

# Capacity Planning Considerations for Autologous Cell Therapies

June 6, 2022

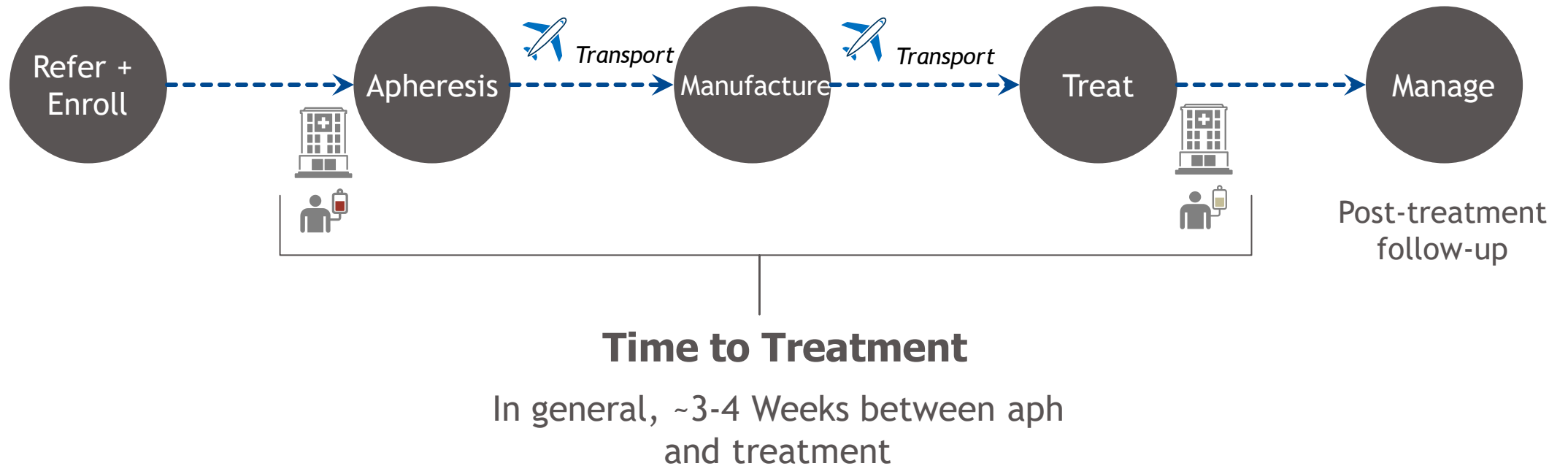
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# Agenda

- 3 general challenges that make capacity difficult
- Unique challenges for autologous cell therapy
- Addressing the challenges

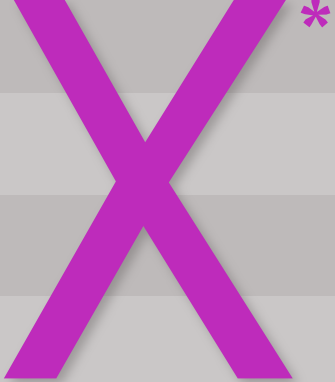
# Patient Cell Journey – Autologous therapies



# General Challenges

- Inventory
- Scaling
- Communication

# What's one the most foundational differences? - Inventory buffer

Inventory Type	Individualized Therapies	Biologics/Small Molecules
Raw Materials	✓	✓
Drug Substance		✓
Drug Product		✓
Finished Goods		✓
Channel		✓

\*Planning, alignment, and communication are critical

# Scaling: Fundamental difference in make to order vs make to stock

1 product lot



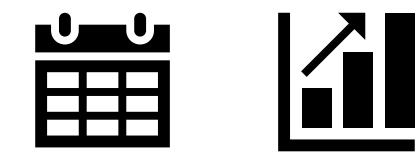
1 patient

1 product lot

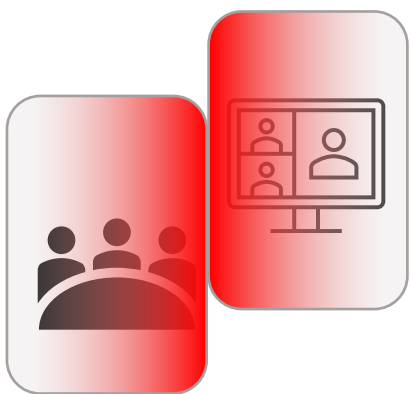


Many patients

# Foundational things you've always done must be more tightly integrated than ever before



Small blips can make  
huge waves



Mis-alignment can directly impact patients

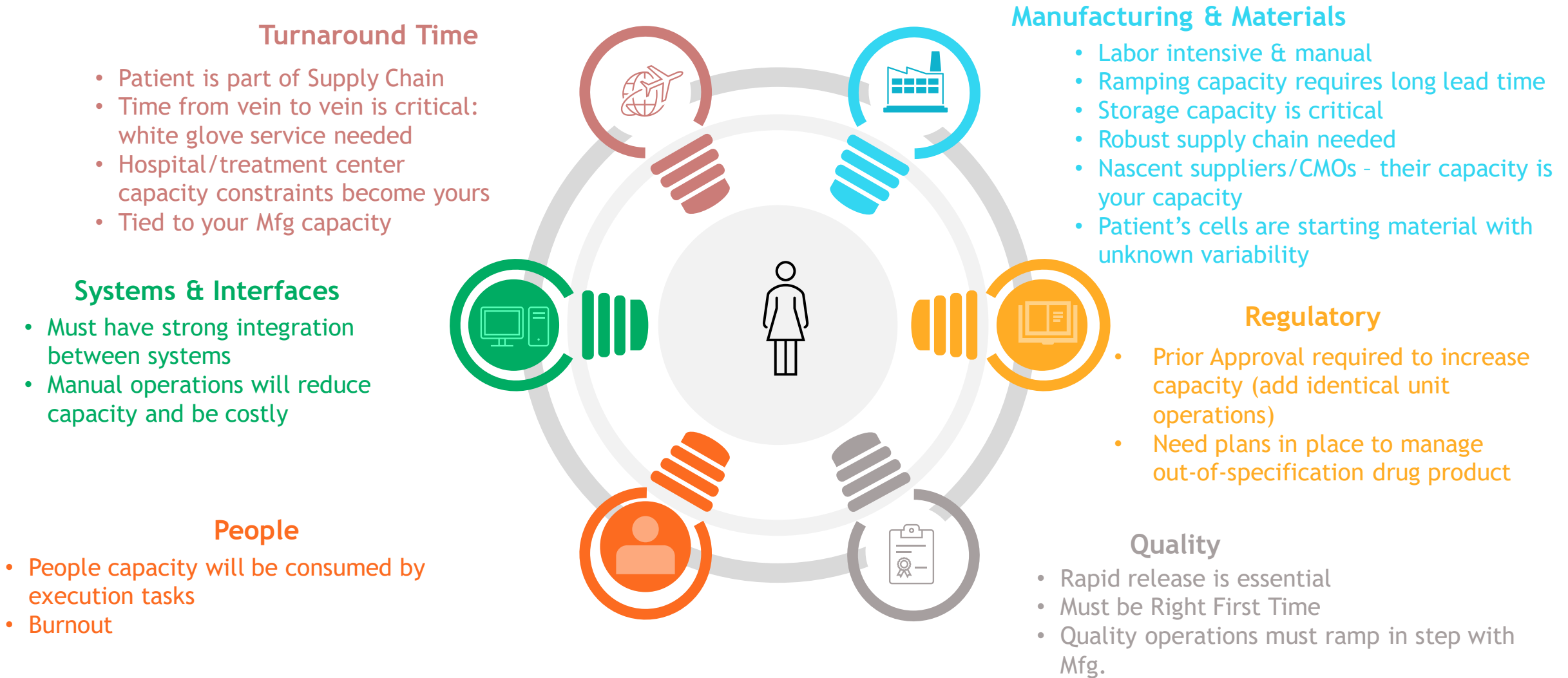


*It will be more complex than  
you think*

*It will take longer than you  
plan*

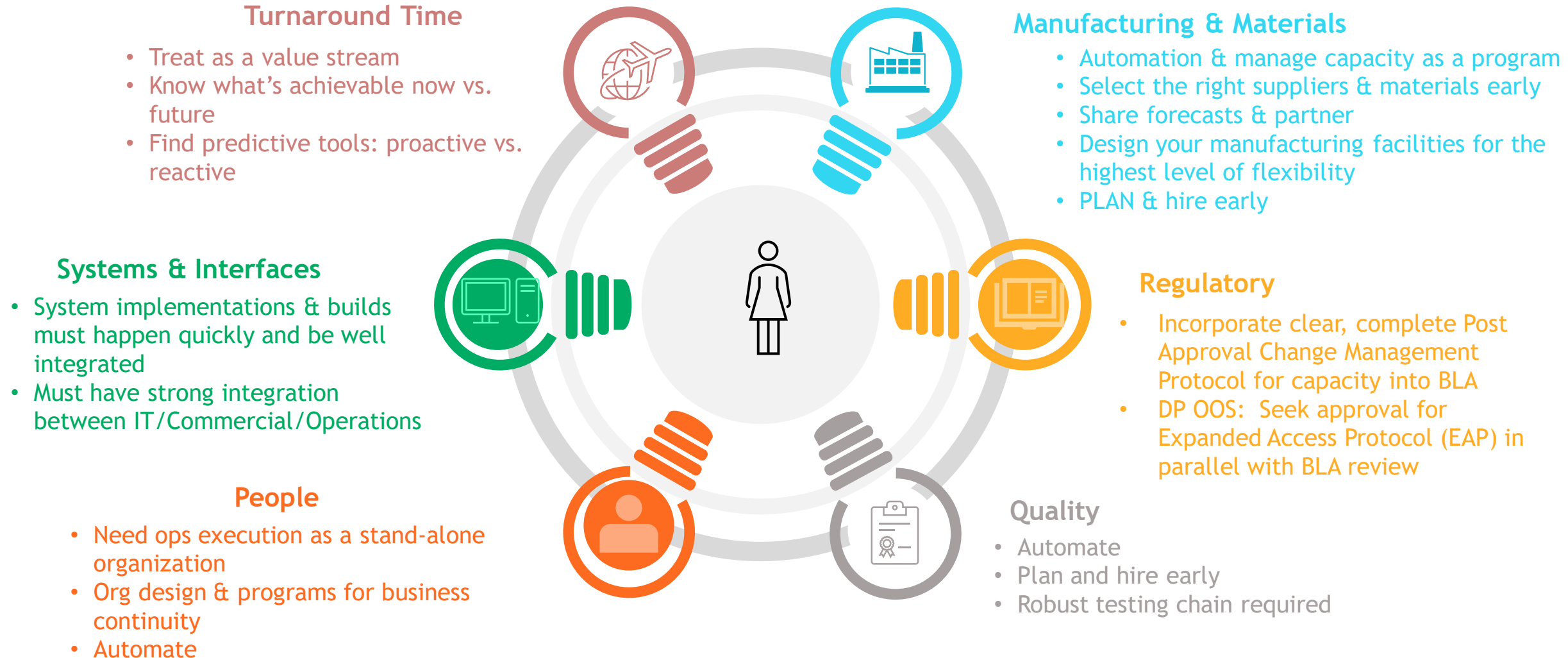
*Unexpected things will  
happen*

# Unique challenges that can impact autologous cell therapy capacity

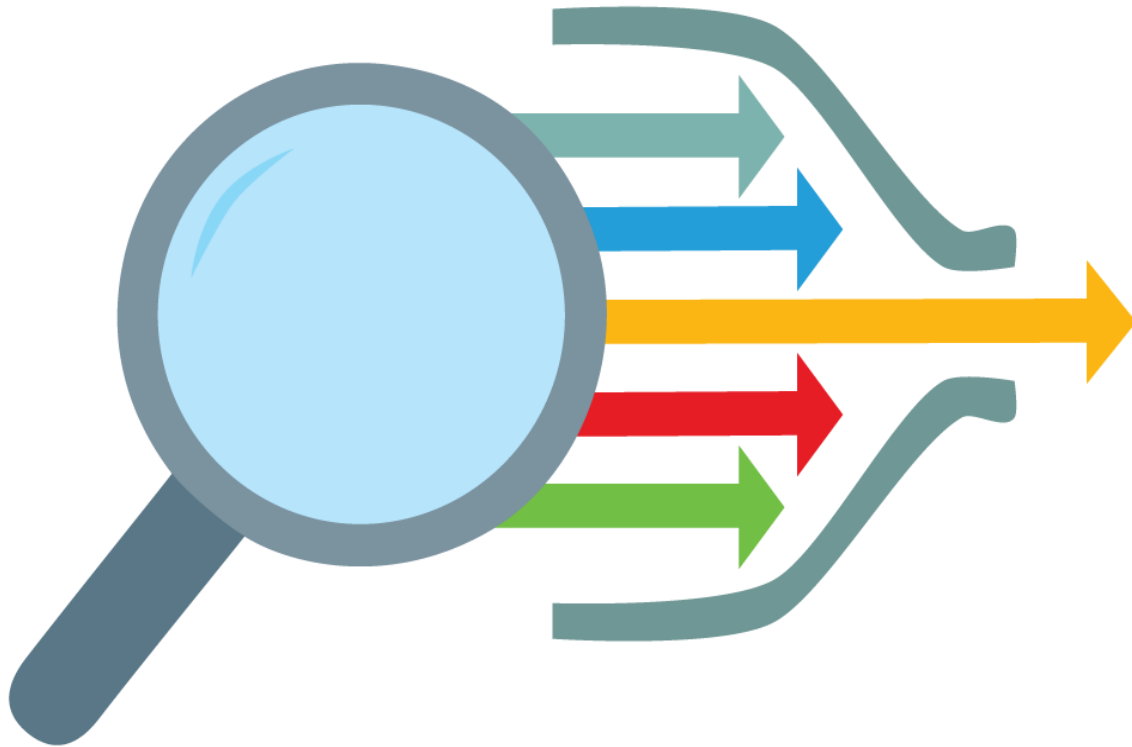




# How to address the challenges



# What's the next bottleneck?



- Harmonize and have consistency across nodes as you increase your capacity or that will impede ability to scale & grow.
- Complexity is here now, even if you think you have time to figure it out.

*It will be more complex than you think*

*It will take longer than you planned*

*Unexpected things will happen*

## In Summary:

- PLAN & Re-plan
- Communicate and Align to plans
  - Create programs to govern and drive things like manufacturing capacity ramps & turnaround times
  - Hire early
  - Be realistic, employ defensive pessimism
  - Always do what's best for patients