal peak: 8 mcg/mL
Goal trough: 1 mcg/mL

Patient Parameters

Age: 62 years
Height: 66 in cm
Weight: 100 kg lbs
Gender: Male / Female
Creatinine: 1.2 mg/dL

Dose by Level

Empiric Dosing / Dose By Level

Provide empiric dosing recommendations based on estimated renal function (not aminoglycoside levels).

Reset Calculate

Recommended Dosing Progress Note Equations

Dosing Schedule

Dose: 160 mg
Frequency: 8 hr
infused over 0.5 hrs
2 mg/kg (dosing weight)

Predicted PK Profile

Peak: 7.8 mcg/mL
Trough: 1.5 mcg/mL
Level < 2 mcg/mL: 1.8 hrs

Consider drawing two aminoglycoside levels (peak and trough) for a patient-specific dosing regimen.

MedCalc: Pediatric Dosing Calculator

Dose: mg/day
Frequency: qD
Weight: kg
Concentration: mg/cc

Calculate Reset

Dose:

Dose (cc) = $\frac{\text{dose (mg/kg/day)} \times \text{weight (kg)}}{\text{concentration (mg/cc)} \times \text{frequency}}$

MedCalc (New Structure)

Drug: Gentamicin
Dose Range: 1.5 - 5 mg/kg/day
Frequency: qD
Weight: 100 kg
Creatinine: 1.2 mg/dL

Recommended Dosing: 160 mg q8h

Predicted PK Profile: Peak 7.8 mcg/mL, Trough 1.5 mcg/mL

The time is right to adopt CDS Platforms and MIPD in healthcare

Cloud-based infrastructure for healthcare,
computational power

Technical
Barriers
Eliminated

Transition to
Electronic Medical
Records



Rise of
diagnostics

Macro-level
Industry Trends

Value-based
healthcare
(pay for value)



Data-driven
patient care

Precision medicine

CDS Platforms outside of MIPD have undergone a transformation over the past several years



Key Evolving Characteristics

User interface/experience

Software integration

Clinical workflow implementation

Analytics

User interface (UI) / user experience (UX)

UI/UX

UI/UX in healthcare lags behind other industries

- ✗ Electronic health record (EHR) systems are outdated
- ✗ Complex clinical workflows
- ✗ Multiple stakeholders involved in decision making
- ✗ Waterfall software design process
- ✗ Clinical user is NOT the buyer
- ✗ Developers are NOT users and NOT in tuned with clinical need
- ✗ Complexity of data inputs and data outputs
- ✗ Abundance of idiosyncratic terminologies (e.g. AUC)

UI/UX

What constitutes an optimal user experience?



The product is **useful**

- It addresses real pain points and problems for the user population.



The product is **user friendly**

- Users can intuitively, or with relatively little training, repeatedly use the product's functionality.



The product is **simple**

- Users demand a simple platform that does not compromise quality.

Know-how



Expert

- Domain expert
- **Clinical pharmacologist**
- **Specialized pharmacists**

Product



Empathy

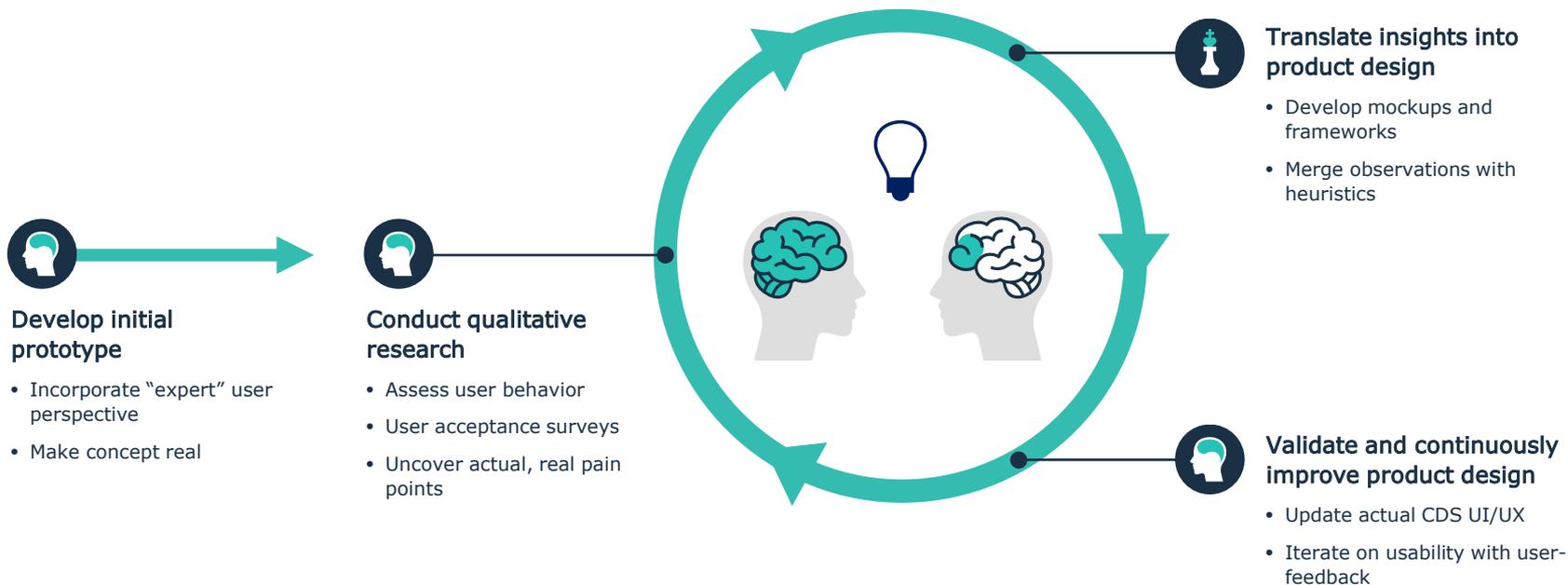


Typical user

- Not a domain expert
- **Physician**
- **Pharmacist**

UI/UX

Usability research studies help us achieve an optimal product design



Updated User Interface Resulting From Usability Studies

▲ Patient list

👤 Teams

Liddell O'Laidey

MRN: 0000000 CSN: 0000000

Notes (07/22/18 12:16 ifaldasz)

Date of birth: 01/01/1946
 Age: 72.6 years
 Sex: Female

Drug: **Vancomycin (adults)**
 Patient indications
 Co-treatment options

Serum creatinine: 0.8 mg/dL 07/22/18
 Weight: 57 kg 07/22/18
 Height: 168 cm 07/22/18
 Creatinine assay: Enzymatic
 eGFR estimation: Cockcroft-Gault
 MIC
 Hemodialysis CL

Absolute eGFR: 56.7 ml/min
 Relative eGFR: 59.7 ml/min/1.73m²
 Weight for eGFR: Total body weight
 Adjusted weight: 58.6 kg
 Ideal weight: 59.6 kg
 BSA: 1.64 m²
 BMI: 20.2 kg/m²
 Fat-free mass: 38.5 kg

Dose information

last updated a few seconds ago, starting with dose #5 at 07/25/18 09:11
 steady state concentrations are calculated 4 days out from 07/25/18

Δ	Dose	Interval	Inf. length	AUC ₂₄	C _{trough,ss}	P _{auc} [*]	P _{conc} [*]	Tox.
<input type="checkbox"/>	<input type="text" value=""/> mg	12 hours	1 hours					

Reference table 📌 More info

<input type="checkbox"/>	-66.7%	250 mg (4.4 mg/kg)	12 hours	1 hours	250 mg/L·hr	8.0 mg/L	0%	0%	5%
<input type="checkbox"/>	-33.3%	500 mg (8.8 mg/kg)	12 hours	1 hours	497 mg/L·hr	15.9 mg/L	98%	4%	11%
<input type="checkbox"/>	previous	750 mg (13.2 mg/kg)	12 hours	1 hours	743 mg/L·hr	23.7 mg/L	100%	89%	25%
<input type="checkbox"/>	+33.3%	1000 mg (17.5 mg/kg)	12 hours	1 hours	989 mg/L·hr	31.6 mg/L	100%	100%	46%
<input type="checkbox"/>	+66.7%	1250 mg (21.9 mg/kg)	12 hours	1.5 hours	1235 mg/L·hr	39.8 mg/L	100%	100%	70%

* P_{auc}: probability that AUC is >400 (efficacy); P_{conc}: probability that C_{trough} is above 20 µg/mL (toxicity);
 Tox: Probability of nephrotoxicity, based on Lodise et al. Clin Infect Dis 2009.

all Population Individual per kg

CL	2.56	1.86 L/hr
V _c	38.5	36.8 L
t _{1/2}	10.9	14.3 hours

Viewing latest: 3 days 1 week all 🔍

Current TDM

Drug monitoring

	Dose	Interval	Start time	Infusion length	TDM	Since dose	Comments
<input type="checkbox"/>	1 750 mg		07/19/18 00:32	1 hours			
<input type="checkbox"/>	2 750 mg	11 h 17 m	07/19/18 11:49	1 hours			
<input type="checkbox"/>	3 750 mg	13 h 11 m	07/20/18 01:00	1 hours			
<input type="checkbox"/>			07/20/18 12:32		19 mg/L		
<input type="checkbox"/>	4 750 mg	12 h 15 m	07/20/18 13:15	1 hours		11 h 32 m	

UI/UX

Consolidated Dashboard Improves Workflow Efficiency

Insight
Jonathan Faldas

▲ Patient list

👤 Teams

Liddell O'Laidey

MRN: 0000000 CSN: 0000000

Dose information

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steady state concentrations are calculated 4 days out from 07/25/18

Δ	Dose	Interval	Inf. length	AUC ₂₄	C _{trough,ss}	P _{auc} *	P _{conc} *	Tox.
	mg (4.4 mg/kg)	12 hours	1 hours	250 mg/L.hr	8.0 mg/L	0%	0%	5%
	mg (8.8 mg/kg)	12 hours	1 hours	497 mg/L.hr	15.9 mg/L	98%	4%	11%
	mg (13.2 mg/kg)	12 hours	1 hours	743 mg/L.hr	23.7 mg/L	100%	89%	25%
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PK Fit info Exposure Covariates

all Population Individual per kg

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V _d	38.5	36.8 L
t _{1/2,T}	10.9	14.3 hours

Viewing latest: 3 days 1 week all 🔍

Patient characteristics

Serum creatinine	0.8 mg/dL	07/22/18
Weight	57 kg	07/22/18
Height	168 cm	07/22/18
Creatinine assay	Enzymatic	
eGFR estimation	Cockcroft-Gault	
MIC		
Hemodialysis CL		

Absolute eGFR	56.7 ml/min
Relative eGFR	59.7 ml/min/1.73m ²
Weight for eGFR	Total body weight
Adjusted weight	58.6 kg
Ideal weight	59.6 kg
BSA	1.64 m ²
BMI	20.2 kg/m ²
Fat-free mass	38.5 kg

Interval	Start time ▲	Infusion length	TDM	Since dose	Comments
	07/19/18 00:32	1 hours			
11 h 17 m	07/19/18 11:49	1 hours			
13 h 11 m	07/20/18 01:00	1 hours			
	07/20/18 12:32		19 mg/L		
12 h 15 m	07/20/18 13:15	1 hours		11 h 32 m	

[Edit doses/TDM](#)

Help

UI/UX

Consolidated Dashboard Improves Workflow Efficiency

Insight
Jonathan Faldas

▲ Patient list

👤 Teams

Liddell O'Laide

MRN: 0000000 CSN: 0000000

Notes (07/22/18 12:16:18)

Date of birth 01/19/72

Sex Female

Drug Variants

Patient indications

Co-treatment options

Serum creatinine 0.8 mg/dL

Weight 57 kg

Height 168 cm

Creatinine assay Enzymatic

eGFR estimation Cockcroft-Gault

MIC

Hemodialysis CL

Absolute eGFR 56.7 ml/min

Relative eGFR 59.7 ml/min/1.73m²

Weight for eGFR Total body weight

Adjusted weight 58.6 kg

Ideal weight 59.6 kg

BSA 1.64 m²

BMI 20.2 kg/m²

Fat-free mass 38.5 kg

Dosing Reference Table

Update ⚙️

last updated a few seconds ago, starting with dose #5 at 07/25/18 09:11
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Reference table									More info
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PK
Fit info
Exposure
Covariates

all
Population
Individual
 per kg

	Population	Individual
CL	2.56	1.86 L/hr
V_c	38.5	36.8 L
	10.9	14.3 hours

Dose AUC Trough

Dose	Interval	Start time	Infusion length	TDM	Since dose	Comments
1	750 mg	07/19/18 00:32	1 hours			
2	750 mg	07/19/18 11:49	1 hours			
3	750 mg	07/20/18 01:00	1 hours			
4	750 mg	07/20/18 12:32	1 hours	19 mg/L	11 h 32m	

UI/UX

Consolidated Dashboard Improves Workflow Efficiency

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Jonathan Faldas

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	mg	12 hours	1 hours					

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Fit info
Exposure
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all
Population
Individual
 per kg

CL	2.56	1.86 L/hr
V _d	38.5	36.8 L
t _{1/2,T}	10.9	14.3 hours

Viewing latest: 3 days 1 week all

Biomarker/TDM Table

Drug monitoring

Edit doses/TDM

	Dose	Interval	Start time	Infusion length	TDM	Since dose	Comments
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Integration into the clinical workflow

EHR INTEGRATION

Why is it so challenging?

- EHR systems are very closed off (Not interoperable)
- Many different standards and architectures for exchange
- Many different implementations of data interchange
- EHR integration requires scarce IT resources
- Clinical workflow within EHR is unclear

EHR INTEGRATION

Different methodologies to overcome integration challenges

Method	Description	Pros	Cons
Custom Integration	Custom integration involves the consideration and agreement between integration partners of the methods of integration (technology stack, security methods, onsite/VPN vs internet, batch processing vs real-time, embedded vs standalone, etc.)	<ul style="list-style-type: none"> Control over integration approach Can potentially allow integrations when there are no other options 	<ul style="list-style-type: none"> IT staff needs to be highly skilled at custom integration work and have capacity IT time/effort Not scalable/reusable Minimal support
HL7	HL7 integration involves setting up import/export data endpoints for the transmission of standardized HL7 messages but with the generation of a mapping/transform layer to handle customizations.	<ul style="list-style-type: none"> International messaging standard for clinical data Widely adopted (as of 2018) 	<ul style="list-style-type: none"> Extensive customization resulting in extra integration work IT time/effort Message semantics not necessarily consistent
EMR Vendor APIs (e.g. Epic, AllScripts, Cerner, Athena Health)	EMR vendors provide their own access methods to their data. External parties must get approval from both the vendor and institutions that use their systems as well as implement vendor-specific data access solutions through the APIs that the vendors provide.	<ul style="list-style-type: none"> EMR vendor responsible for data access and support Web-based APIs available 	<ul style="list-style-type: none"> Each vendor has their own set of APIs Technologies may be complex and difficult to use Data access methods may be mixed (e.g. APIs + HL7)
EHR Vendor App Stores (e.g. Epic AppOrchard, Athenahealth MDP marketplace)	EHR vendors also provide solutions modeled after the Apple App Store or Google Play distribution service where 3rd parties can develop their applications (under the vendor's protocol for app store development) and make them available for distribution through the store.	<ul style="list-style-type: none"> Use of standardized, modern REST APIs in most cases (FHIR) Scalable / easier application distribution Simplified integration setup 	<ul style="list-style-type: none"> Cost of integration with EHR vendor
Third Party Applications (Open Standards Based Integration using FHIR)	If a clinical application/data provider has a FHIR server that is made accessible to 3rd parties seeking data, these 3rd parties can develop FHIR API clients which have the ability to access this data using a modern, standards-based, REST API.	<ul style="list-style-type: none"> Standards-based APIs and protocol Modern REST-based APIs and authentication schemes Granular access to clinical data Ability to easily integrate applications into EMRs via HTML5 	<ul style="list-style-type: none"> 3rd parties may not have full implementations of FHIR resources FHIR specification evolves at a faster pace than adoption (version issues)

EHR INTEGRATION

Different methodologies to overcome integration challenges

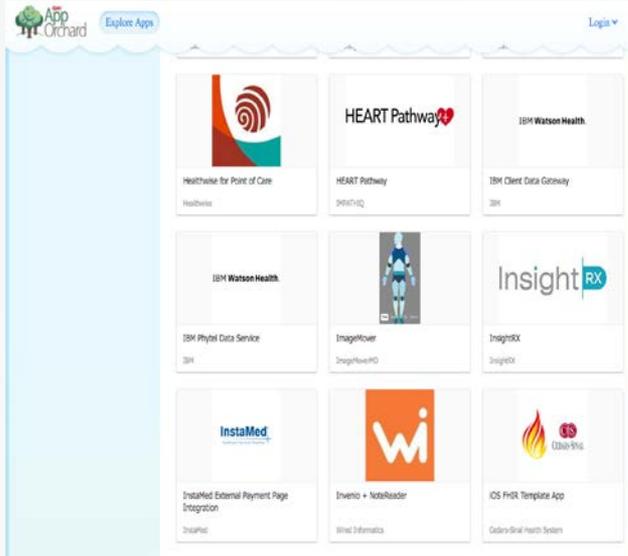
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Most
scalable

EHR INTEGRATION

Integration through a EHR app store

App Store



EHR System →

CDS Tool →

Clinical Workflow

The screenshot displays a clinical workflow interface for a patient named Julia. The top section shows patient demographics and clinical status. Below this, the 'External Application' section is active, displaying 'Dose information' and 'Parameters & Predictions'.

External Application

Dose information

Update

Last updated a few seconds ago, starting with dose #4 at 02/21/18 08:43

Δ	Dose	Interval	Inf. length	AUC _{0-∞}	C _{0.5mg,1h}	P _{0.5mg} ⁺	P _{0.5mg} ⁺	Tox.
<input type="checkbox"/>	350 mg (7.3 mg/kg)	8 hours	1 hour	157 ng _{0-1h} /Lr	3.2 mg/L	0%	0%	3%
<input type="checkbox"/>	425 mg (8.9 mg/kg)	8 hours	1 hour	191 ng _{0-1h} /Lr	3.9 mg/L	0%	0%	3%
<input type="checkbox"/>	previous 500 mg (10.4 mg/kg)	8 hours	1 hour	224 ng _{0-1h} /Lr	4.6 mg/L	2%	0%	3%
<input type="checkbox"/>	425 mg (8.9 mg/kg)	8 hours	1 hour	258 ng _{0-1h} /Lr	5.2 mg/L	5%	0%	3%
<input type="checkbox"/>	425 mg (8.9 mg/kg)	8 hours	1 hour	292 ng _{0-1h} /Lr	5.9 mg/L	12%	0%	4%

* P_{0.5mg}⁺ probability that AUC is >400 (arbitrary); P_{0.5mg}⁺ probability that C_{0.5mg} is above 25 μg/mL (arbitrary); Tox: Probability of nephrotoxicity, based on Lodise et al. Clin Infect Dis 2009

Parameters & Predictions

Parameter	Population	Individual	per kg
CL	6.65	6.65	L/h
V _d	32.4	32.4	L/kg
t _{1/2}	3.62	3.62	hours

Viewing latest: 3 days 1 week all

Concentration (mg/L)

■ Current ■ TDM

Patient monitoring

Dose	Interval	Start time	Infusion length	TDM	Since dose	Comments
3	1	02/15/18 12:37	1 hours	4 mg/mL		
2	1	02/19/18 11:38	1 hours			
2	2	02/19/18 19:57	1 hours			
3	3	02/20/18 03:32	1 hours			

EHR INTEGRATION

Third Party Applications: Integration through open standards using FHIR

Clinical surveillance system (Theradoc)

CDS Tool

The screenshot displays the Theradoc clinical surveillance system interface for a patient named HAN SOLO. The interface is divided into several sections:

- Header:** Patient name (HAN SOLO), date (05/23/2019), and user information (SOL, HAN, P.Y. 05/18).
- Demographics:** Age (77 years), Sex (Male), Height (67 in), Weight (166.1 lb), and Blood Pressure (136/80 mmHg).
- Medication:** Vancomycin (adult) with a target AUC₀₋₂₄ of 100 mg_h/L.
- Dose Information:** A table showing the current dose (1000 mg, 12 hours interval) and a reference table with various dosing regimens and their predicted AUC values.
- Patient Monitoring:** A table listing individual doses with columns for Dose, Interval, Start time, Int. length, TDM, and Sero dose.
- Graphs:** A line graph showing the concentration of Vancomycin over time, with a target range (TDM) indicated.

Arrows from the text labels point to the 'Clinical surveillance system (Theradoc)' and 'CDS Tool' sections of the interface.

Clinical Analytics

CLINICAL ANALYTICS

Why is data collection post-implementation necessary?

Key Questions Post-Implementation

Institution-specific

- What is the clinical benefit to using the tool?
- Will we save money by improving patient outcomes?
- Are users satisfied with the product? Is it being used?
- What is the operational benefit to my organization?
- Will the module work in other indications? Other patient populations?

Beyond the institution

- How do we improve implementation process at other institutions?
- How can we collect the right the data to demonstrate clinical value and identify the right predictors of drug response?

Key Hospital Stakeholders

Chief Medical Officer

Director of Pharmacy

Chief Quality Officer

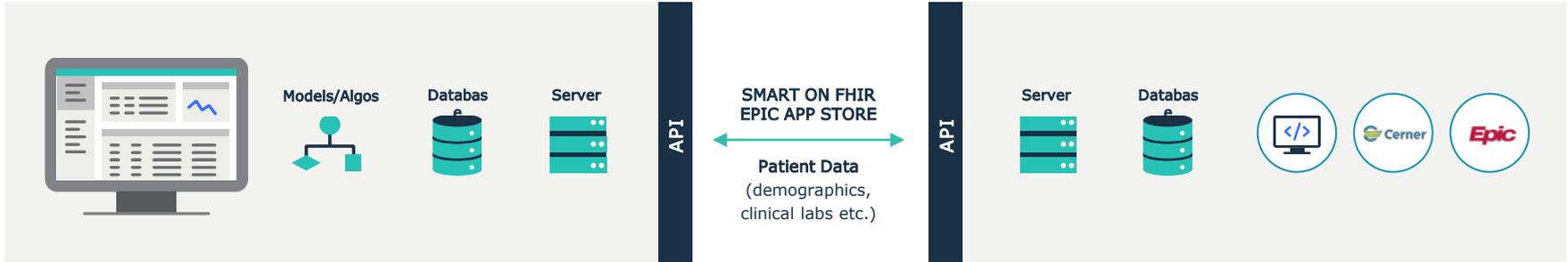
Clinical Pharmacist

Physician

CLINICAL ANALYTICS

A well architected framework will enable the proper collection of data to address post-implementation questions

Clinical Decision Support



Clinical Analytics and Continuous Learning



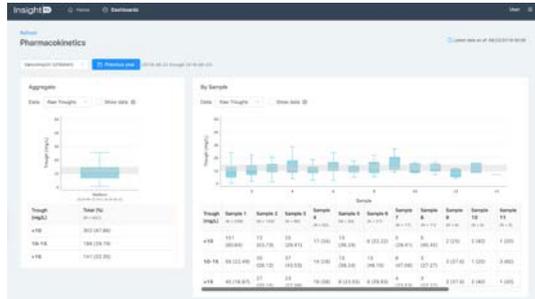
Administrator/Key Stakeholder

- What is the clinical benefit to using the tool?
- Will we save money by improving patient outcomes?
- Are users satisfied with the product? Is it being used?
- What is the operational benefit to my organization?
- Will the module work in other indications? Other patient populations?

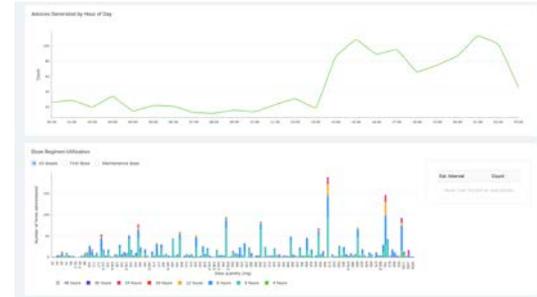
CLINICAL ANALYTICS

Framework enables a real-time assessment of clinical and operational data

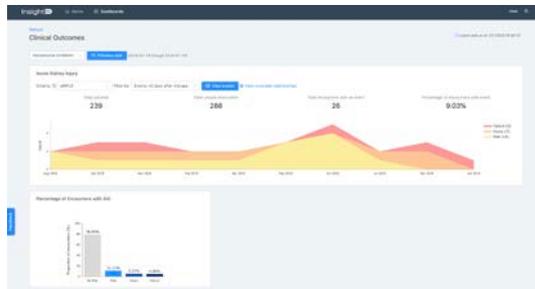
Pharmacokinetic assessment



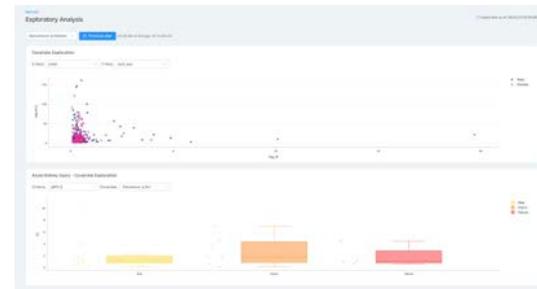
Treatment utilization



Clinical outcomes

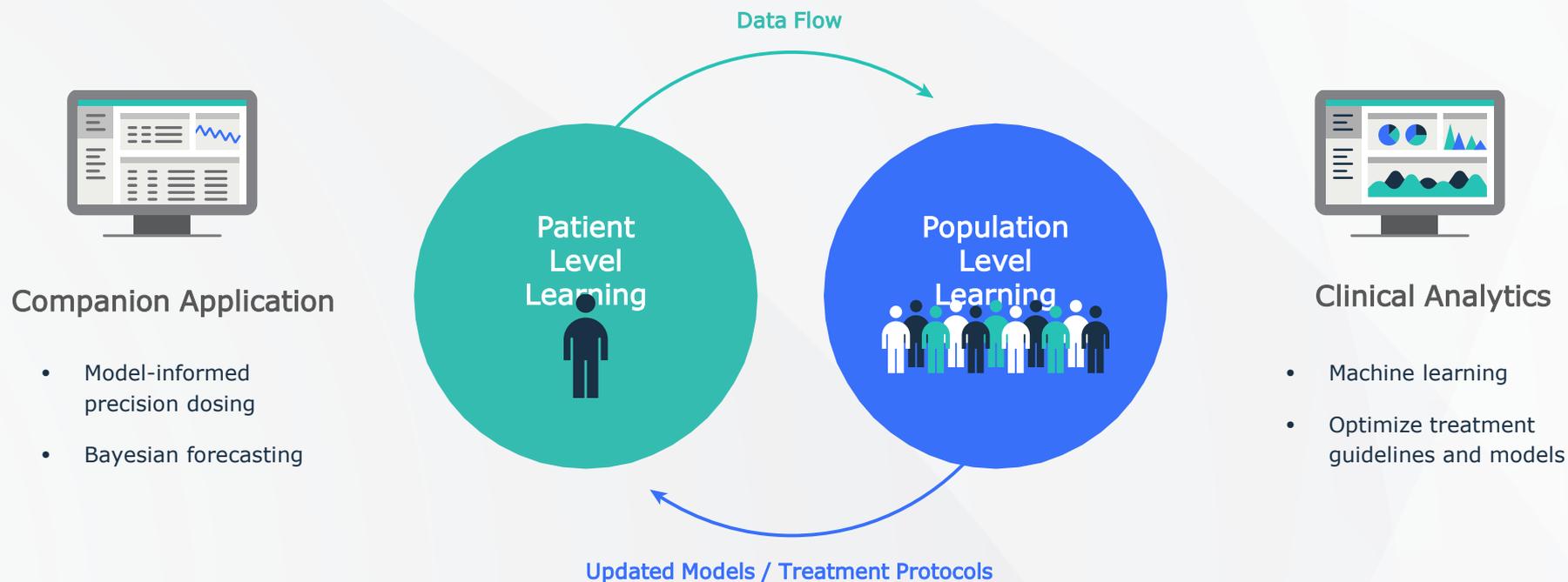


Data exploration



Future of Precision Dosing

Precision dosing by leveraging patient and population level learning



Thank you

Further Reading:

1. Keizer, R. J., ter Heine, R., Frymoyer, A., Lesko, L. J., Mangat, R., & Goswami, S. (2018). Model-Informed Precision Dosing at the Bedside: Scientific Challenges and Opportunities. *CPT: Pharmacometrics & Systems Pharmacology*, 7(12), 785–787.
2. Goswami, S., Krishnamurthi, A, Jamal, D. (2018), Does Healthcare Need Its Own OS?. *Towards Data Science*
3. Goswami, S., Overcoming Adoption Barriers of Cloud-Based Precision Dosing. ASCPT Webinar (2018)