XAVIER HEALTH

Holistic Risk Profile Assessment

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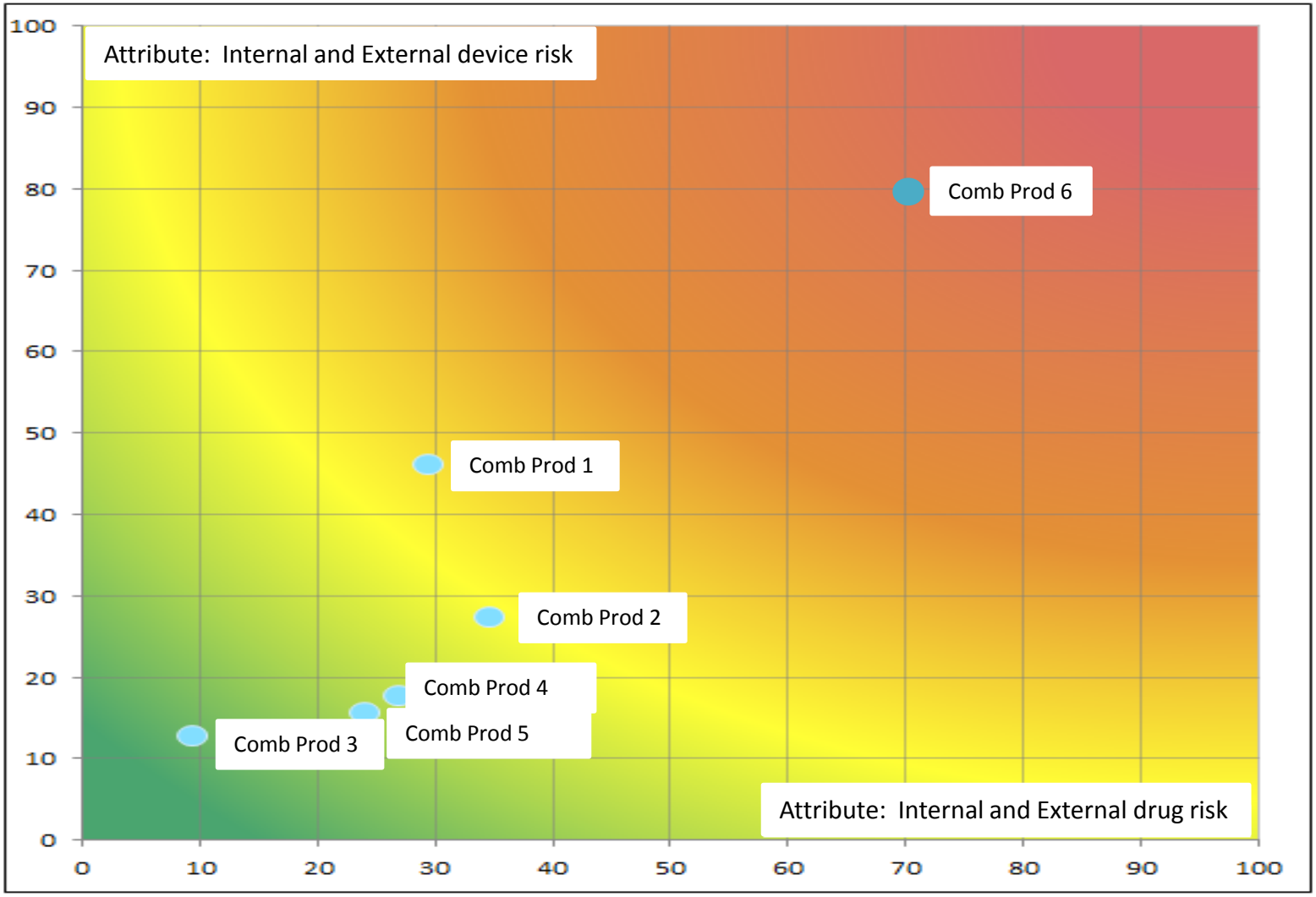
Benefit of Heat Maps

- **High level view of comparative risks**
  - X axis = drug component risk of the combination product
  - Y axis = device component risk of the combination product
  - Heat map = total risk of the combination product
- **Assessment over time quickly pinpoints changes**
  - Change to higher risk = focus area
  - Change to lower risk = learning opportunity
- **Created from rolled-up detailed risk analyses**
  - Multiple sources of input
  - Allows for a drill down to exact root causes and impact

With the End in Mind



Device Risk

Drug Risk

Today's Analysis

Best Ever Company has 2 configurations on the market for the BlockUV combination product:

1. Injectable liquid, vial configuration, weekly dosage, administered by a health care professional

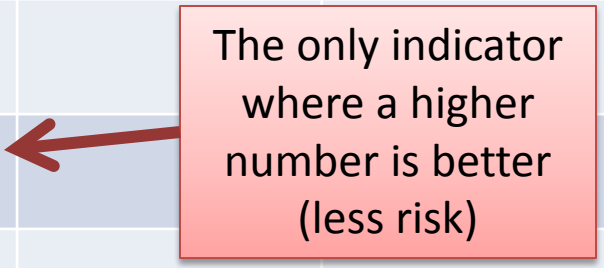
2. Injectable liquid, prefilled disposable multi-dose syringe, weekly administration, self-administered

Overview of Steps

1. Determine which indicators to include per axis.
2. Determine the importance rating of each indicator.
3. Identify the historical range of data per indicator. Create an index of each indicator from 0 to 100 based on the historical range.
4. Collect the current data to be assessed for each indicator.
5. Determine the index score for the current data collected per indicator.
6. Multiply the index score for each indicator by its importance rating.
7. Sum all index scores for each axis to get the risk score for that component of the combination product.

Step 1. Identify Indicators for X axis

Indicator	Importance Rating	Historical Range	Current Data	Index Score	Final Score (Index Score x Imp. Rating %)
Scrap Rate					
Product failures					
Process Capability					
Cost of failure					
Cycle time					
Critical Complaints					
Major Complaints					
Recalls					
Adverse Events					



Step 2. Importance Rating

- Each indicator is assigned a weighted Importance Rating to ensure resources are dedicated to the true areas of risk:
  - Might have a low risk issue, but it persistently occurs that increases its impact.
  - Might have a high risk issue, but there is no history of its occurrence with the product in question and a low likelihood of its occurrence.

- The total sum of all Importance Ratings should = 100

Step 2. Importance Rating

Indicator	Importance Rating	Historical Range	Current Data	Index Score	Final Score (Index Score x Imp. Rating %)
Scrap Rate	5				
Product failures	10				
Process Capability	5				
Cost of failure	5				
Cycle time	5				
Critical Complaints	15				
Major Complaints	10				
Recalls	30				
Adverse Events	15				

This is our ranking for our case study product

Step 3. Historical Ranges

Indicator	Importance Rating	Historical Range	Current Data	Index Score	Final Score (Index Score x Imp. Rating %)
Scrap Rate	5	7 – 32%			
Product failures	10	0.7 – 18%			
Process Capability	5	93 – 98%			
Cost of failure	5	$11k – 37.5k			
Cycle time	5	3.5d – 13d			
Critical Complaints	15	2 – 17%			
Major Complaints	10	14 – 43%			
Recalls	30	0 – 6			
Adverse Events	15	3 - 11			

Fictitious historical ranges for our case study product

Step 4. Identify Current Data

Indicator	Importance Rating	Historical Range	Current Data	Index Score	Final Score (Index Score x Imp. Rating %)
Scrap Rate	5	7 – 32%	30		
Product failures	10	0.7 – 18%	16		
Process Capability	5	93 – 98%	97.8		
Cost of failure	5	$11k – 37.5k	28		
Cycle time	5	3.5d – 13d	12.5		
Critical Complaints	15	2 – 17%	15		
Major Complaints	10	14 – 43%	40		
Recalls	30	0 – 6	1		
Adverse Events	15	3 - 11	9		

Let's convert scrap rate into an index score.

Fictitious current data for our case study product

Step 5. How to Establish the Index Score

Need to standardize the data in order to compare the various outputs of the indicators

Example: Scrap rate

Step 1:

- Scrap range is 7 - 32% from historical data
- Assign score of 0-100 to the range

Scrap rate of 7% (or less) score =	0	index score (lowest risk)
Scrap rate of 32% (or more) score =	100	index score (highest risk)

Every other point in the historical range is linearly calculated on the 0 to 100 scale (see next slide for calculation)

Step 5. How to Establish the Index Score

Example: Scrap rate (continued)

Scrap rate of 7% (or less) score = 0 index score (lowest risk)

Scrap rate of 32% (or more) score = 100 index score (highest risk)

Calculate the index score for all other values in the historical range as follows:

$$\frac{(\text{Actual Data Point} - \text{Best Case})}{(\text{Worst Case} - \text{Best Case})} \times 100 \quad \Rightarrow \quad \frac{(\text{Actual Data} - 7)}{(32 - 7)} \times 100$$

So a scrap rate of 19.5% =

$$\frac{(19.5 - 7)}{(32 - 7)} \times 100 = 50$$ (this is the midpoint of our index score)

Actual data from our table = 30

$$\frac{(30 - 7)}{(32 - 7)} \times 100 = 92$$

Step 5. Index Score

Indicator	Importance Rating	Historical Range	Current Data	Index Score	Final Score (Index Score x Imp. Rating %)
Scrap Rate	5	7 – 32%	30	92	
Product failures	10	0.7 – 18%	16	88	
Process Capability	5	93 – 98%	97.8	4	
Cost of failure	5	$11k – 37.5k	28	64	
Cycle time	5	3.5d – 13d	12.5	74	
Critical Complaints	15	2 – 17%	15	87	
Major Complaints	10	14 – 43%	40	90	
Recalls	30	0 – 6	1	100	
Adverse Events	15	3 - 11	9	75	

Flip the risk scoring, since higher is better. 98% = 0, and 93% = 100%

Could dictate that any recall is automatically 100%

Step 5. How to Establish the Index Score

Example: How to calculate the Index for Process Capability

Since a higher number for Process Capability is better, then the index is set-up as follows:

- Process Capability of 98% (or less) score = 0 index score (lowest risk)
- Process Capability of 93% (or more) score = 100 index score (highest risk)

Calculate the index score for all other values in the historical range as follows:

Notice the order is switched →

$$\frac{(\text{Best Case} - \text{Actual Data}) \times 100}{(\text{Best Case} - \text{Worst Case})}$$

$$\frac{(98 - \text{Actual Data}) \times 100}{(98 - 93)}$$

Actual data from our table = 97.8

$$\frac{(98 - 97.8) \times 100}{(98 - 93)} = 4$$

Step 6. Drug Component Final Score

Indicator	Importance Rating	Historical Range	Current Data	Index Score	Final Score (Index Score x Imp. Rating %)
Scrap Rate	5	7 – 32%	30	92	92 x 5% = 4.6
Product failures	10	0.7 – 18%	16	88	8.8
Process Capability	5	93 – 98%	97.8	4	0.2
Cost of failure	5	$11k – 37.5k	28	64	3.2
Cycle time	5	3.5d – 13d	12.5	74	3.7
Critical Complaints	15	2 – 17%	15	87	13.0
Major Complaints	10	14 – 43%	40	90	9.0
Recalls	30	0 – 6	1	100	30.0
Adverse Events	15	3 - 11	9	75	11.25

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Process Capability	5	93 – 98%	97.8	4	0.2
Cost of failure	5	$11k – 37.5k	28	64	3.2
Cycle time	5	3.5d – 13d	12.5		3.7
Critical Complaints	15	2 – 1			13.0
Major Complaints	10	14 – 43			9.0
Recalls	30	0 – 6	1	100	30.0
Adverse Events	15	3 - 11	9	75	11.25

Step 7. Total Risk for the Drug Component = 83.75

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Now it's Your Turn!

We need the Y axis score for the device component

Y Axis Data – Device Component

Indicator	Importance Rating	Historical Range	Current Data	Index Score	Final Score (Index Score x Imp. Rating %)
Scrap Rate	5	5 – 25%	20		
Product failures	10	3 – 20%	18		
Process Capability	5	88 – 95%	88		
Cost of failure	5	$20 – 59k	55	90	
Cycle time	5	7.5 – 21d	15	56	
Critical Complaints	15	7 – 19%	9	17	
Major Complaints	10	22 – 41%	33	58	
Recalls	30	0 – 11	4	**100**	
Adverse Events	15	0 - 8	2	25	

Calculate the Index Score for these 3 indicators

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Cycle time	5	7.5 – 21d			2.8
Critical Complaints	15	7 – 19%	9	17	2.6
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Recalls	30	0 – 11	4	**100**	30
Adverse Events	15	0 - 8	2	25	3.75

Calculate Final Score for these 3

Y Axis Data – Device Component

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Scrap Rate	5	5 – 25%	20	75	3.75
Product failures	10	3 – 20%	18	88	8.8
Process Capability	5	88 – 95%	88	100	5
Cost of failure	5	$20 – 59k	55	90	4.5
Cycle time	5	7.5 – 21d	15	56	2.8
Critical Complaints	15	7 – 19%	9	17	2.6
Major Complaints	10	22 – 41%	33	58	5.8
Recalls	30	0 – 11	4	100	30
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Scrap Rate	5	5 – 25%	20	75	3.75
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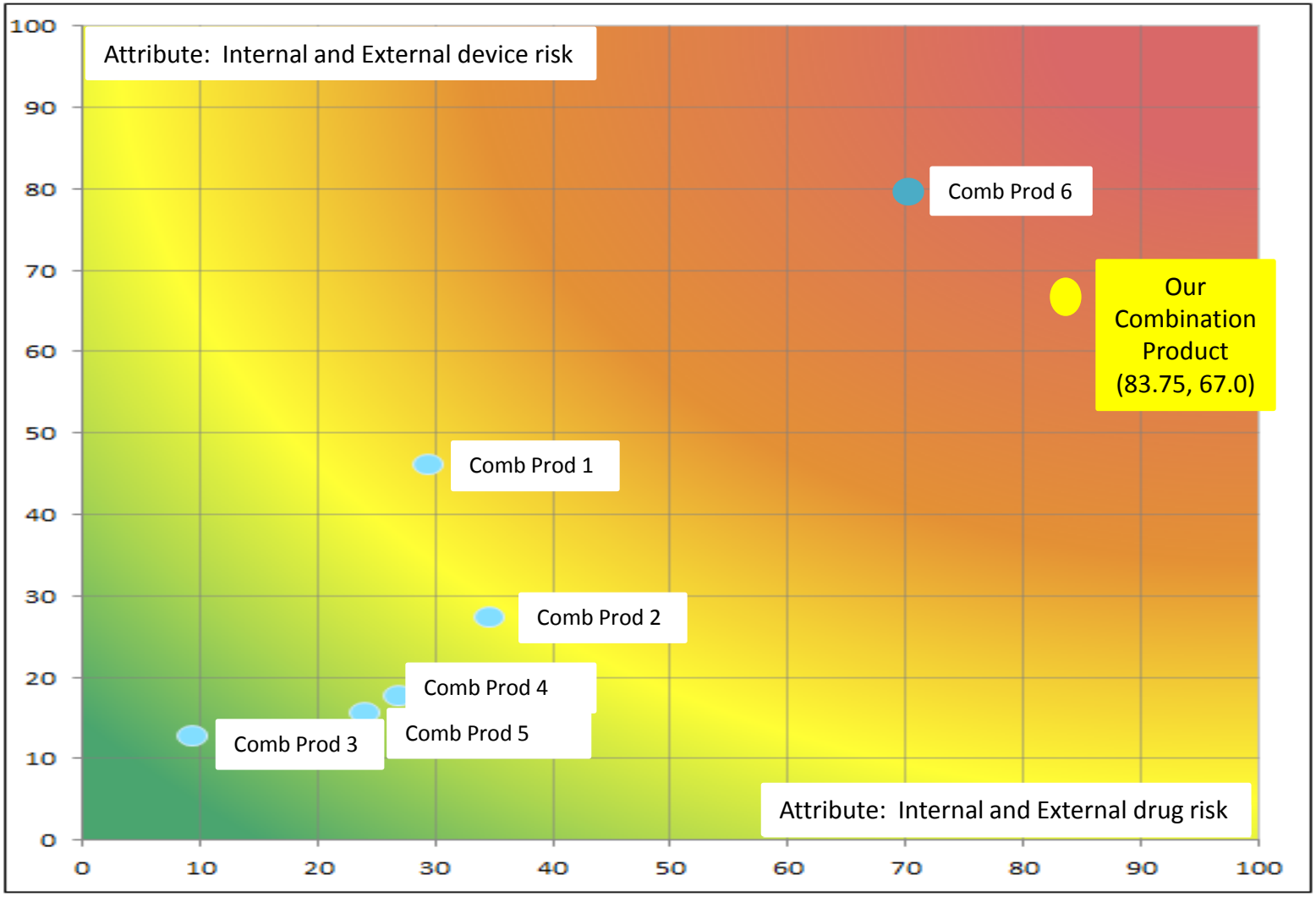
Process Capability	5	88 – 95%	88	100	5
Cost of failure	5	$20 – 59k	55	90	4.5
Cycle time	5	7.5 – 21d	15	56	2.8
Critical Complaints	15	7 –			2.6
Major Complaints	10	22 –	33	58	5.8
Recalls	30	0 – 11	4	100	30
Adverse Events	15	0 - 8	2	25	3.75

Total Risk for the Device Component = 67.0

Our Combination Product

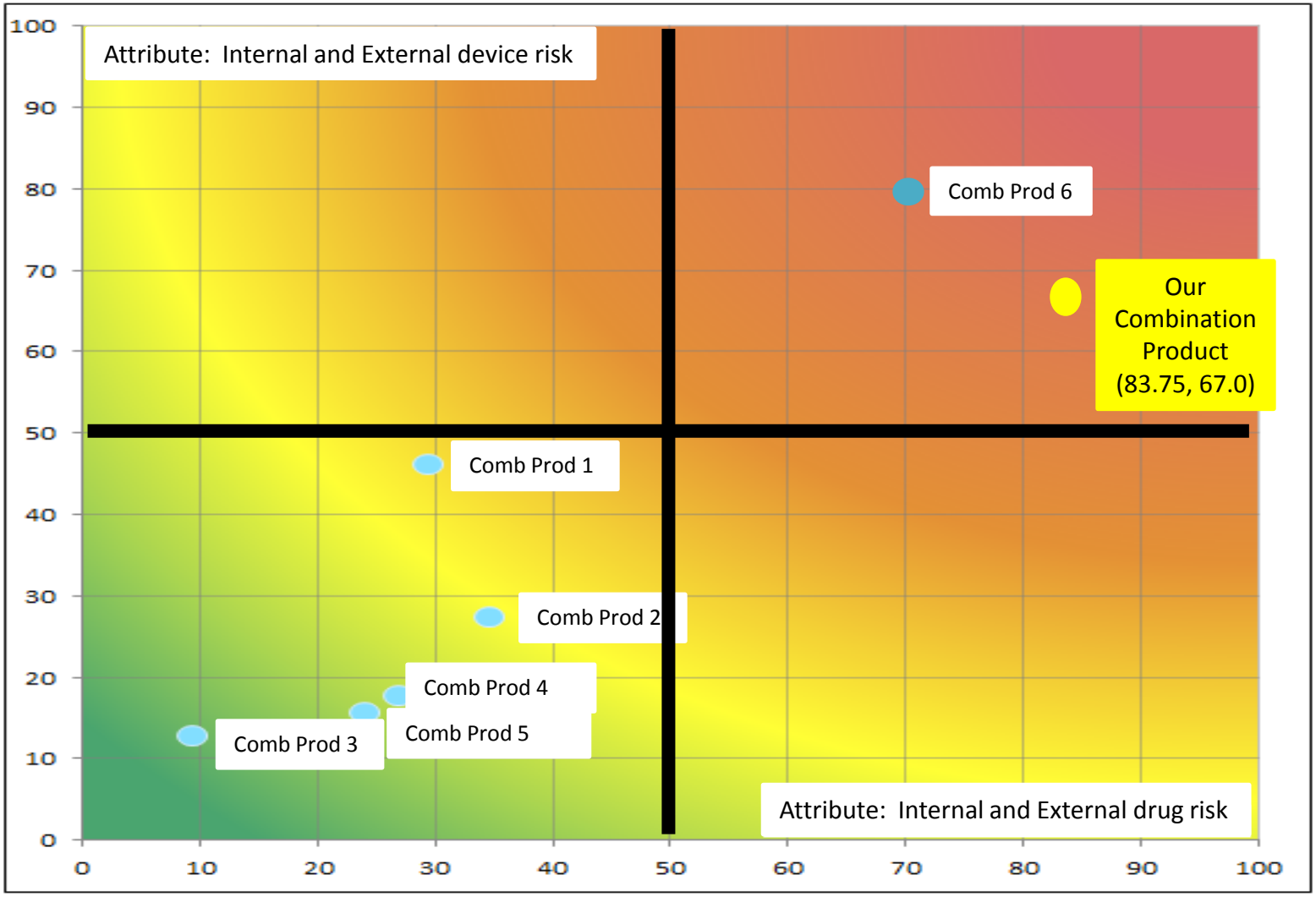


Device Risk

Drug Risk

Inform Decision. Trigger Action!

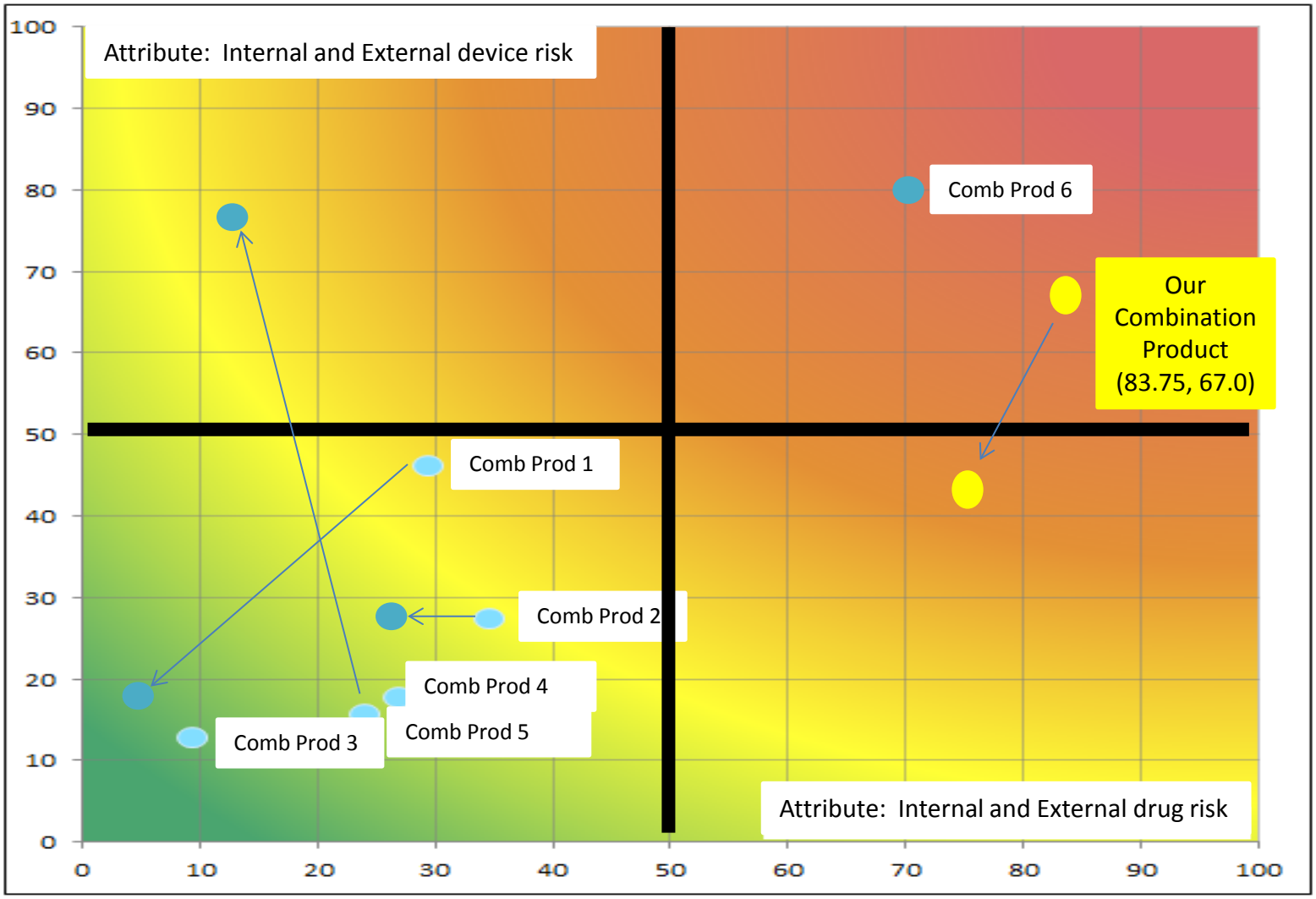
Device Risk



Drug Risk

What can we learn? Where to focus?

6 months later



Device Risk

Drug Risk

Summary of Benefits of Heat Maps

- **High level view of comparative risks**
  - X axis = drug component risk of the combination product
  - Y axis = device component risk of the combination product
  - Heat map = total risk of the combination product
- **Assessment over time quickly pinpoints changes**
  - Change to higher risk = focus area
  - Change to lower risk = learning opportunity
- **Created from rolled-up detailed risk analyses**
  - Multiple sources of input
  - Allows for a drill down to exact root causes and impact

Drill down to understand the “why” behind the data

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Questions….Ideas

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