

From Design to Delivery: An Interactive Workshop on Planning Risks Assessments

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OIG's View *of* Risk Assessments



“
Who in the world am
I? *Ah*, that's the great
puzzle...”

OIG's View *of* Risk Assessments



Who

Compliance Committee should be responsible for conducting and implementing

What

Risk to the organization stemming from **violations of law, regulations, or other legal requirements**

When

Conducted at least annually

How

[Use] a variety of external and internal sources, evaluate and prioritize them, and then decide which risks to address and how to address them

Why

Compliance Committee can work with the compliance officer to prioritize resources and **develop the compliance work plan**, including audits and monitoring of identified risks based on priority

What road you take...
depends on where you're going.

“What road do I take?”

The cat asked, “Where do you want to go?”

“I don't know,” Alice answered.

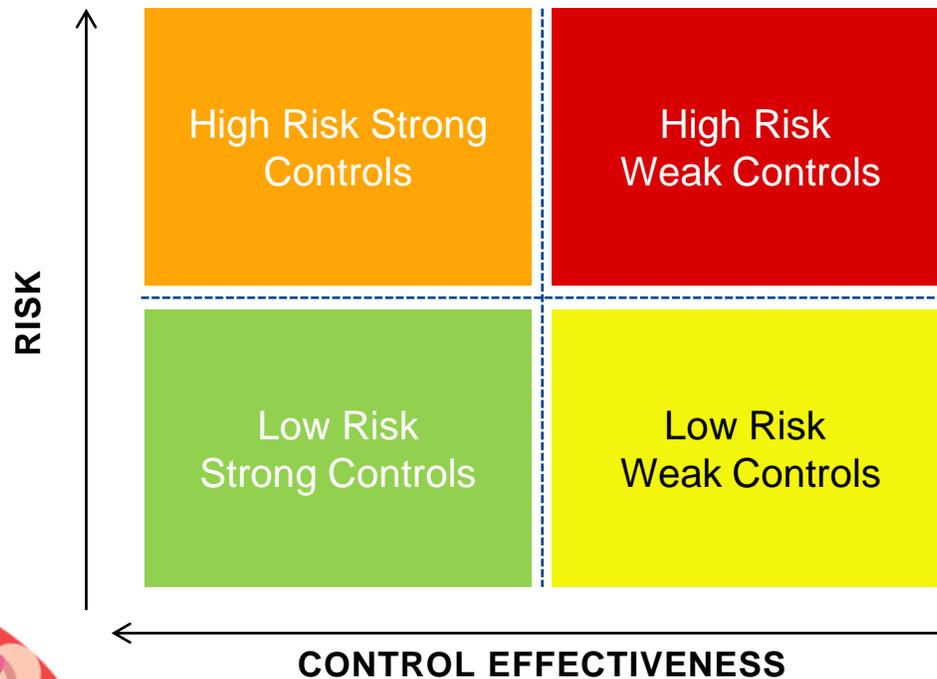
“Then,” said the cat,

“it really doesn't matter, does it?”



Start with the *end* in mind

- OIG: “Develop the Compliance Work Plan”
- Work Plan - Actions to Detect and Prevent Risk
- Need to Evaluate Both Risks and Controls



Risk-based
Audit Plan

RISK
1 Live and Retro

RISK
2 Retrospective Only

RISK
3 Live Monitoring



Preventative
Action Plans

Policy Development

New Systems/Processes

Training

Communication

OIG's Guidance *on* how to do risk assessments

OIG references multiple other sources such as COSO and GAO

- Approach — Evaluate likelihood and impact
- Suggests you consider adding other variables such as:
 - Velocity
 - Vulnerability
 - Speed of onset
 - Risk interactions/dependencies

Figure 1.1 The COSO 2013 Framework



Figure 4.4 Likelihood vs impact matrix

	1 Insignificant	2 Minor	3 Serious	4 Disastrous	5 Catastrophic
5 Almost Certain	Green	Yellow	Red	Red	Red
4 Likely	Green	Yellow	Yellow	Red	Red
3 Possible	Green	Green	Yellow	Yellow	Red
2 Unlikely	Green	Green	Yellow	Yellow	Yellow
1 Rare	Green	Green	Green	Yellow	Yellow

**OIG's Guidance *on*
how to do risk
assessments**



“Speak English!” said the
Eaglet.

“I don’t know the meaning of
half of those long words and I
don’t believe you do either!”

“

It would be so nice
if something made
sense for a change.

– Alice



Ways *to* analyze risks



Key Decision: Qualitative vs. Quantitative

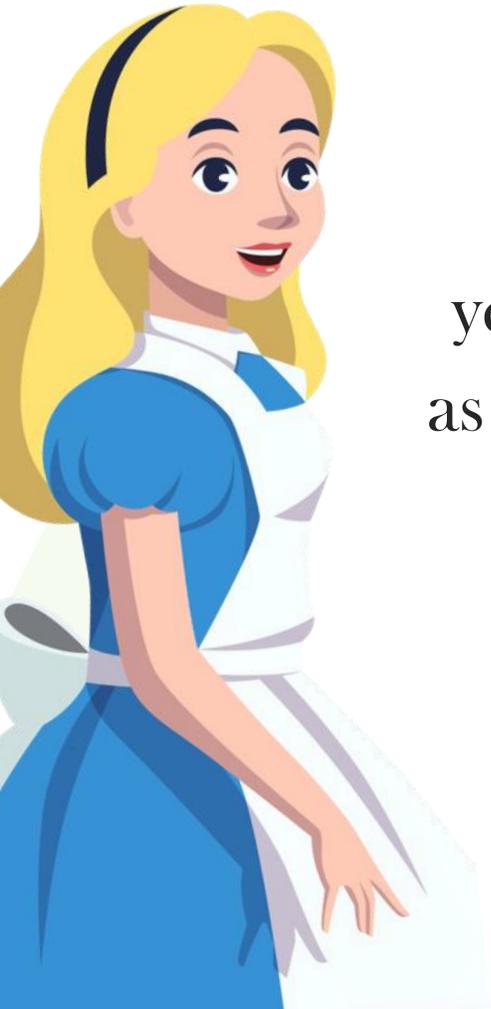
	Advantages	Disadvantages	Approaches
Qualitative	<ul style="list-style-type: none">• Quicker• Easy to Understand	<ul style="list-style-type: none">• Imprecise	<ul style="list-style-type: none">• Surveys• Interviews• Cross-functional Workshops
Quantitative	<ul style="list-style-type: none">• Provides Greater Differentiation	<ul style="list-style-type: none">• Time and \$• Often Lacks Context	<ul style="list-style-type: none">• Analysis of Existing Data• Benchmarking• Scenario Analysis

Key Decision: Risk Score or Risk Rank?

What can go wrong *and* Tips for success

“

Dear, dear! How queer
everything is to-day! And
yesterday things went on just
as usual. I wonder if I've been
changed in the night?



What can go wrong *and* Tips for success



Methodological Biases

What Can Go Wrong?

**Reluctance to Create
“Hot Document”**

Scope Creep

Cultural/Business Unit Differences

Not Enough Differentiation

Tips for Success

Focus on continuous improvement
Alignment = Action-oriented

Planning: Clearly define the stakeholders and scope

Calibrate results

Risk Ranking: Forces differentiation
Risk Scoring: Calibration

“

But that's just the trouble with me. I give myself very good advice, but I very seldom follow it.

– Alice



What can go wrong *and* Tips for success

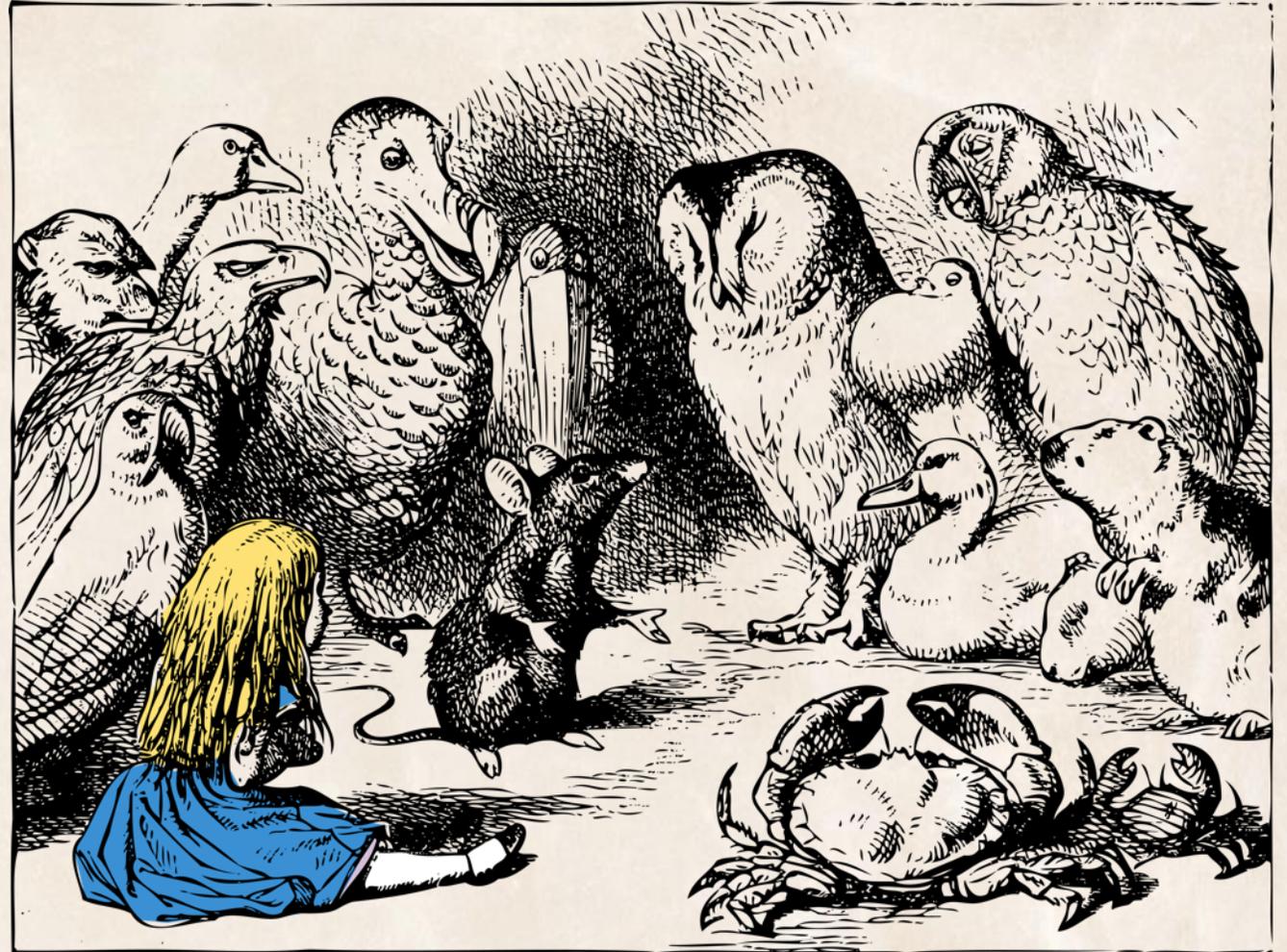
Cognitive and Behavioral Biases

What Can Go Wrong?	Tips for Success
Recency and Availability Biases	Awareness and Identification of bias
Group Think	Mix of data gathering approaches – Don't rely only on workshops
Reluctance to Point Out Errors; Too nice	Focus on continuous improvement; Be self-aware

“

The best way
to explain it is
to do it.

A Caucus-Race and a Long Tale
Chapter 3, *Alice's Adventure in Wonderland*



Introduction > Risk Assessment Scenario

Workshop

Introduction



Your Role

- Director of Compliance
 - You have been tasked with leading a risk assessment which you will co-present with the GC/CCO to the Compliance Committee
 - You are only responsible for US Activities

Navilla Therapeutics

- Two therapeutic areas: Nephrology and Oncology
- This is Navilla's first compliance risk assessment
 - A "sub-par" enterprise risk assessment was performed one year ago — compliance mostly omitted
- Japanese HQ-company with April 1-March 31 fiscal year

2 Approved Products

- CYSTIZIA (Nephrology - rare disease)
 - Infusion therapy - Approved February 2022
 - First-line treatment of nephropathic cystinosis in adults with CTNS mutation
- ZAX (Oncology)
 - Injectable - Approved February 2024
 - Competitor product approved at basically the same time; concurrent launches
 - First-line treatment for adults newly diagnosed with stage 3/4 PDAC (Pancreatic ductal adenocarcinoma) that are ineligible for surgery as combo chemo treatment
 - Ongoing trials in other solid tumor types (e.g., esophageal, prostate)

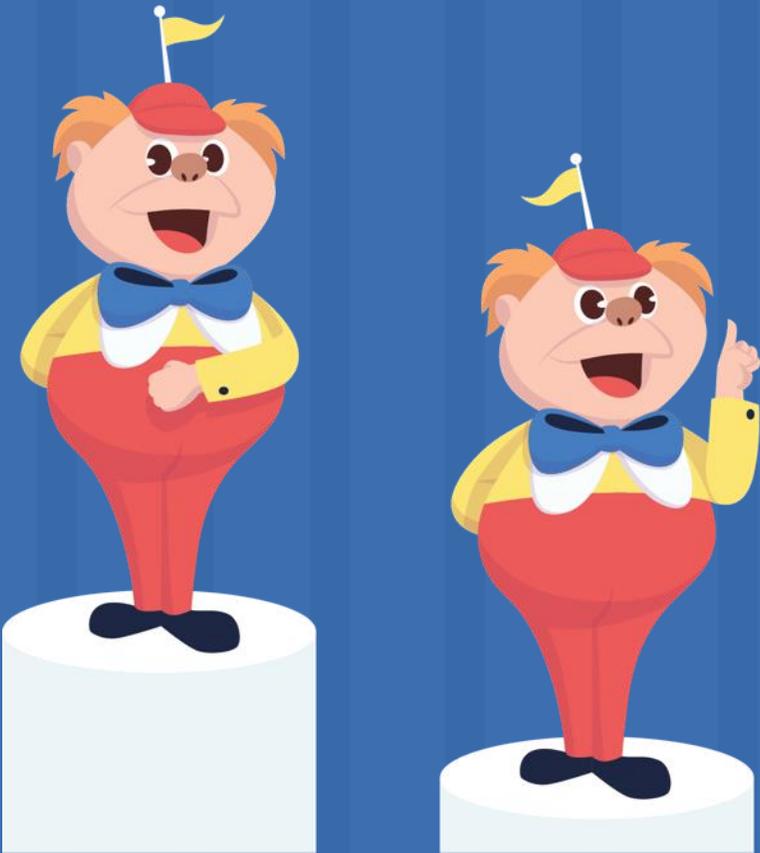


Please note:

All information provided is fictional and for educational purposes only.

ASSIGNMENT No.1

Set-up *and* Design



Objectives

- Identify scope of risk assessment and stakeholders
- Plan a high-level approach for methodology and gathering data

Key Questions

- Who will be involved in creating the risk assessment?
- Will you conduct interviews and/or surveys? If so, with whom?
- Are you using data to assess risks? If so, what data should you use?
- What is your assessment criteria for risks and controls?
- What output are you generating?

Recap for Going Forward



Scope: Limited to healthcare compliance – interactions with HCPs, HCOs, payers, and patients

Who is Involved: Compliance and legal team to collaborate and calibrate

- First pass by legal and compliance, review by compliance committee

Interviews/Surveys: Discussions with SMEs in functional areas in addition to legal and compliance colleagues

Data: Actively seek out information on actual and planned volume activity (e.g., review brand plans, budgets, transparency data)

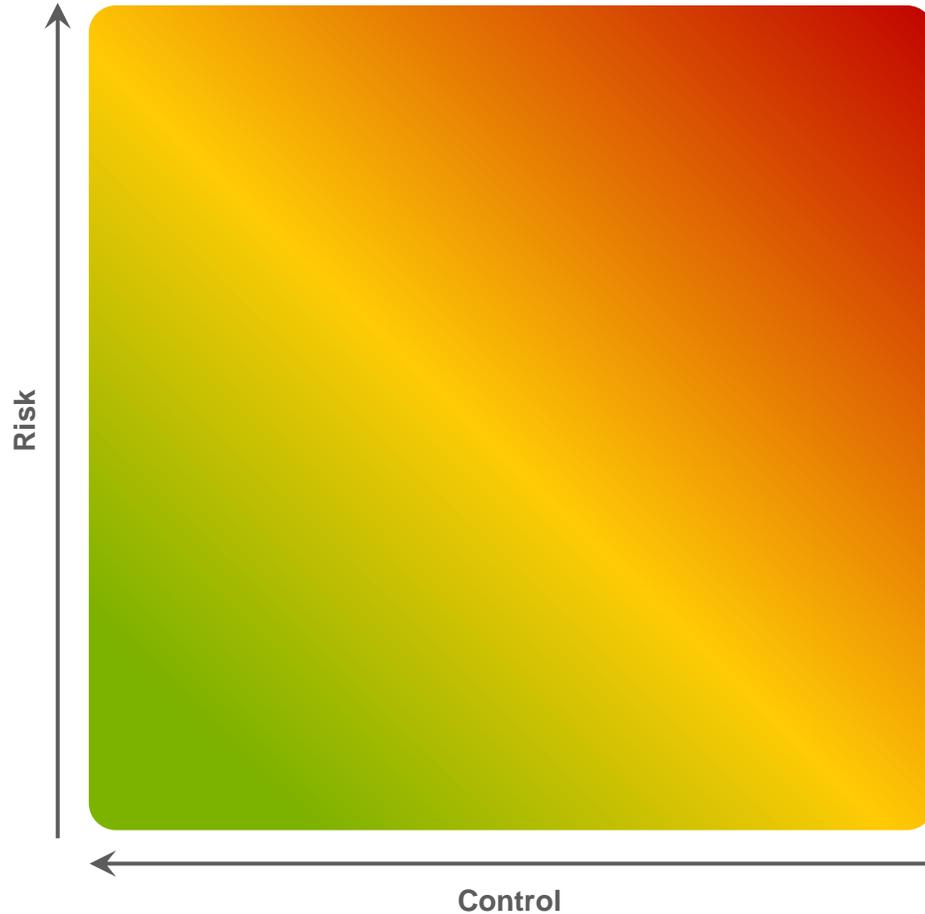
Output: Heat Map – Perceived risks and perceived control effectiveness

- Use Heat Map to inform overall compliance work plan

Assessment Criteria:

- Risk: Seriousness of violation (e.g., criminal vs. reputational), pervasiveness, public focus/enforcement, company prior history
- Controls: IT system controls, documented procedures, existing training and communication, business unit monitoring, audit/investigations history

Risk Assessment Heat Map



#	Activity	Risk	Control
1			
2			
3			
4			
n			

Set-up and Design:

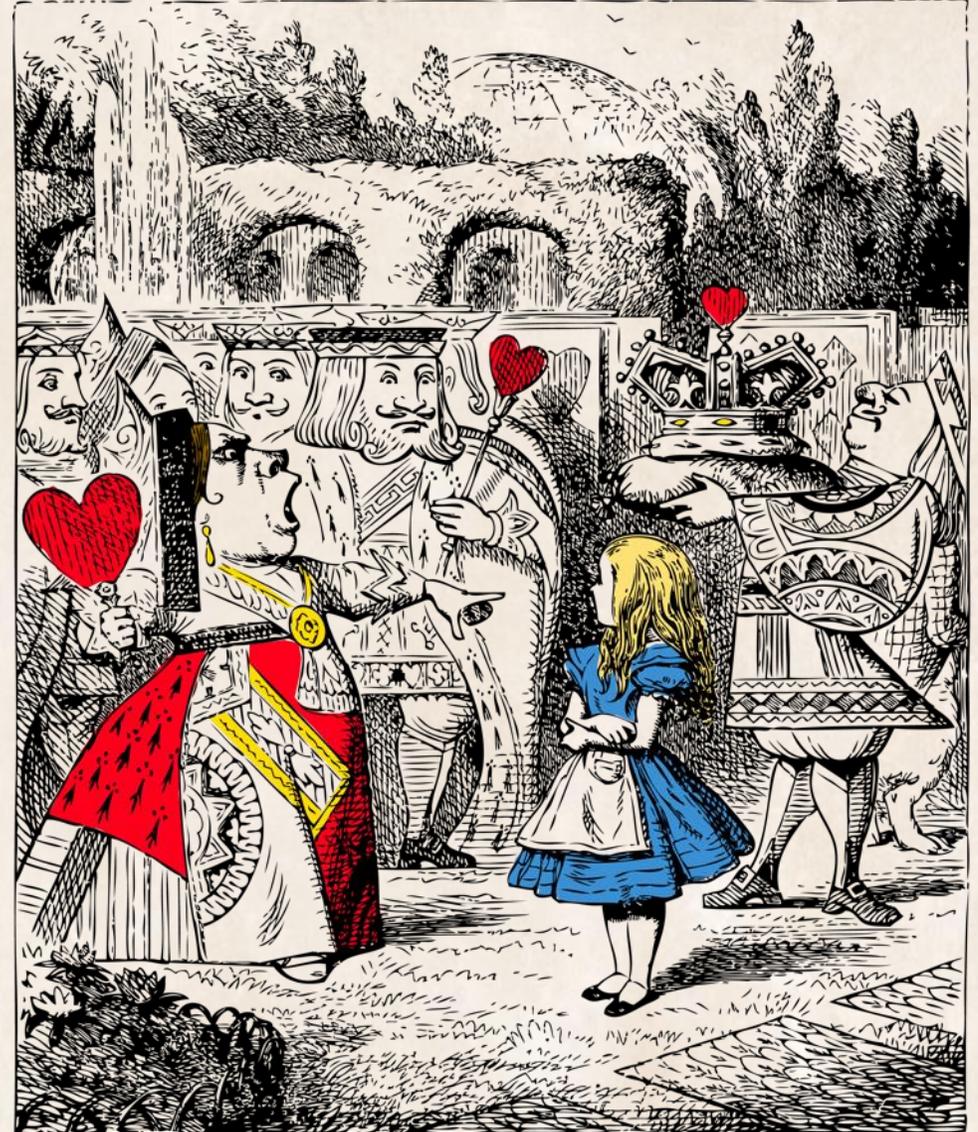
- Scope is healthcare compliance: Interactions with HCPs, HCOs, Payors, and Patients
- Compliance and Legal
- Interviews with L&C and SMEs in functional areas
- Use available data and information on current and planned activities
- Output: Heat Map - Risks and Controls



“

I would have done
it in a much more
complicated way.

— Red Queen



Methodology

Objectives

- Align on the approximate number of risks to evaluate
- Consider risk scores vs. risk ranking
- Plan how results will be organized (e.g., function, law or topic)

Key Questions

- How is Risk Calculated? What inputs will be used?
 - Will the risk assessment include be fully qualitative or will it include both qualitative and quantitative metrics?
- Will risks be ranked relative to one another or scored?
 - What consideration of controls needs to be included?
- Should separate deliverables be created for each product?
- Approximate number of risks to evaluate?
- How will risks be organized (e.g., function, law or topic)?



Answer Key and Recap

How Risk is Calculated: Hybrid - Team members independently review and compare results

Ranking vs. Scoring: Risk score

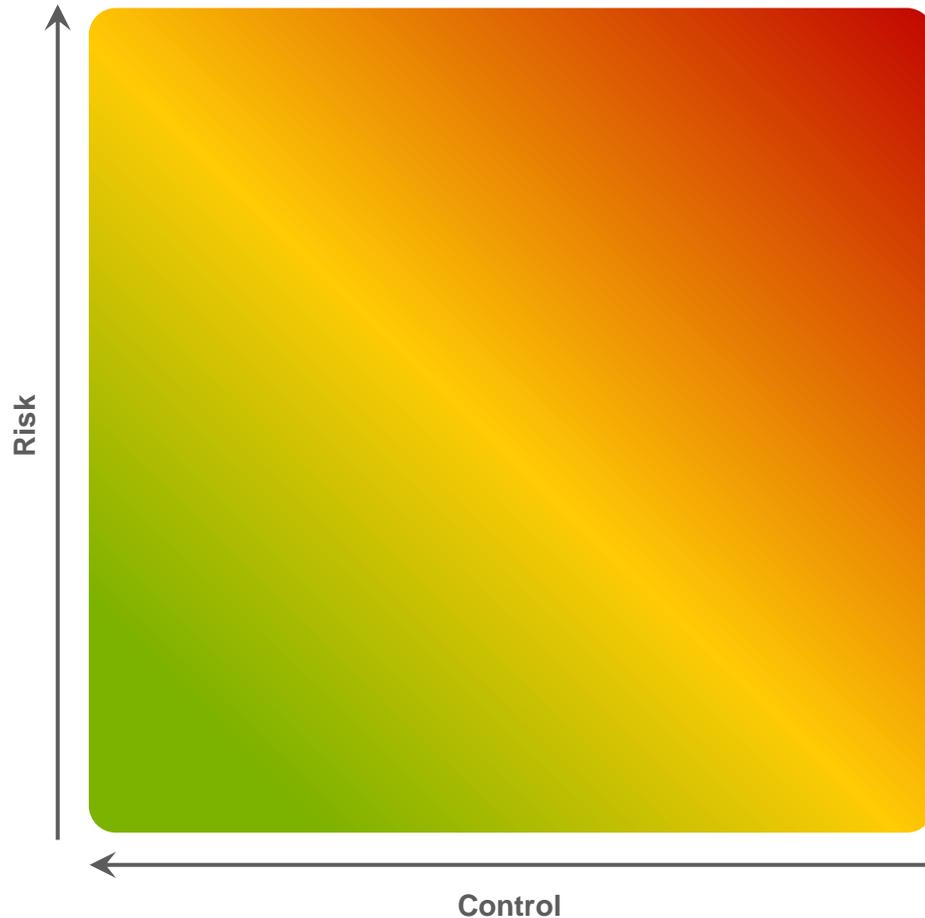
Differentiate by Product: No need to differentiate by product, keep it simple; consider adjusting monitoring plans accordingly

How Many Risks: 15–20

Organization: Risks organized by topic (e.g., Interactions with HCPs, Payors, HCOs, and Patients). Align closely to existing policy structure, where possible



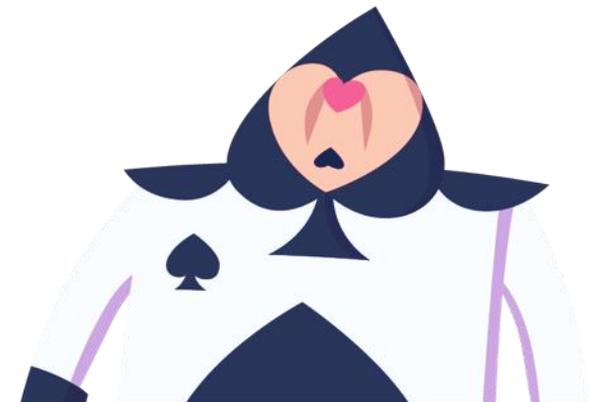
Risk Assessment Methodology



#	Activity	Risk	Control
<i>Interactions with HCPs</i>			
1			
2			
<i>Interactions with Payors</i>			
3			
4			
<i>Interactions with HCOs</i>			
5			
6			
<i>Interactions with Patients</i>			
7			
n			

Methodology:

- One heat map
- Hybrid, risk score
- 15-20 risks to evaluate
- Organize by topic and align with policy structure



“

Some go this way.
Some go that way.
But as for me,
myself, personally, I
prefer the short cut.

— The Cheshire Cat



Categories



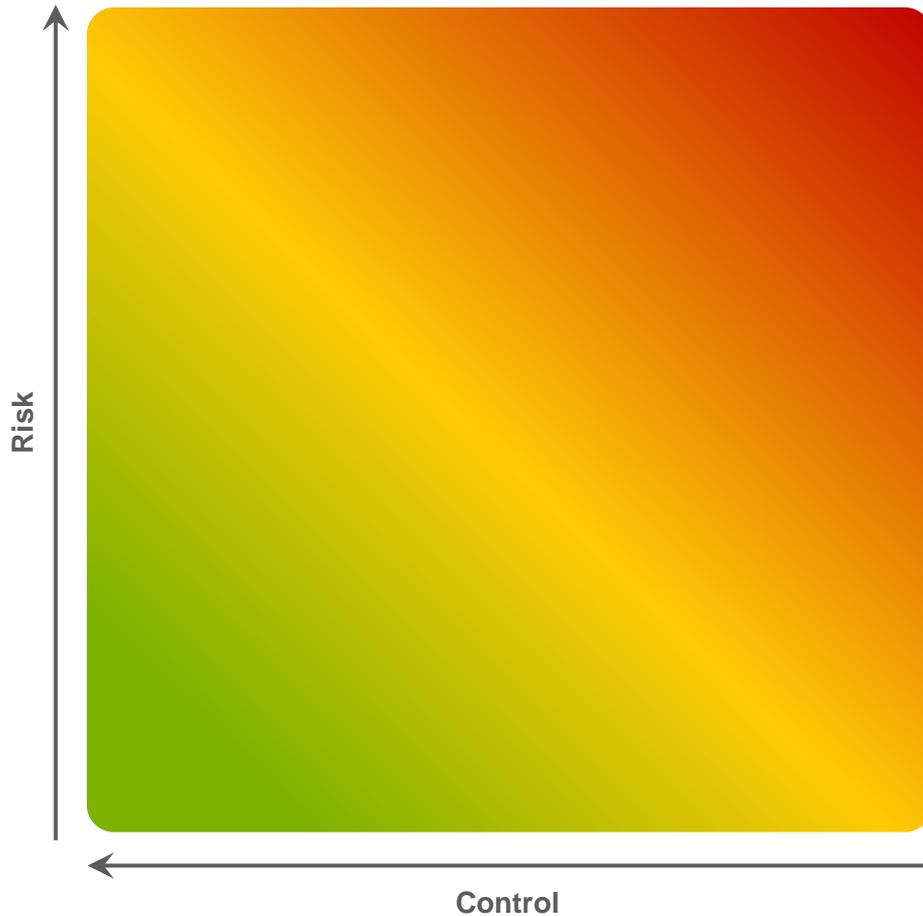
Objectives

- Identify which risks to include in the risk assessment

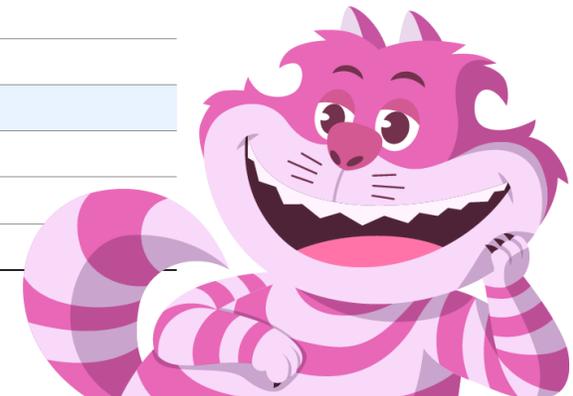
Key Questions

- What 15–20 risks should we include in our heat map?
- Why are you considering these 15–20 risks and not others?

Risk Assessment Categories



#	Activity
<i>Interactions with HCPs</i>	
1	Contracting with HCPs (e.g., consulting, speaking)
2	Speaker Programs (logistics, content, training, transparency)
3	Advisory Boards
4	In-Office Meals
5	Promotional Communications with HCPs
6	Non-Promotional Communications with HCPs
7	Promotional Materials Review
8	Non-Promotional Materials Review
9	Joint Interactions
10	Targeting, Call Plans, and Incentive Compensation
<i>Interactions with Payors</i>	
11	Access and Adherence (Hub Interactions, FRMs)
12	Payor Interactions (Formulary & Coverage Communications)
<i>Interactions with HCOs</i>	
13	Company-Sponsored Trials & Publications
14	Investigator-Initiated Trials
15	Grants, Donations, & Sponsorships
<i>Interactions with Patients</i>	
16	Communications with Patients / Caregivers
17	Contracting with Patients
18	Interactions with Patient Organizations



“

I'm late, I'm late!
For a very important
date! No time to say
'hello, goodbye,' I'm late,
I'm late, I'm late!

— White Rabbit



Next Steps



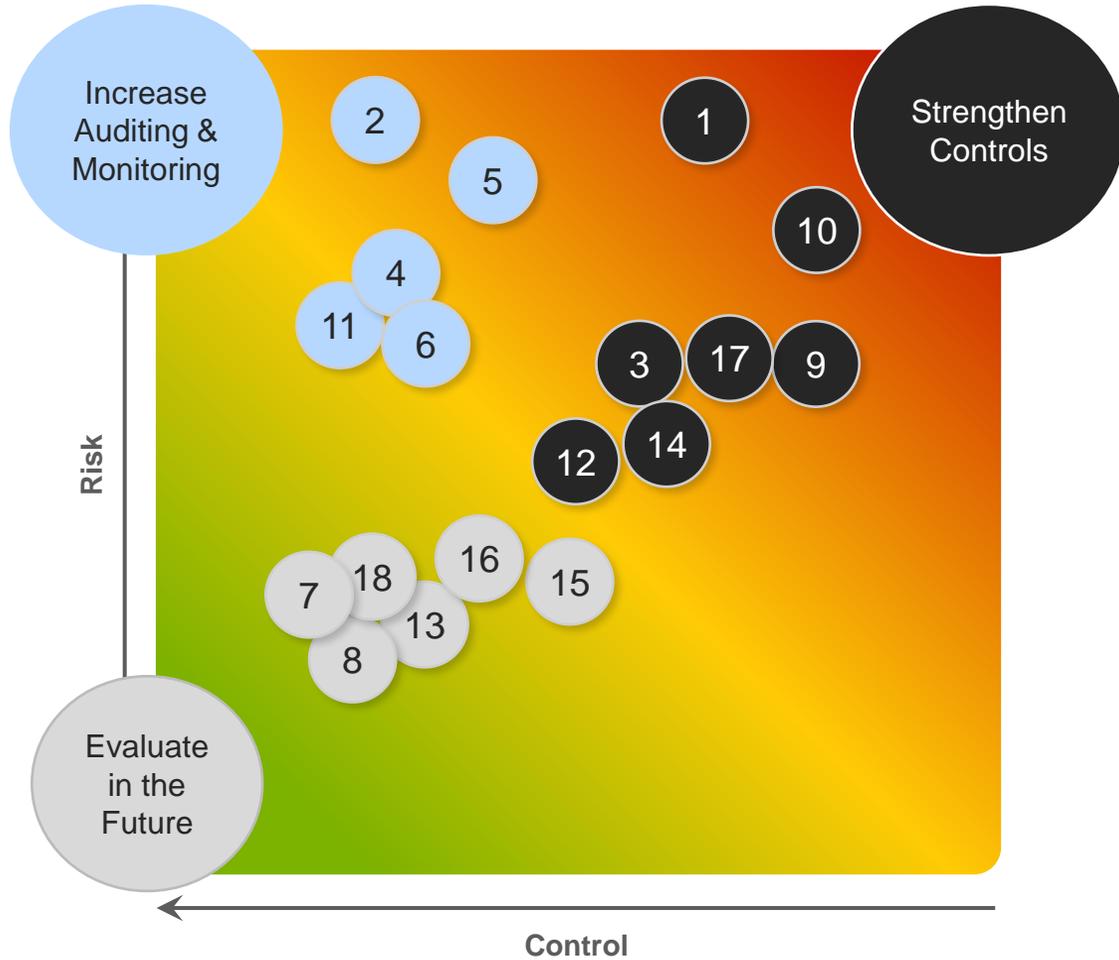
Objectives

- Plan next steps after a completed risk assessment
- Identify areas for strengthening controls and auditing/monitoring
- Discuss how to improve future risk assessments

Key Questions

- What actions are needed to: “prioritize resources and develop the compliance work plan, including audits and monitoring of identified risks based on priority?”
- Where should you strengthen controls? How?
- What are the priorities for auditing and monitoring?
- What changes are needed for future risk assessments?
- When should you do your next risk assessment?

Risk Assessment Results – Action Planning



#	Activity	Inherent Risk	Navilla Risk	Navilla Control
2	Speaker Programs (logistics, content, training, transparency)	9	9	7
4	In-Office Meals	7	7	7
5	Promotional Communications with HCPs	8	8	6
6	Non-Promotional Communications with HCPs	6	7	7
11	Access and Adherence (Hub Interactions, FRMs)	6	7	8
1	Contracting with HCPs (e.g., consulting, speaking)	9	9	4
3	Advisory Boards	5	6	5
9	Joint Interactions	6	6	3
10	Targeting, Call Plans, and Incentive Compensation	7	7	3
12	Payor Interactions (Formulary & Coverage Communications)	5	5	5
14	Investigator-Initiated Trials	5	5	4
17	Contracting with Patients	5	6	4
7	Promotional Materials Review	5	4	8
8	Non-Promotional Materials Review	4	3	8
13	Company-Sponsored Trials & Publications	4	4	7
15	Grants, Donations, & Sponsorships	7	4	5
16	Communications with Patients / Caregivers	5	4	6
18	Interactions with Patient Organizations	5	4	8

Risk Assessment Results – Action Planning

	Activity	IR ¹	NR ²	NC ³	Action Steps
Emerging Risk Area	Sponsorship of Genetic Testing	*	*	*	<ul style="list-style-type: none"> Continue to evaluate and work with legal counsel as topic undergoes legal analysis
Increase Auditing & Monitoring	Speaker Programs (logistics, content, training)	9	9	7	<ul style="list-style-type: none"> Live monitoring: Increase live Speaker Programs monitoring volume; transactional review
	In-Office Meals	7	7	7	<ul style="list-style-type: none"> Aggregate and risk-based transactional auditing
	Promotional Comms with HCPs	8	8	6	<ul style="list-style-type: none"> Live monitoring: Launch live monitoring for Zax; maintain live monitoring for Cystizia. Slightly higher weight for Zax based on potential for off-label uses
	Non-Promotional Comms with HCPs	6	7	7	<ul style="list-style-type: none"> Build out policy controls for Nurse Educator function in 1H Begin live monitoring of Field Medical and Nurse Educators in 2H Aggregate monitoring of MIRF process
	Access and Adherence (Hub Programs)	6	7	8	<ul style="list-style-type: none"> Maintain Live Monitoring of FRM team for Cystizia, add Zax team Initial “Testing” of business processes of Hub team (small scale process audit)
Strengthen Controls	Contracting with HCPs	9	9	4	<ul style="list-style-type: none"> Implement HCP engagements system, including consistent use of FMV approach
	Advisory Boards	5	6	5	<ul style="list-style-type: none"> Revise policy and create SOPs/supporting tools to reinforce controls Conduct formal “on-boarding” of ad board vendors to clarify expectations
	Joint Interactions	6	6	3	<ul style="list-style-type: none"> Roll-out communication campaign with supporting quick-cards/policy highlights to reinforce policy requirements for separating Field Medical and Commercial activities
	Targeting, Call Plans, and Incentive Compensation	7	7	3	<ul style="list-style-type: none"> Update incentive compensation process to only compensate for Zax scripts using approved ICD-10 Code Discuss with the business allowing free product to be eligible for IC Perform annual T&A aggregate review to ensure appropriate HCPs are included in the call plan
	Payor Interactions	5	5	5	<ul style="list-style-type: none"> Training on FDA guidance Monitoring call activity reports and field activity
	Investigator-Initiated Trials	5	5	4	<ul style="list-style-type: none"> Create SOP for reviewing, approving, and overseeing Investigator-Initiated Trials
	Contracting with Patients	5	6	4	<ul style="list-style-type: none"> Evaluate new FMV rates for patients using reputable methodology and data sources



“

Everything's got a
moral. If only you can
find it.

– The Duchess

