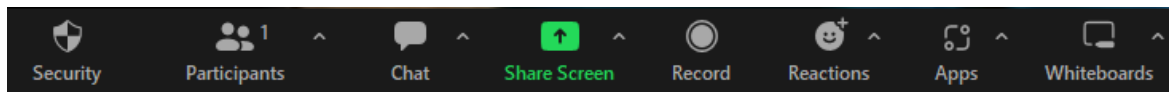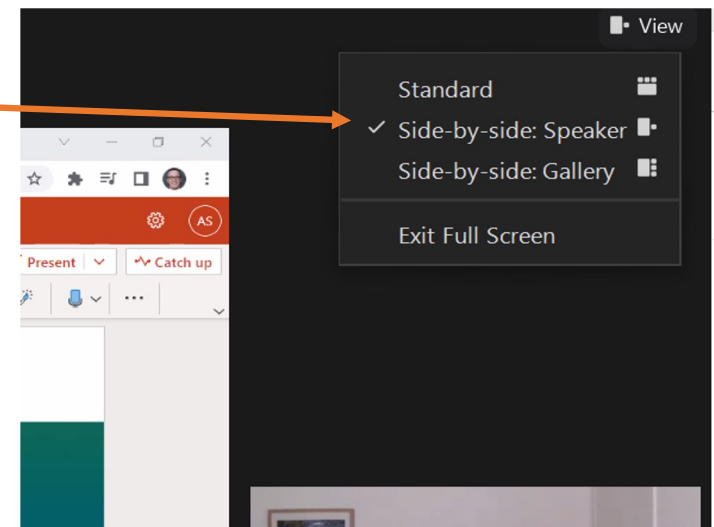# This Webinar will be Recorded

- Please set your Zoom 'View' Setting to Side-by-Side Speaker

- Please type your questions in the Chat Box

Demand Forecasting and the Management of IRT

Asia-Pacific Clinical Supplies Webinar Series

24 FEB 2023, 2PM (1400) SGT

Today's Agenda

- GCSG - Who are we and what do we do

- 1st Speaker: Key Considerations in Demand Planning and Forecasting by Misae Kimura (Pfizer)

- 2nd Speaker: IRT Parameters - Beyond User-Defined Supply Strategies by Takuya Kitami (4G)

- Panel Discussion: IRT, Forecasting & Optimization in Clinical Supplies (Pfizer, 4G, N-Side, Kyowa Kirin)

- Post Webinar Survey

- Upcoming GCSG Events

GCSG – Who Are We

- Member-run

- Not-for-profit

- Dedicated to clinical supplies

- Membership for professionals involved in all aspects of the clinical supply chain

- Our first conference was held in 1988

- Global presence

- Largest clinical supplies organization in the world!

GCSG Board of Directors

Karen Ellis – Board Chair
(Infinity, US)

Joe Iacobucci
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(Global BioPharm
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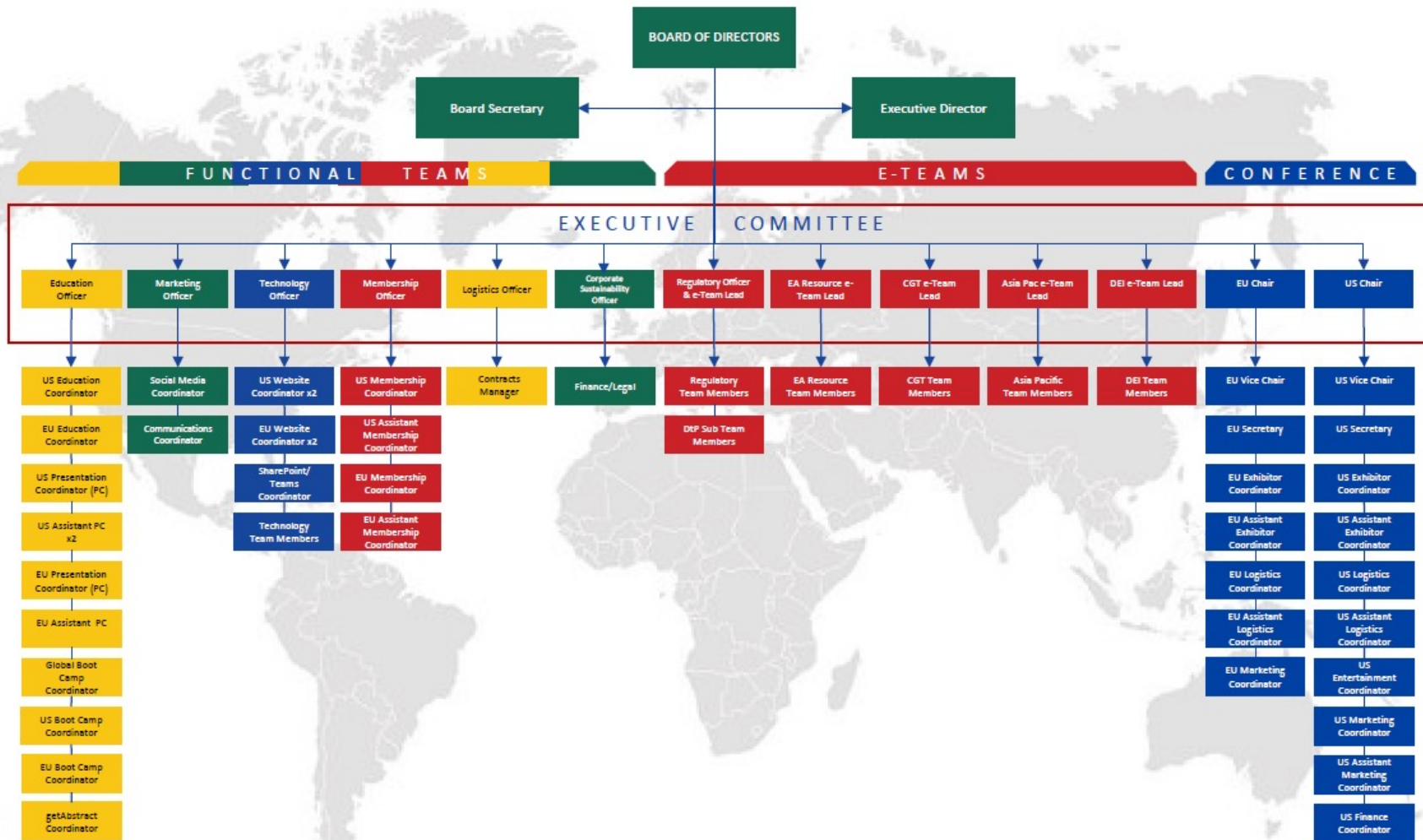Secretary
(Inceptua, US)

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Executive Director (US)

BOARD OF DIRECTORS

Board Secretary ↔ **Executive Director**

FUNCTIONAL TEAMS | **E-TEAMS** | **CONFERENCE**

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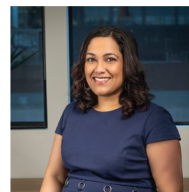
GCSG Asia-Pacific e-Team

Richard Rossi - Lead
Global Cold Chain & Strategic Projects Director
(CRYOPDP, Australia)
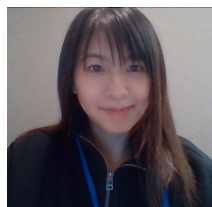
Clare Hsu
Supply Chain Lead
(Pfizer, Japan)

Masako Ota
Clinical Supply Manager
(Kyowa Kirin, Japan)

Arishma Narayan
Senior Quality Manager
(Akesa, Australia)

Puvi Bala
Global Comparator Services Manager
(Catalent, UK)

Philip Gregory
VP, Asia
(Inceptua CTS, China)

Mervin Sulistyo
Value Engineering Consultant APAC
(World Courier, Singapore)

Linda Kim
Founder & CEO
(Cold Chain Platform, S Korea)

Takuya Kitami
Country Director - Japan
(4G Clinical, Japan)

Celin Ong
VP, Cell and Gene APAC
(Marken, Singapore)

Dong Rim Jeong
Account Executive
(N-Side, Belgium)

GCSG – Our Aim

- Provide a forum for open discussion

- Share knowledge and industry best practices

- Educate those who are new to our industry

- Provide solutions to problems

- Networking!

A SHORT POLL ON FORECASTING

Misae Kimura

Asia Team Leader, Global Clinical Supply, Pfizer

- Bachelor's Degree in Pharmacology
- Licensed Pharmacist in Japan
- Trained in the development, execution and maintenance of supply chain strategies
- Responsible for ensuring clinical supply for all Pfizer studies in Asia

Key Considerations in Demand Planning and Forecasting

Disclaimer:
Presentations are intended for educational purposed only. Statements of fact and opinions expressed are personal and, are not the opinion or position of the Pfizer Inc.

Session Agenda

- Forecasting / Demand Planning

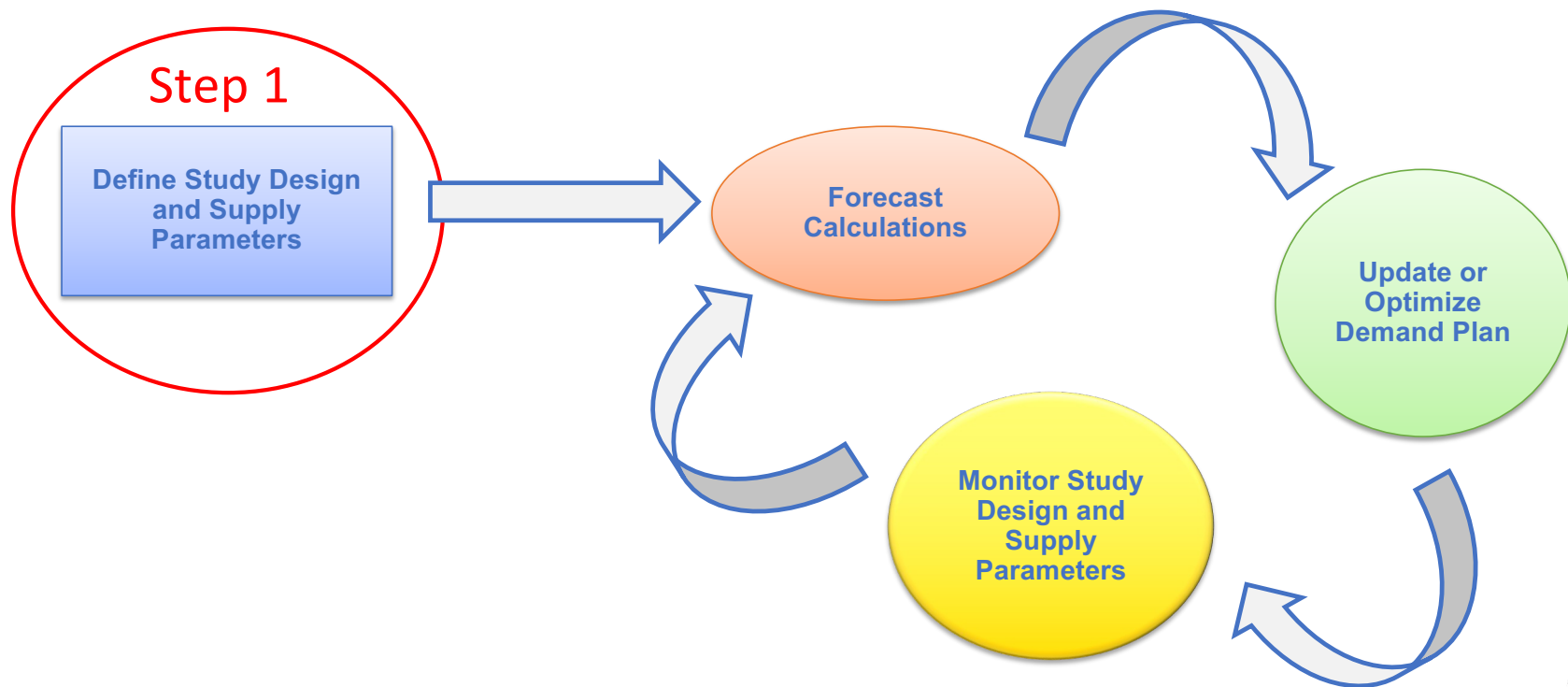- Phase 1

- Phase 3

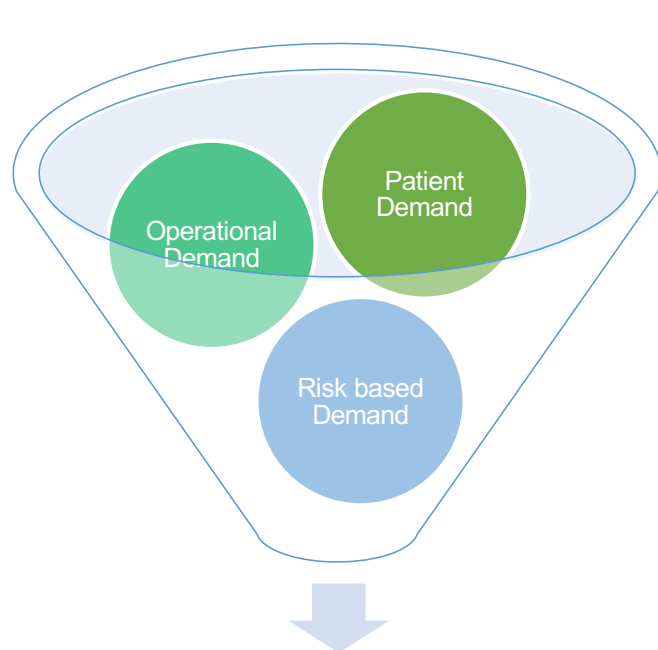- Key Points for Consideration

- Q&A

Why Demand Planning?

Define Study Design and Supply Parameters

Forecast Calculations

Update or Optimize Demand Plan

Monitor Study Design and Supply Parameters
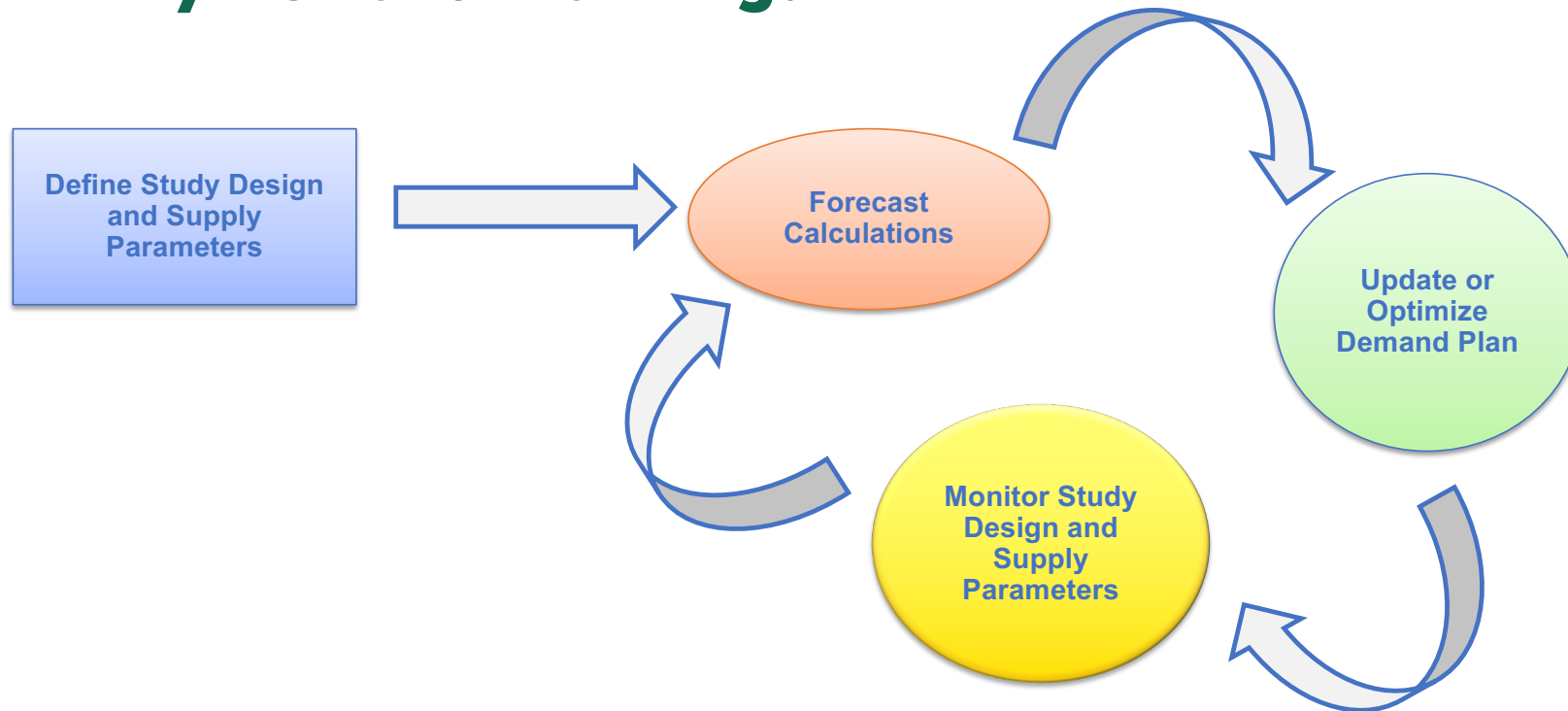
Investigational Product (IP) Logistical Flow

Forecasting

Manufacture /Source Drug Products

Package & Label Clinical Supplies

Store & Distribute Clinical Supplies

Deliver IPs Clinical Sites

Dispense to the Patients

Protocol Enrollment Plan

CAN
Kirkland, Canada

US
Andover, MA
Groton, CT
New York, NY
Collegeville, PA
Sanford, NC
Lake Forest, IL

EU
Walton Oaks, U...
Sandwich, U...
Berlin, Germany

APAC
Beijing, China
Shanghai, China
Tokyo, Japan
Mumbai, India
Manila, Philippines

LATAM
Sao Paolo, Brazil
Buenos Aires, Argentina

AfME

How do we start Demand Planning?

Demand Parameters

Total Demand

Patient Demand

Treatment Groups Per Cohort
Dosage type per Treatment Group
 # visits (cycles) per treatment group
Drop out/attrition rate
doses per subject per visit (cycle) per treatment group
Variable # of doses per cycle
Variable type of dose per visit / cycle
 # Subjects per treatment group / ratio
Stratification
Block size
Re-randomization

Operational Demand

Time interval between visits
Randomization type
Enrollment rate
Number of countries
Country to subject ratio
Number of sites
Site floor/ceiling
Shipping frequency
Number of depots
Importation Timelines
Seeding quantity per depot
IP Shelf Life

Risk based Demand

Changes from initial assumptions
Randomization rate change
Enrollment rate per country
Number of subjects per country
Country start-up timelines
Over enrollment
Unpredictable Variability
Shelf life per lot of comparator
Lead time per order of comparator
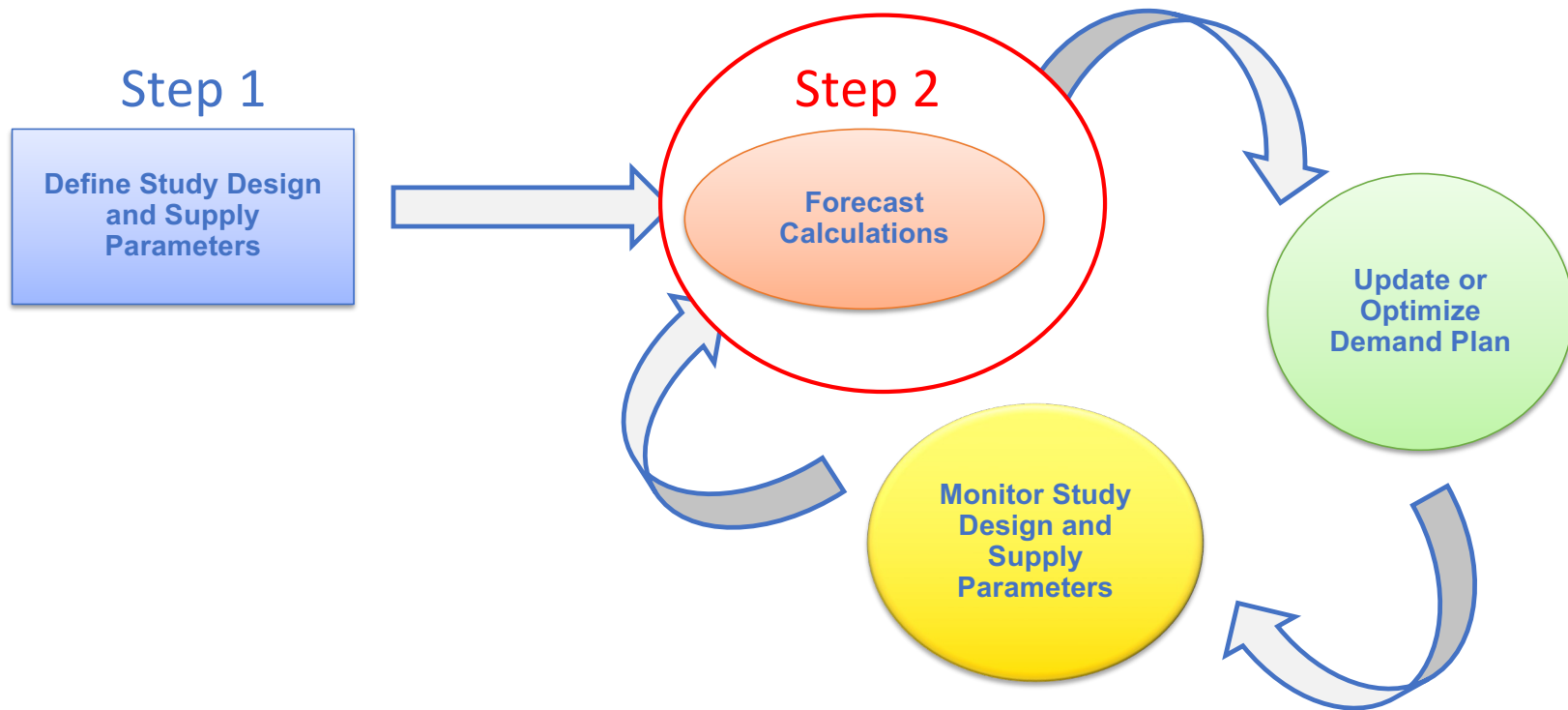**Unanticipated Loss of IP**
IP Loss During Shipment/ temperature excursions
External Factors
Regulatory requirements
Source market of comparator
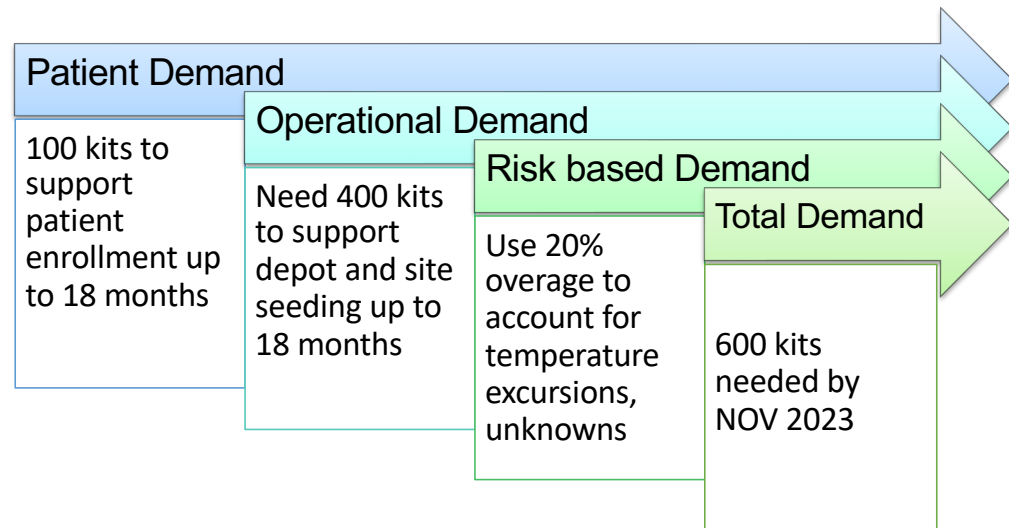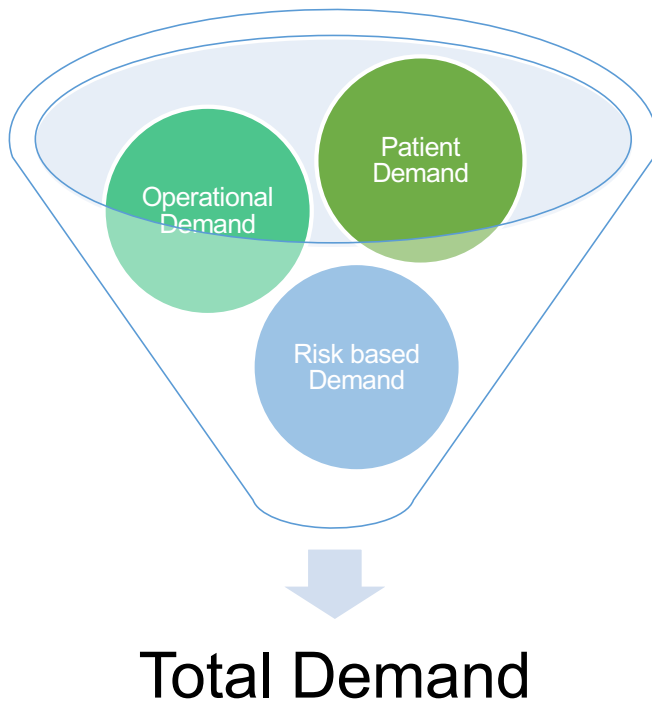Currency in the market where comparator is sourced

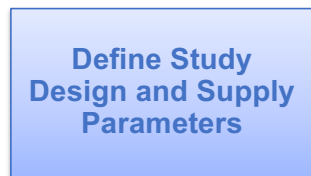# What is the Next Step after all Parameter Values are available?

Examples of Step 2 for a Study Start

Total Demand

Patient Demand

100 kits to support patient enrollment up to 18 months

Operational Demand

Need 400 kits to support depot and site seeding up to 18 months

Risk based Demand

Use 20% overage to account for temperature excursions, unknowns

Total Demand

600 kits needed by NOV 2023

What is the Next Step after Demand has been Calculated?

Step 1
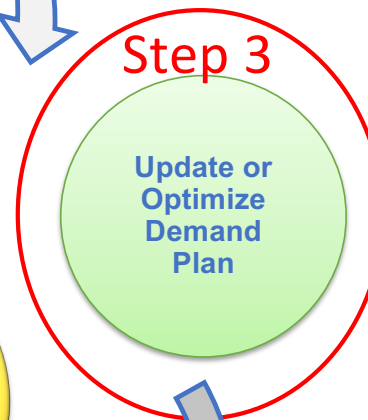
Define Study Design and Supply Parameters

Step 2

Forecast Calculations

Step 3

Update or Optimize Demand Plan

Monitor Study Design and Supply Parameters

Re-supply Plan

Depot Transfers in IRT Systems

Budget Allocation

How can we Monitor Study Progress and Supply Consumption?

Step 1

Define Study Design and Supply Parameters

Step 2

Forecast Calculations

Step 3

Update or Optimize Demand Plan

Step 4

Monitor Study Design and Supply Parameters

Actual data from IRT reports

Updated timeline from clinical team

Materialization of risks

Demand Planning (Forecasting) is a Closed–Loop Exercise for the Life of the Study

Phase 1

M
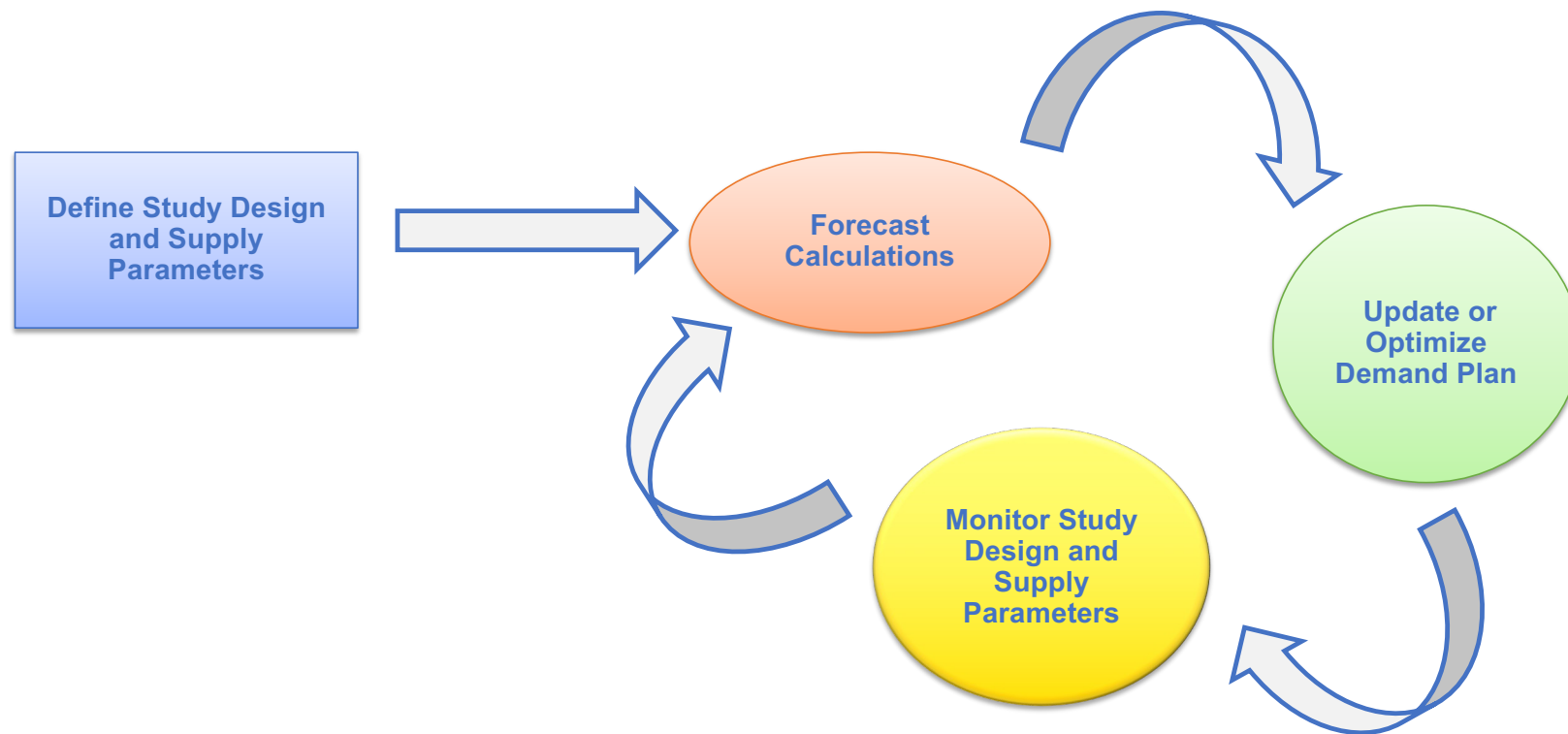
Key Points to Consider for Phase 1 (First in Human/First in Patient)

- **Understand that change is inevitable!**

    o   Changes in labelling strategy

    o   Need to drop or add! e.g. a new strength

- **One of the best flexibility strategies**

    o   Never plan to use up all your supplies in the first package job!

- **Be OK with not having a crystal ball**

    o   Use assumptions laid out in the protocol

    o   Updates to resupply, manufacturing and packaging jobs as timelines shift

- **Get in tight with your clinical study team!**

Phase 3

Phase 3 Study

A randomized, double-blind, placebo-controlled, multicenter, parallel-group.

Approximately 255 subjects will be randomized to one of 3 treatment groups in a 1:1:1 ratio (approximately 85 subjects per group).

Drug A	Day1	Week 8	Week 16	subjects	site numbers
X mg	1	1	1	85	91
Y mg	1	1	1	85	91
PBO	1	1	1	85	91

Subjects will receive a total of 3 injections:
First dose is administered at week 1, second dose at week 8 and the last does at week 16.

Key Parameters - Changes in 6 months

sites   patients   countries

Table A

Location	Sites	Rand Subjects	Country Depot
Argentina	1	3	
Australia	7	23	YES
Austria	5	16	
Belgium	1	3	
Brazil	10	17	YES
Chile	1	3	
Colombia	1	2	
Czech Republic	6	15	
France	3	9	
Hungary	6	8	
Israel	5	12	
Japan	9	21	YES
Mexico	1	2	
Poland	7	23	
Romania	3	11	
Serbia	4	9	
Slovakia	5	9	
South Korea	5	19	YES
Spain	7	24	
Sweden	3	11	
Turkey	1	6	
United Kingdom	3	9	Main Depot
Total: 22 Countries	94	255	

Table B

Location	Sites	Subjects	Country Depot
Australia	7	20	YES
Austria	6	12	
Brazil	12	39	YES
Czech	8	24	
France	4	8	
Japan	9	35	YES
Poland	10	31	
Serbia	6	16	
Slovakia	6	12	
South Korea	6	16	YES
Spain	6	16	
UK	4	8	Main Depot
Sweden	3	12	YES
Belgium	4	8	
China	15	30	YES
Total: 15 Countries	106	287	

Key Parameters – Understanding Regulatory Requirements in Different Countries

Clinical Trial Application(CTA)

- ☐ CTA requirement
- ☐ Review Period
- ☐ CMC (Chemical Manufacturing and Control) Changes

IL / Importation

Depot name	Timeline*
UK/EU- Central	NA
Brazil	2 month
Japan	3 weeks
S.Korea	2-3 weeks
Sweden	1 week
China	2.5 month

* The timeline is example only

Expiry Update

- ☐ Expiry date update requirements
- ☐ Clinical label requirements
- ☐ Importation requirements

Demand Parameters

Total Demand

Patient Demand

Treatment Groups Per Cohort
Dosage type per Treatment Group
 # visits (cycles) per treatment group
Drop out/attrition rate
doses per subject per visit (cycle) per treatment group
Variable # of doses per cycle
Variable type of dose per visit / cycle
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Stratification
Block size
Re-randomization

Operational Demand

Time interval between visits
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Number of countries
Country to subject ratio
Number of sites
Site floor/ceiling
Shipping frequency
Number of depots
Importation Timelines
Seeding quantity per depot
IP Shelf Life

Risk based Demand

Changes from initial assumptions
Randomization rate change
Enrollment rate per country
Number of subjects per country
Country start-up timelines
Over enrollment
Unpredictable Variability
Shelf life per lot of comparator
Lead time per order of comparator
Unanticipated Loss of IP
IP Loss During Shipment/ temperature excursions
External Factors
Regulatory requirements
Source market of comparator
Currency in the market where comparator is sourced

Optimize Plan and Review Supply Parameters

Define Study Design and Supply Parameters

Forecast Calculations

Update or Optimize Demand Plan

Monitor Study Design and Supply Parameters

Re-supply Plan

Depot Transfers in IRT Systems

Budget Allocation

Actual data from IRT reports

Updated timeline from clinical team

Materialization of risks
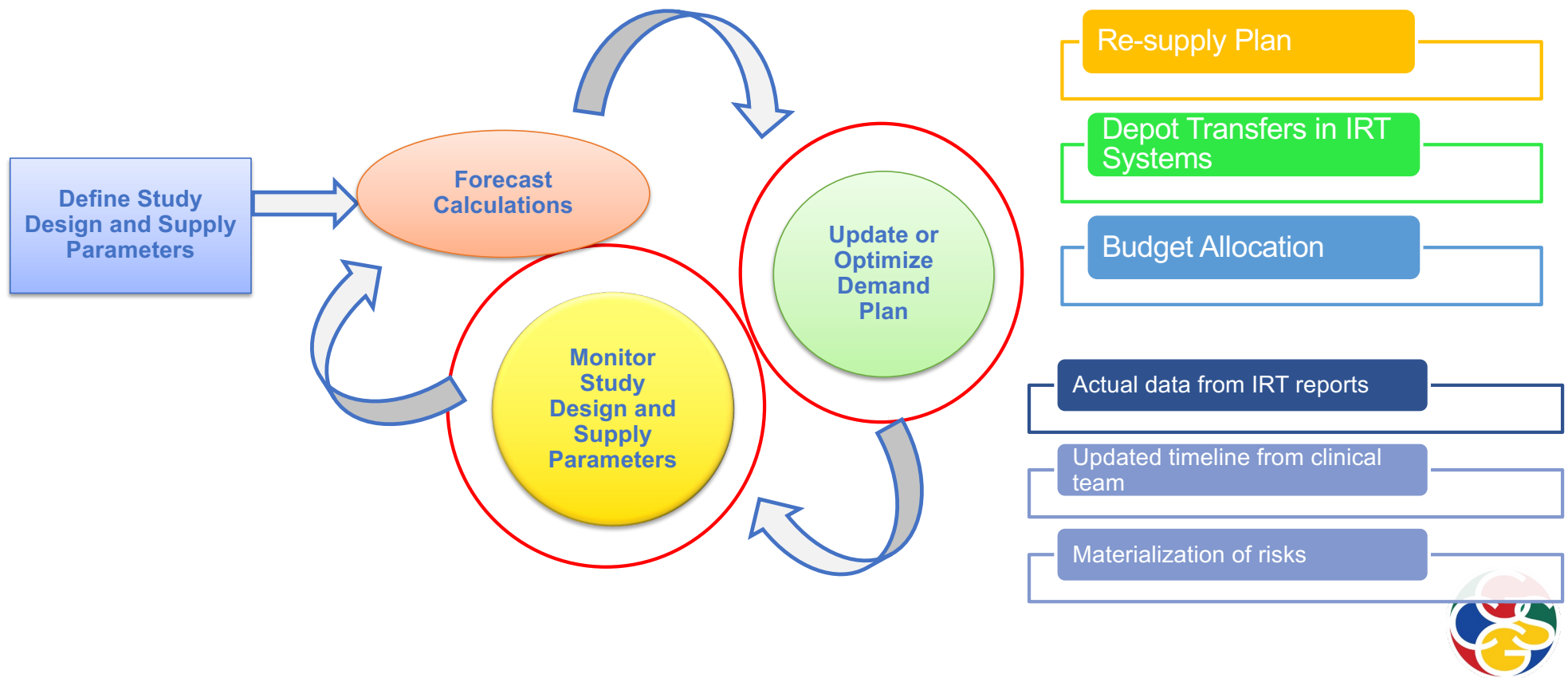
Key Points to Consider for Phase 2/Phase 3 Studies

- **Before Study Start – Planning Stage**

  o Communicate with your clinical/study team

- **During the Study – Monitoring Stage**

  o Regularly monitor your study

- **When the Assumptions Change, Re-evaluate to Avoid risk to patients**

  o Stay engaged with your clinical/study team

Risks are not expected… Russia vs Ukraine, COVID-19, flight booking, manufacturing failure, expiry update…

Misae Kimura

Asia Team Leader, Global Clinical Supply, Pfizer

- Bachelor's Degree in Pharmacology
- Licensed Pharmacist in Japan
- Trained in the development, execution and maintenance of supply chain strategies
- Responsible for ensuring clinical supply for all Pfizer studies in Asia

Questions?

A SHORT POLL ON IRT

Session Agenda

- Universal RTSM site inventory management concepts

- Challenges related to buffer trigger and resupply value maintenance

- Automatic buffer trigger and resupply calculation with unpredictable demand forecasting

Universal RTSM Site Inventory Management Concepts

Basic Objective

Patient Demand at One Site

Universal Concept

Trigger

IF

Site Stock

<

Max Demand in Max Site Shipment Lead Time

THEN

Trigger Resupply Shipment

Resupply

Max Demand in Max Site Shipment Lead Time

+

Avg Demand in Long Window

−

Site Stock

=

Site Shipment Quantity

Balancing Cost vs. Risk

Trigger

IF

Site Stock

<

Max Demand in Max Site Shipment Lead Time

Consider max demand

THEN

Trigger Resupply Shipment

Resupply

Consider average demand

Max Demand in Max Site Shipment Lead Time

+

Avg Demand in Long Window

-

Site Stock

=

Site Shipment Quantity

Traditional IRT

Trigger

Traditional IRT

Resupply

IF

Site Stock

Predictable Demand
+
Supply Strategy Trigger

Max Demand in Max Site
Shipment Lead Time

<

+

Max Demand in Max Site
Shipment Lead Time

Avg Demand in Long
Window

THEN

Predictable Demand
+
Supply Strategy Resupply

−

Trigger Resupply
Shipment

Site Stock

=

Site Shipment Quantity

Traditional IRT

Supply Strategies

- *Pros*
  - Simple(r) to set up
  - Predictable behavior

Prediction
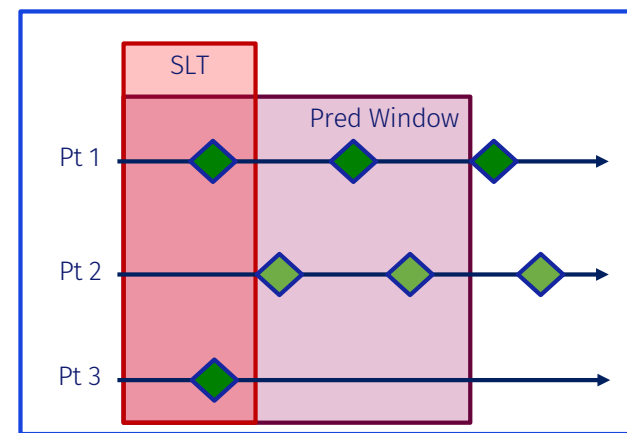
- *Cons*
  - Static behavior
  - Supply Strategy values challenging to optimize
    - Cost vs. risk

Challenges Related to Buffer Trigger and Resupply Value Maintenance

Defining IRT Supply Strategy Values
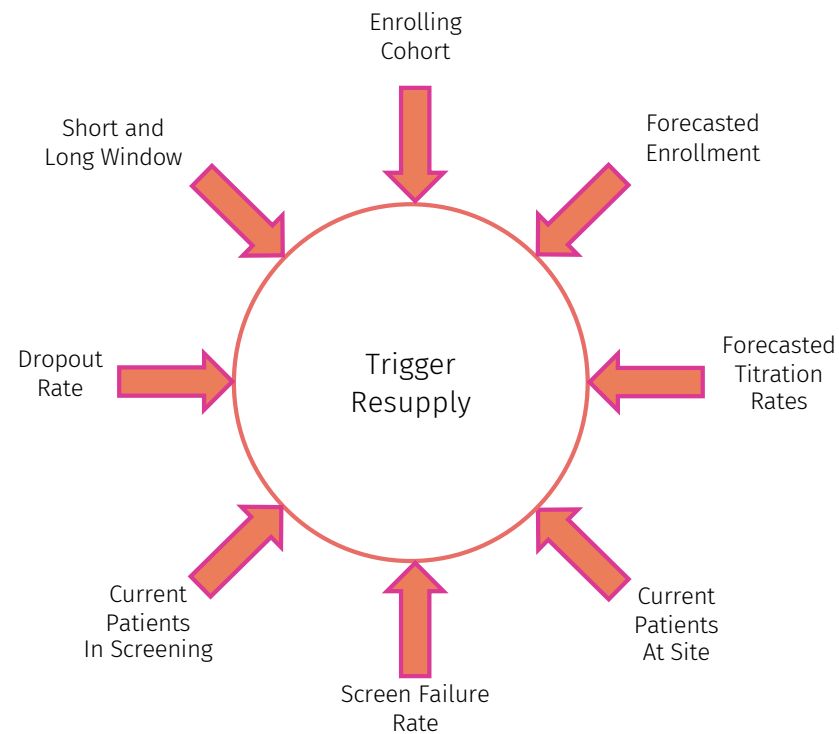
Many factors

Defining IRT Supply Strategy Values

Many factors

Evolving over time

Defining IRT Supply Strategy Values

Many factors

*Evolving over time
At many sites...*

Enrolling Cohort

Short and Long Window

Forecasted Enrollment

Dropout Rate

Trigger Resupply

Forecasted Titration Rates

Current Patients In Screening

Screen Failure Rate

Current Patients At Site
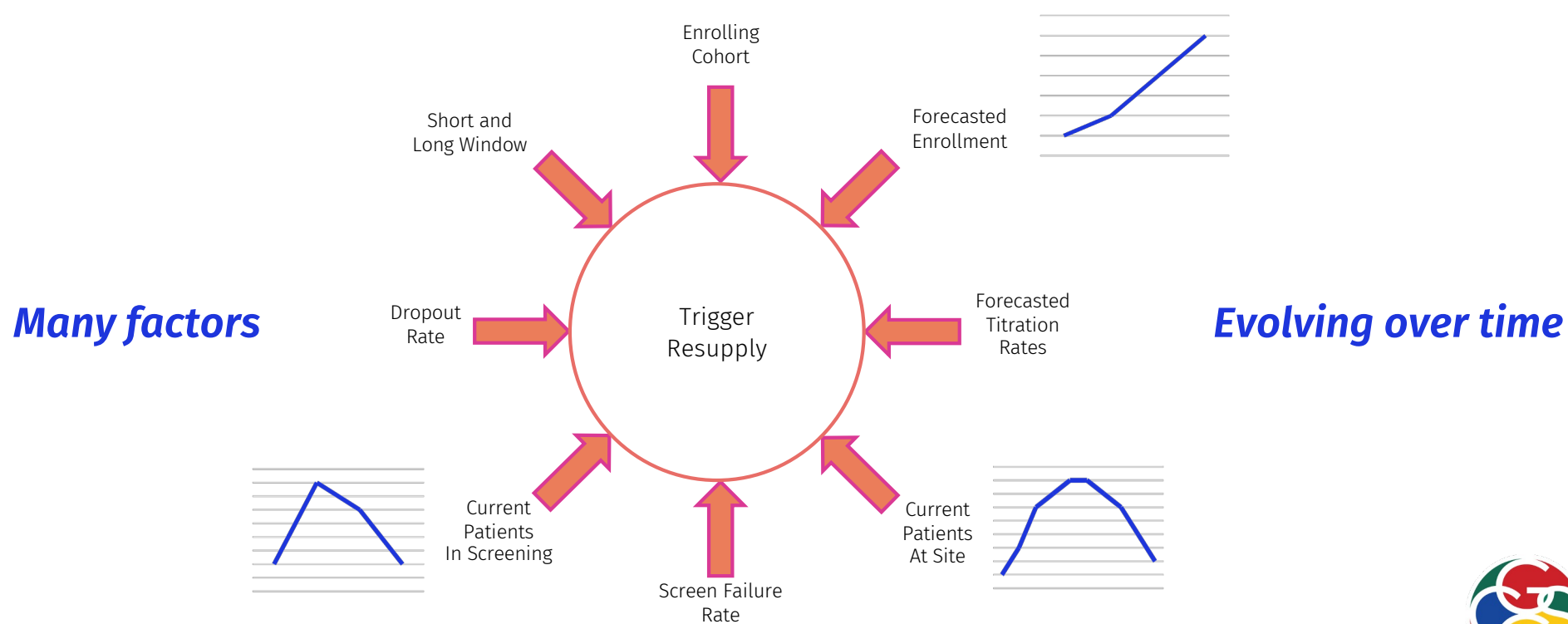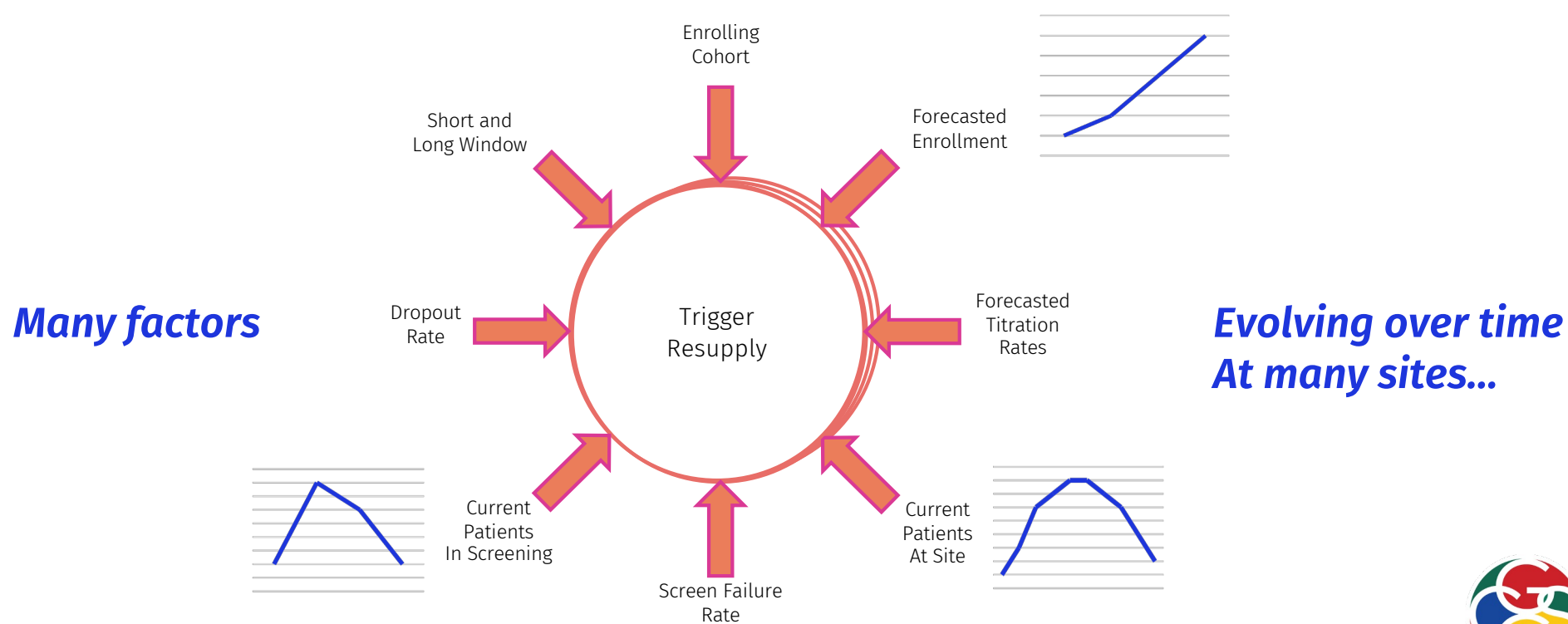
Traditional IRT Inventory Management

Supply Strategies
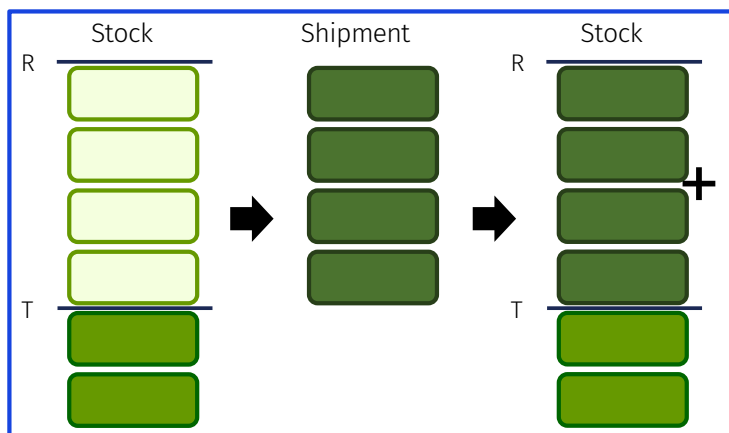
- **Pros**
  - Simple(r) to set up
  - Predictable behavior
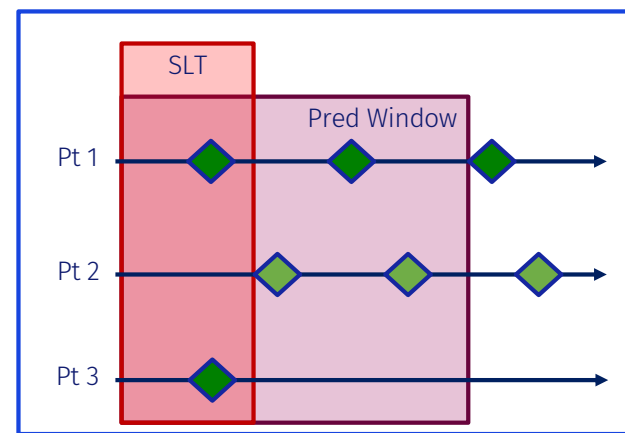
Prediction

- **Cons**
  - Static behavior
  - Supply Strategy values IMPOSSIBLE to optimize
    - Cost vs. risk

Automatic Buffer Trigger and Resupply Calculation with Unpredictable Demand Forecasting

Unpredictable Demand Forecasting

Trigger

Prancer RTSM®

Resupply

IF

Site Stock

<

Max Demand in Max Site Shipment Lead Time

THEN

Trigger Resupply Shipment

Predictable Demand
+
Unpredictable Demand

Predictable Demand
+
Unpredictable Demand

Max Demand in Max Site Shipment Lead Time

+

Avg Demand in Long Window

−

Site Stock

=

Site Shipment Quantity
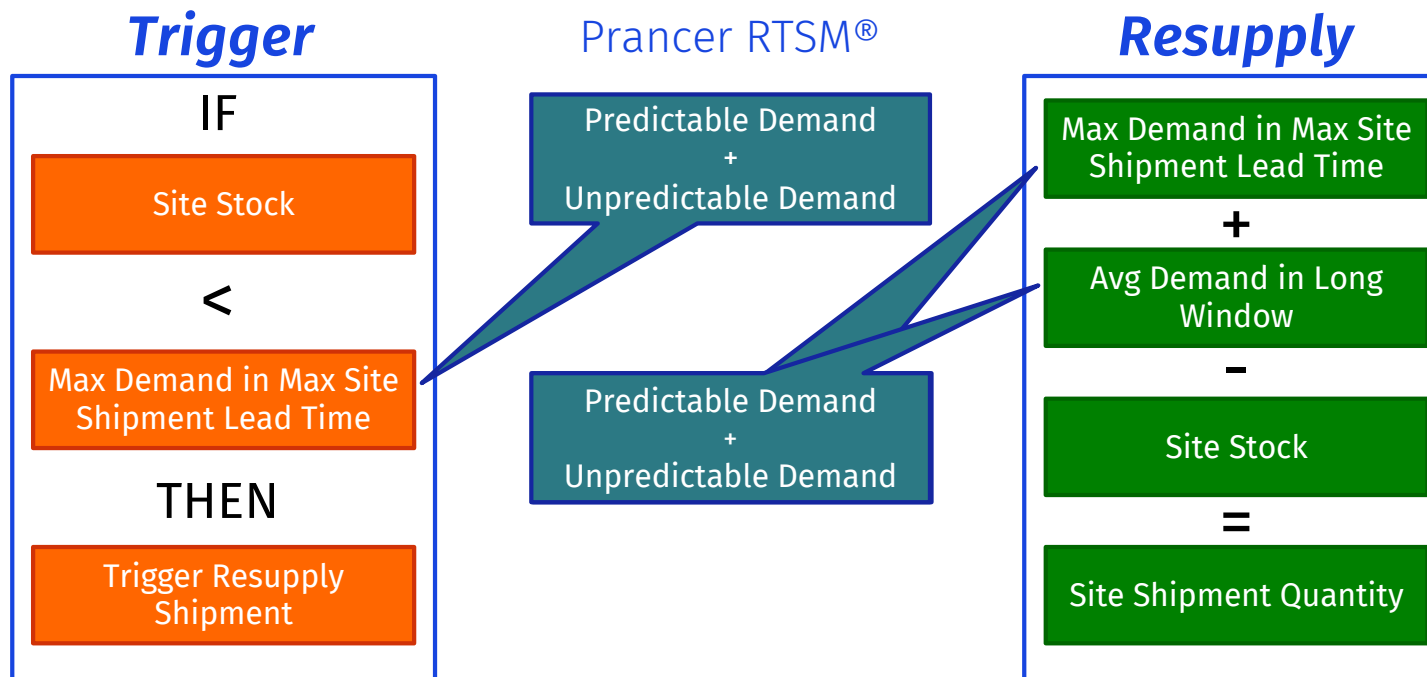
Predicting the Unpredictable

Patient Forecasting Tree
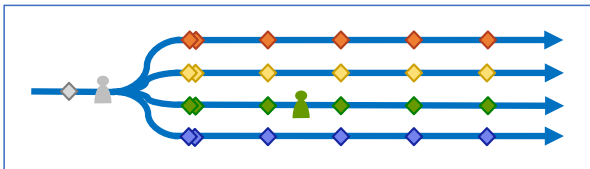
New Patient Arrival Forecast

1 pt/mth = 0.3 pt/sw

Single Patient Demand Distributions

PD   CUD   UUD
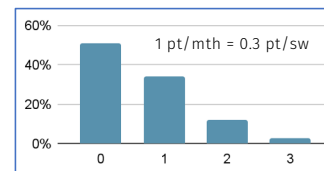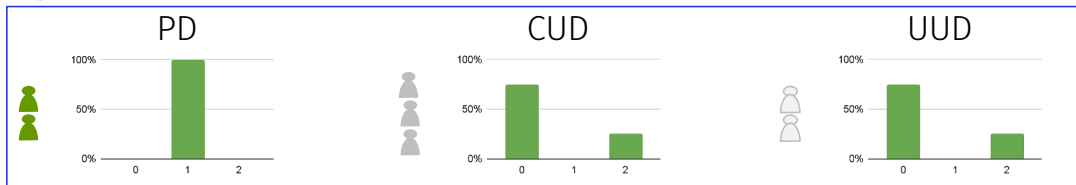
Site Demand Distribution

Safety Stock

90 %
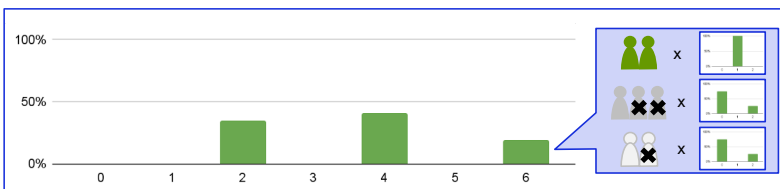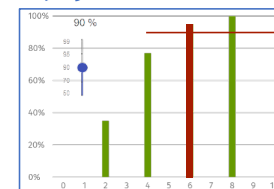
- **Cons**
  - Challenging to set up
  - Behavior difficult to predict
- **Pros**
  - Buffer values computed dynamically
  - ✓ *Optimization of cost and risk*

Forecasting Unpredictable Patient Demand

Legend:
- No dispensing (grey diamond)
- Dispense one red kit (red diamond)
- Dispense one yellow kit (yellow diamond)
- Dispense one green kit (green diamond)
- Dispense one blue kit (blue diamond)

Timeline:
- Screening
- V2 (Rand) — 28d -27+3d
- V3 — 14d V2 +- 3d
- V4 — 28d V2 +- 3
- V5 — 42d V2 +- 3d
- V6 — 56d V2 +- 3d
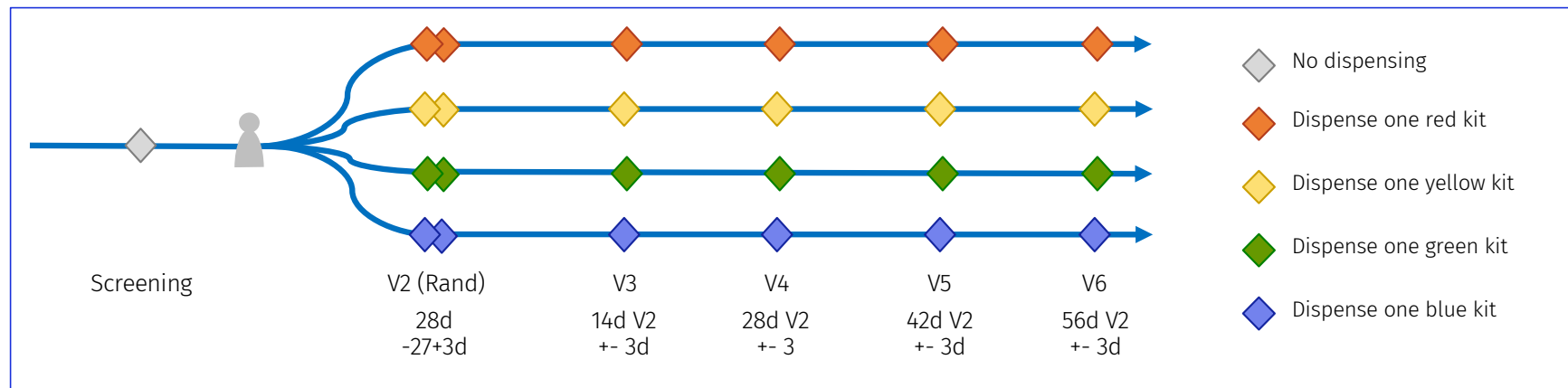
Demand distribution of green kit

Next Visit

Remainder of Treatment
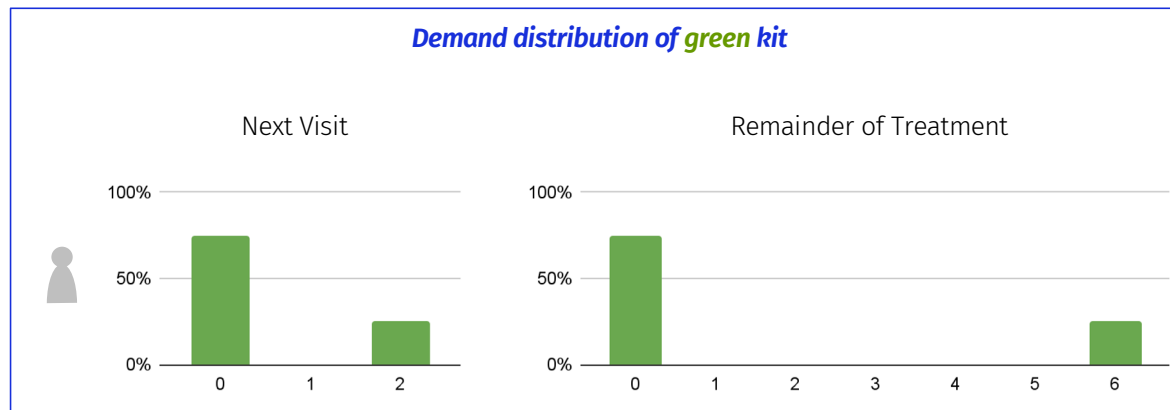
Correlated Unpredictable Demand (CUD):
Demand from known patients with future variability

Combining Patient Demand Forecasts

Single patient demand distributions
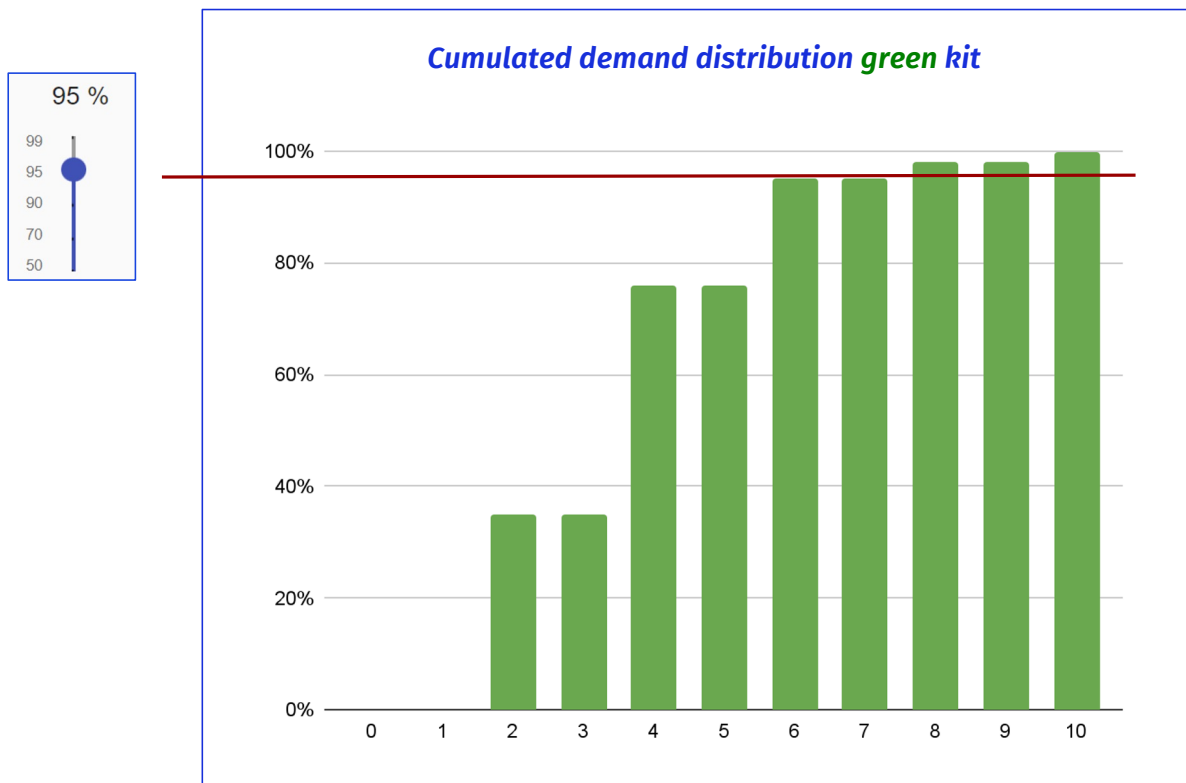
PD   CUD   UUD
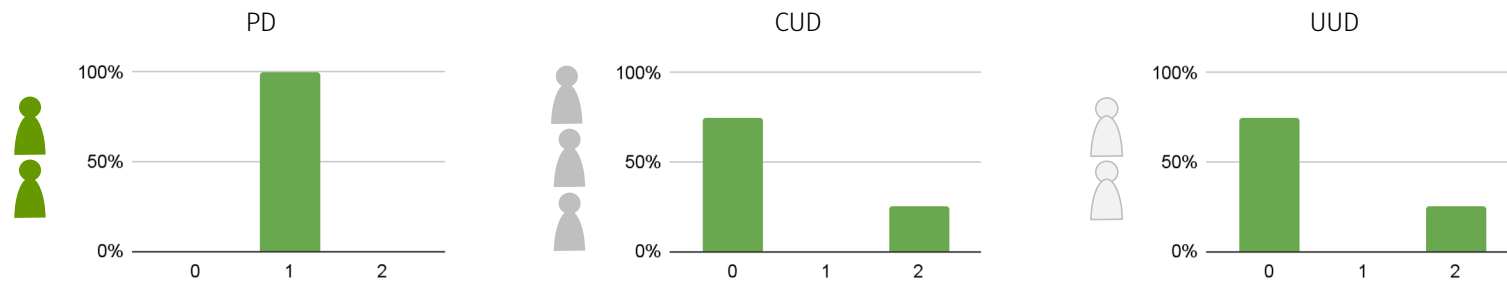
Site demand distribution

Determining the Safety Stock
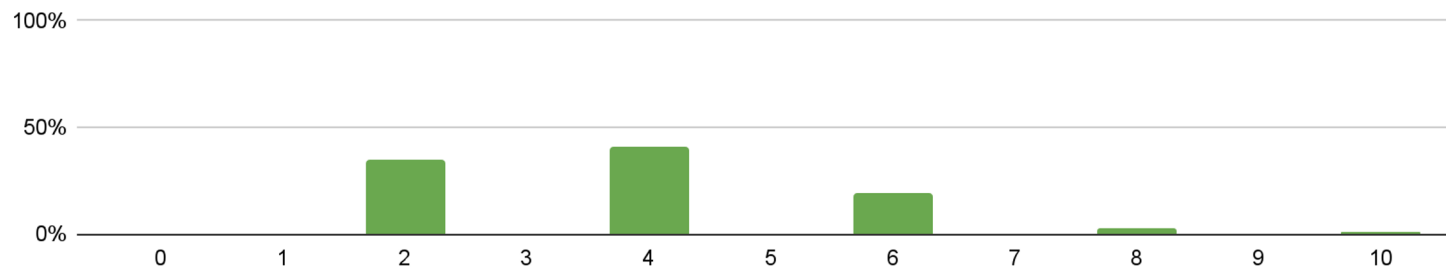
Determining the Safety Stock

Cumulated demand distribution green kit

95 %
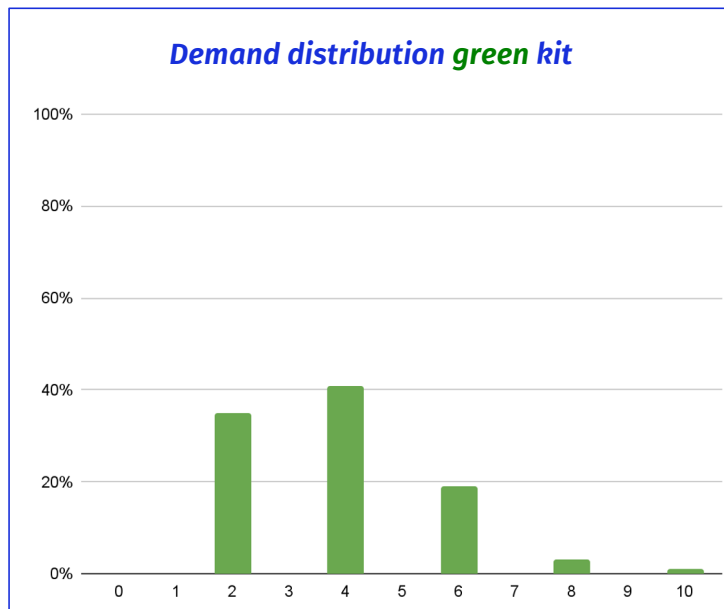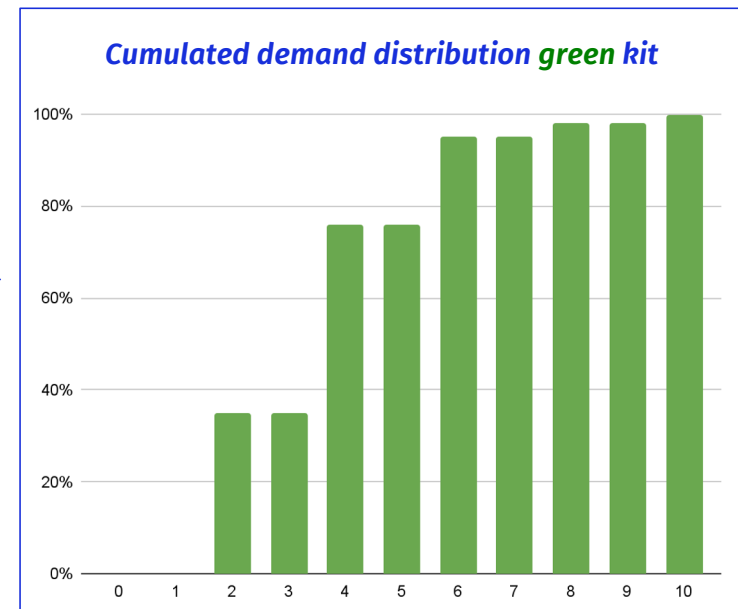
8 green kits needed to cover 95% of probable next visit demand situations

User Perspective: Enrollment Groups

Keep recruitment forecasts maintained

Group name	pts/s/m
Low	0,5
Med	1
High	2

Site	Open for Inbound Shipping	Enrollment Group
101		High ▾
102		Med ▾

⚠ If enrollment rates are not maintained, there is an increased risk of missed visits

User Perspective: Confidence Interval

Manage risk using the confidence slider settings

User Perspective: Long Window Setting

Balance costs using the long window settings

P
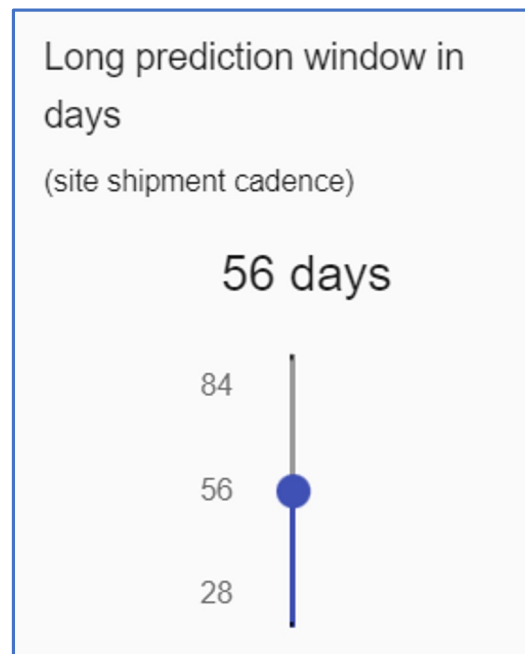
Takuya Kitami

Country Director for Japan, 4G Clinical

- Joined 4G Clinical in 2018
- Prior to that, worked for CROs in Japan
- 12 years' experience in clinical trial logistics and supply chain management
- Almost 5 years' experience in Randomization and Trial Supply Management
- GCSG Asia Pacific E-Team Member

Questions?

Panel Discussion on
IRT, Forecasting & Optimization in Clinical Supplies

Our Panellists

Takuya Kitami

Director for Japan

4G Clinical

Masako Ota

Clinical Supply Manager

Kyowa Kirin, Japan

Misae Kimura

Asia Team Leader, Global Clinical Supply

Pfizer, Japan

Amaury Jeandrain

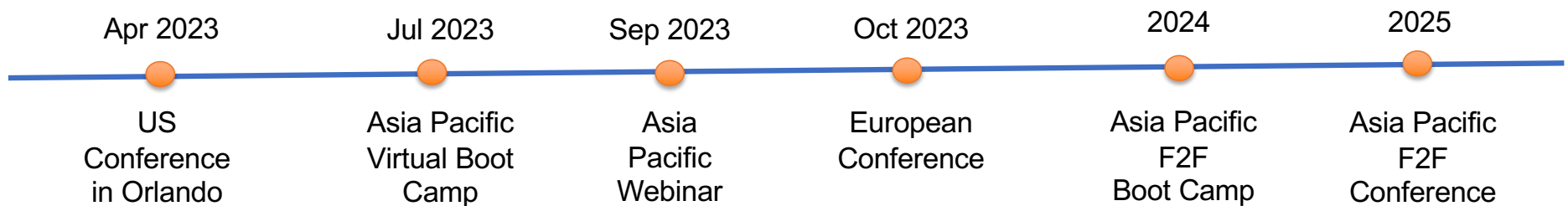Senior Director, Solutions Engineering & Partnerships

N-Side, Belgium

POST WEBINAR SURVEY

Upcoming Events..

Next GCSG Asia Pacific Webinar is in Sep 2023 – Cell & Gene Therapy

Apr 2023	Jul 2023	Sep 2023	Oct 2023	2024	2025
US Conference in Orlando	Asia Pacific Virtual Boot Camp	Asia Pacific Webinar	European Conference	Asia Pacific F2F Boot Camp	Asia Pacific F2F Conference

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In Closing…

- Thank you for your attendance, questions, comments and feedback

- Please share your experience with your managers and colleagues

- GCSG website www.mygcsg.com

- Consider volunteering

- Job Board https://mygcsg.com/jobs/

- Contact: asiapac@mygcsg.com