



COMPETITIVE INTELLIGENCE: CUSTOMIZED ANALYSES FOR R&D STRATEGY

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Scientific & Competitive Intelligence

Medical Intelligence & Patient Perspectives

Sanofi

DISCLAIMER

- ◆ The views and opinions expressed in the following PowerPoint slides are those of the individual presenter and should not be attributed to any organization with which the presenter is employed or affiliated.

AGENDA

AVM Boston 2019



Introduction

**Workflow
&
Examples**

Conclusions



INTRODUCTION

Medical Value & Strategy



Ginamarie Foglia



Laurence Bessac

Product Viability & Patient Need



Juliette Muszka



Daniel Fiebig



Laurence Bondoux



Alexandre Jaballah

MEDICAL INTELLIGENCE & PATIENT PERSPECTIVES TEAM



Joseph
Collins
Head of MIPP

Competitive Intelligence



Amy Huang



Kristen Terranova

Project Management



Mingling Wang

Executive Assistant



Aisha Akhter

HISTORIC IMBALANCE EXISTS

Should We?

Patient Need

Medical Value

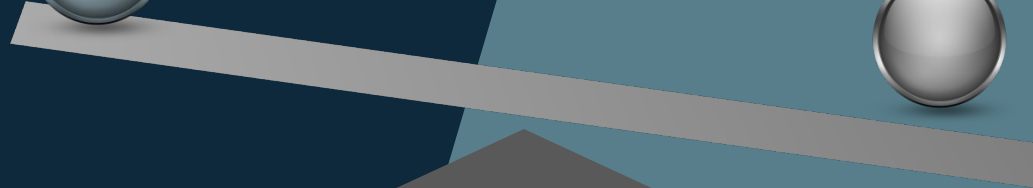
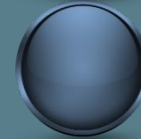


Can We?

Science

Bias

Developability





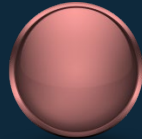
MIPP TEAM FOCUSES ON 4 CRITICAL PILLARS

MIPP OBJECTIVE: EMPHASIS ON VALUE

Should We?

Patient Need

Medical Value

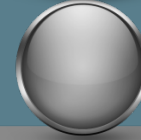
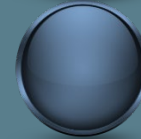


Can We?

Science

Bias

Developability





CI WORKFLOW & EXAMPLES

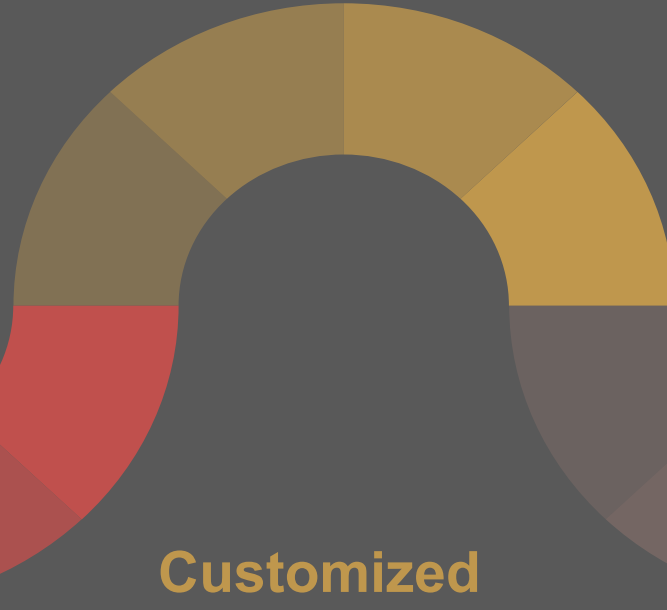
MIPP Competitive Intelligence

Roles & Responsibilities



**7 Therapeutic
Areas**

Support R&D in all
indications of interest



**Customized
Assessments**

With a focus on the
science



**40+ Projects
Annually**

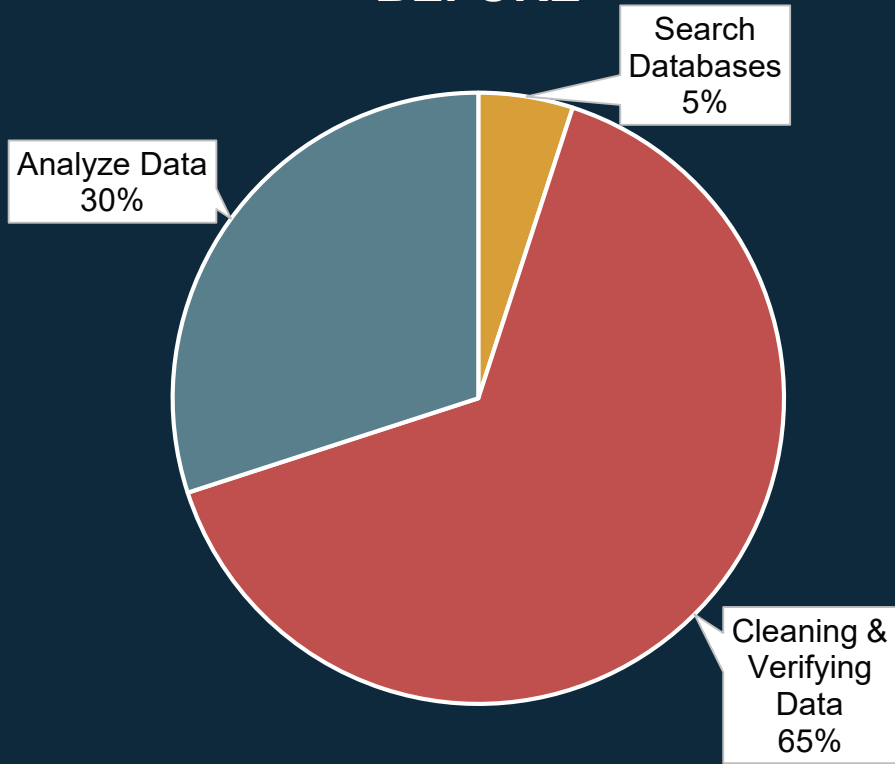
Average of 1.5 weeks per
indication



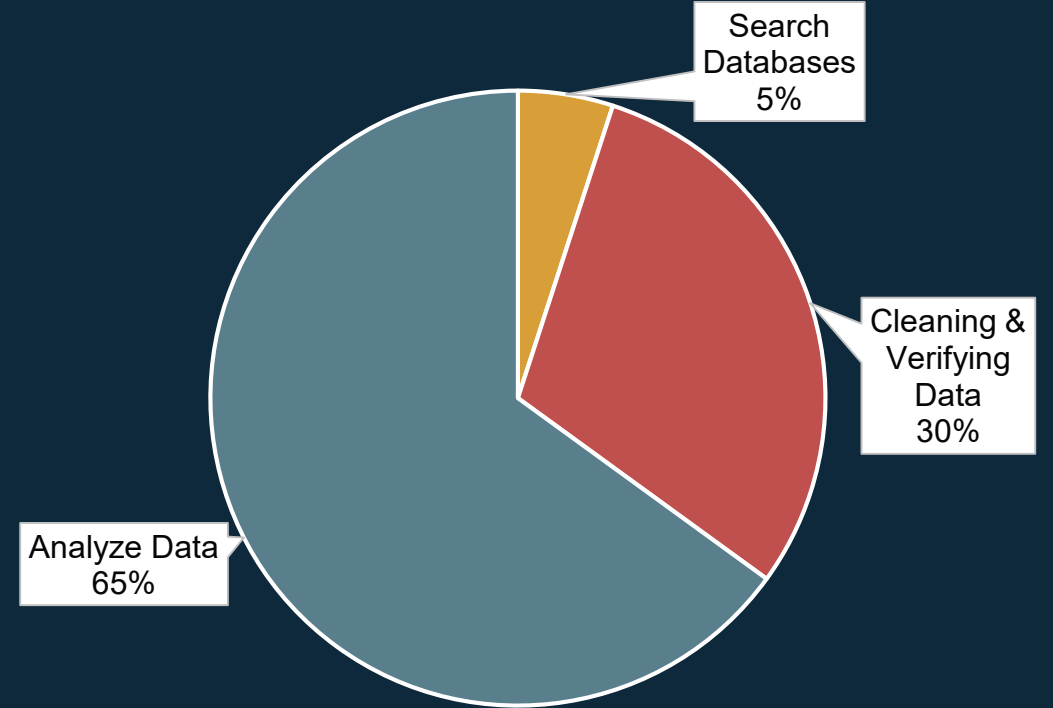
**Creative
Outputs**

High level CI overviews to
guide project direction

BEFORE



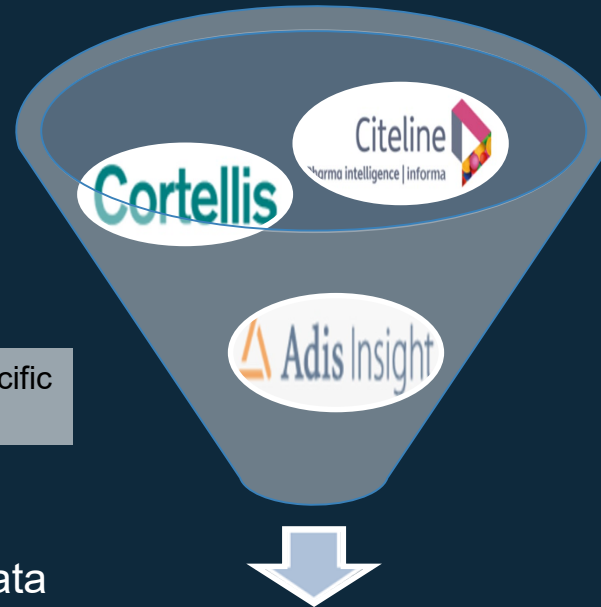
CURRENT



OPTIMIZING CI EFFICIENCY

① Search Databases

- ◆ Indication Specific
- ◆ MOA Specific



② Cleaning & Verifying Data



Initial information
download

Cleaning &
consolidation

Additional
verification
processes

Visualizations

Use of standardized templates to
streamline & expedite process

WORKFLOW OVERVIEW

③ Analyze Data

CI Basics:

- ◆ Competitive Landscape
- ◆ Key Competitors Table
- ◆ CI Highlights

Additional customized visualizations

CLEANING & VERIFYING DATA

VantagePoint

- ◆ Export “Final Bizint Template” to VP-SCE and to Excel
- ◆ VP-SCE: create visualizations
- ◆ Excel: create key competitors chart, CI highlights, and other analyses

Bizint v1

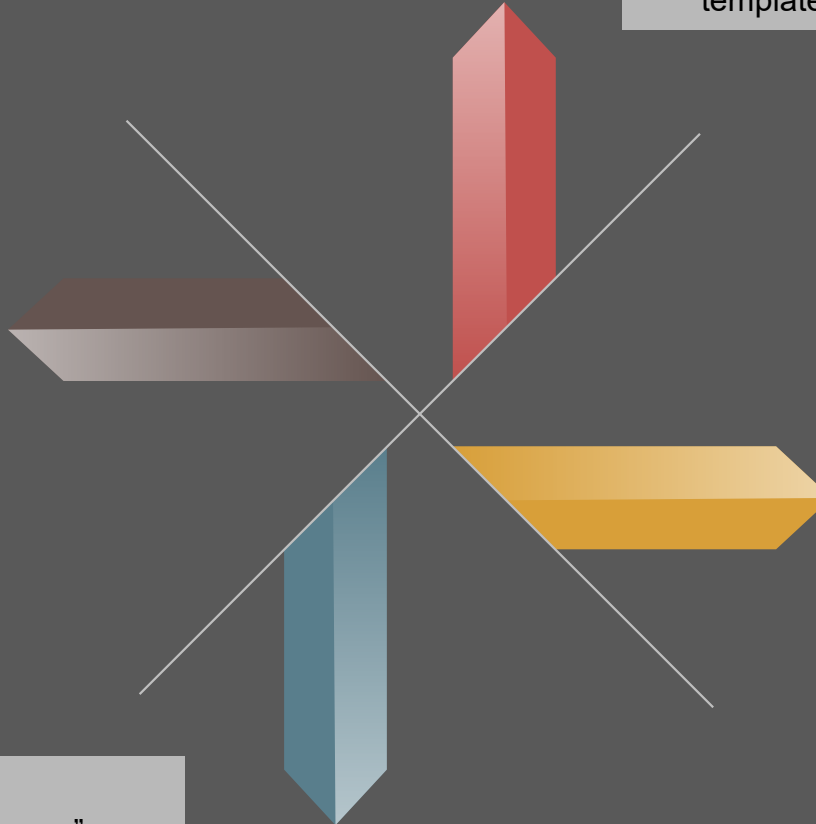
- ◆ Identify common drug names
- ◆ Apply a “Pre-reference rows” template

Reference Rows

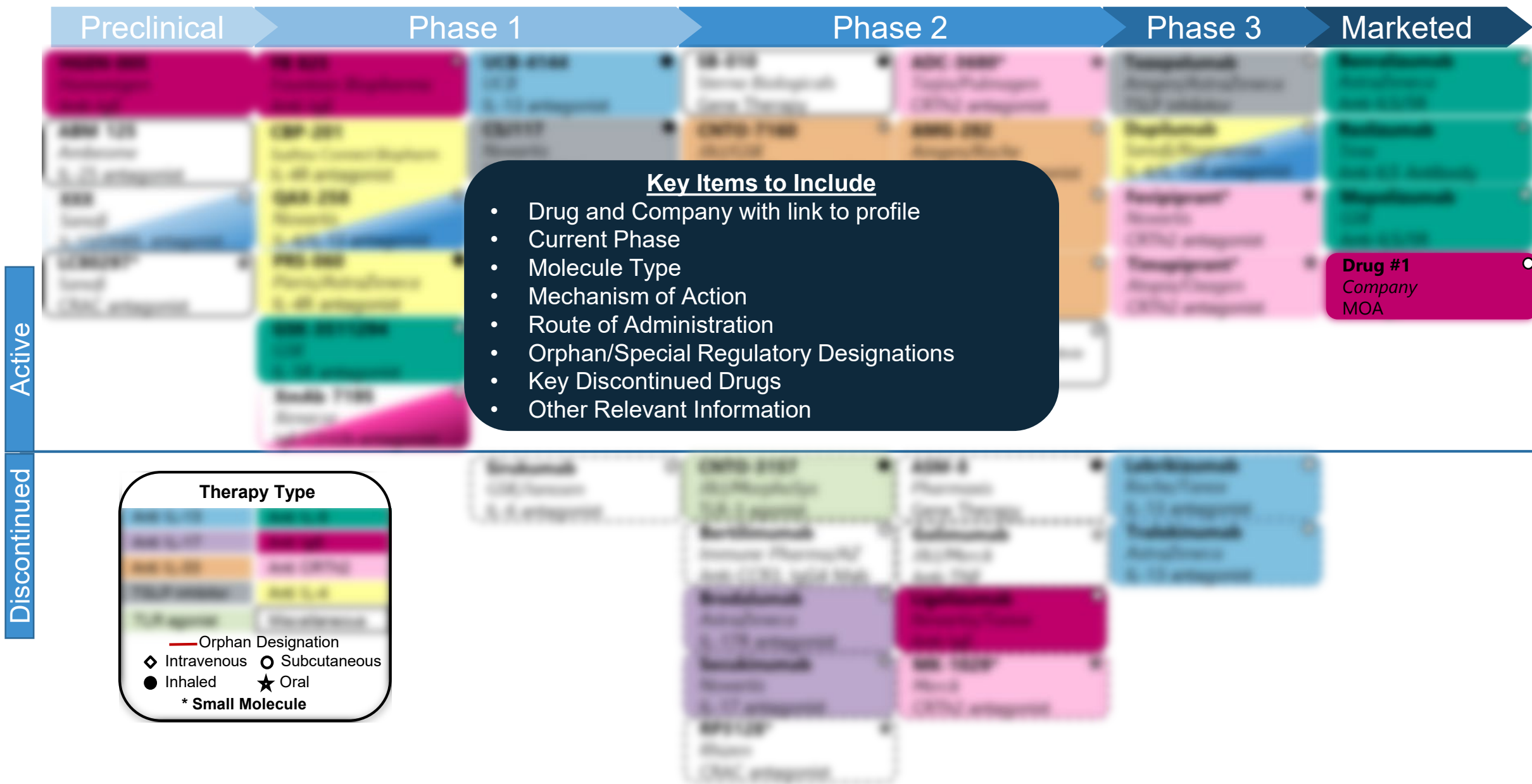
- ◆ Apply “Reference rows template” with custom rules
- ◆ Export & save HTML

Bizint v2







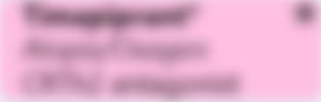
- ◆ Apply “Post-reference rows” template
- ◆ Toggle between Bizint & Reference Rows
- ◆ Make edits directly onto Bizint



Landscape Creation: Example



Key Competitors Chart: Example

Competitor	Status	Description	Clinical Trials	Outcomes
	Marketed	BC pills targeting L-1 receptor indicated for add-on maintenance of severe eosinophilic asthma in ages 18+	IMPACT program: Phase 3 association trials (IMPACT, CALDER, C3) ongoing since 2016/18	US approval Nov 2017
	Marketed	BC pills targeting IL-5 indicated for add-on maintenance of severe eosinophilic asthma age 18+	IMPACT Phase 3 trial supported approval: BC formulation (Phase 3) NOT INDICATED/terminated	US approval Mar 2018
	Marketed	BC light BC pills for add-on maintenance of severe eosinophilic asthma age 18+ as 2018 product	Phase 3 trial presented May 2018	US approval Dec 2018 Similar safety & efficacy to marketed
Drug #1 Company MOA	Marketed	BC with light BC pills for persistent asthma	Phase 3 trial supported approval: 2018, secondary in 2018	US approval for 12+ 2018 Approval for 18+ Jul 2018
	Marketed	BC respiratory pills against L-1 and L-13 signaling with food & fluids. First for maintenance of mild to severe persistent asthma in age 18+	LIBERTY QUEST & VENTURE Phase 3 trials support sBLA	FDA/EMA Dec 20, 2018
	Phase II	BC fully human pills against TSLP and TSLPR (17A class). Upstream BTK has potential to treat wider range of patients. In 2014, positive opinion from EMA's Pediatric Committee	SCIENCE & INNOVATION Phase 3 trial began Dec 2017. Interim results show reduction up to 71% of exacerbations	Breakthrough designation US, EU & Japanese Signs expected 2021
	Phase II	BC small molecule, PDE4/5H2 antagonist (17A class). Dual approach: inhibit eosinophils while stopping inflammation & repairing damage	Dec 2017: Two Phase 3 trials (LUSTRO) add-on to BC, stratified by blood eosinophils in 12+	Phase 3 trial (P3) treatment in 20 yrs. NDA submission in 2019
	Phase II	BC small molecule, PDE4/5H2 antagonist for mild to severe persistent eosinophilic asthma	Ongoing Phase 3 trial in Russia (enrollment complete). Observing L-13, L-4, and L-4 as biomarkers	Phase 3 results show improvement equivalent to high-dose ICS

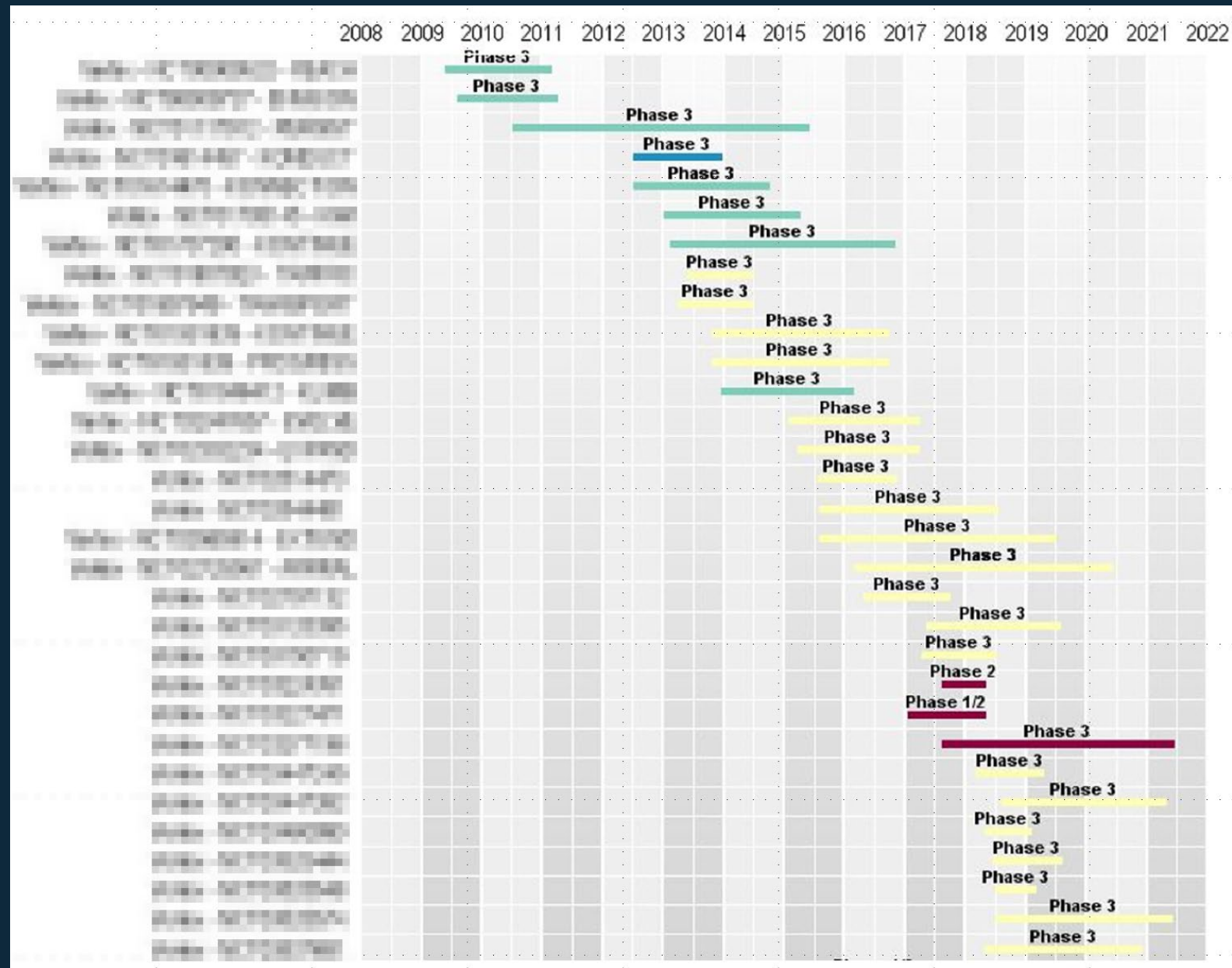
Quick, Easy, & Informative

- Already generated as part of the “Cleaning & Verifying Data” process
- Limits duplicative work

CUSTOMIZED ANALYSES: EXAMPLES

OVERVIEW				DESCRIPTION	
Drug	Investigative Drug(s)	Company	Indication	MOL Type	Monoclonal antibody used intravenously
Indications	Auto-inflammatory	Auto-inflammatory		MOA	Anti-IL-1β antibody
Phase	Phase III	Phase III		Phase III results showing efficacy and safety in patients with auto-inflammatory diseases.	
Regulatory	Approved (FDA, EMA, etc.)	Phase III, Phase IV		RECENT NEWS	
Route	IV	Schedule	Phase III	Phase III results showing efficacy and safety in patients with auto-inflammatory diseases.	
Patents	Patent status: Active (US, EU, etc.)				Phase III results showing efficacy and safety in patients with auto-inflammatory diseases.
Key Dates	Key dates: Phase III completion (2023), FDA approval (2024)				Phase III results showing efficacy and safety in patients with auto-inflammatory diseases.
CLINICAL TRIALS SUMMARY				SWOT ANALYSIS	
				Strengths	Weaknesses
<p>Phase III Results:</p> <ul style="list-style-type: none">Significant reduction in disease activity (p < 0.001) compared to placebo.Highly effective in patients with moderate to severe disease.Well-tolerated with no serious adverse events. <p>Phase IV Results:</p> <ul style="list-style-type: none">Continued efficacy and safety in long-term follow-up.Significant reduction in disease activity (p < 0.001) compared to placebo.Highly effective in patients with moderate to severe disease.				<ul style="list-style-type: none">Highly effective in patients with moderate to severe disease.Significant reduction in disease activity (p < 0.001) compared to placebo.Highly effective in patients with moderate to severe disease.	
				Opportunities	Threats
<p>Safety:</p> <ul style="list-style-type: none">No serious adverse events.Highly effective in patients with moderate to severe disease.Significant reduction in disease activity (p < 0.001) compared to placebo. <p>Efficacy:</p> <ul style="list-style-type: none">Highly effective in patients with moderate to severe disease.Significant reduction in disease activity (p < 0.001) compared to placebo.Highly effective in patients with moderate to severe disease.				<ul style="list-style-type: none">Highly effective in patients with moderate to severe disease.Significant reduction in disease activity (p < 0.001) compared to placebo.Highly effective in patients with moderate to severe disease.	

CUSTOMIZED ANALYSES: EXAMPLES

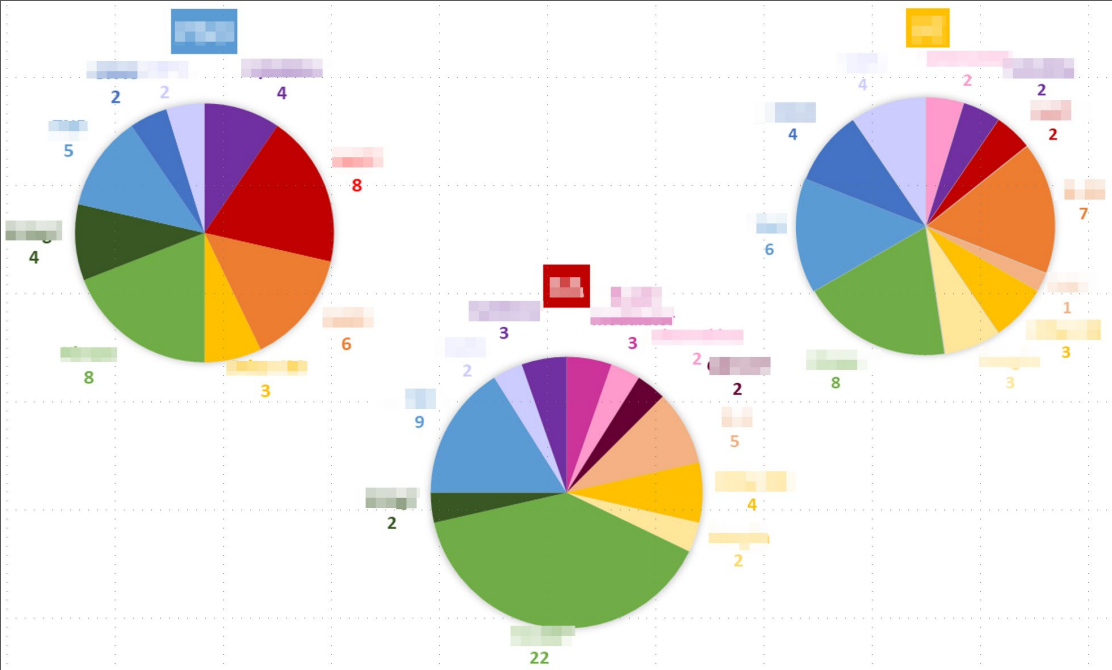


Drug	MOA	PD1	PD1b	VE	CD	MA	MS	MS	MS
Indinavir (Viracept)	PI	Mkt	Mkt	Mkt	Mkt	Mkt	Mkt		
Didanosine (Videx)	PI	Mkt	Mkt		Mkt	Mkt	Mkt		
Zalcitabine (Ziagen)	PI	Mkt	Mkt		II: D/C	Mkt	Mkt		II: D/C
Abacavir (Ziagen)	PI		Mkt	Mkt		Mkt	Mkt		
Indinavir (Viracept)	PI	Mkt	Mkt	Mkt	Mkt	Mkt	Mkt		
Didanosine	PI		I: D/C		I: D/C	IIb/III	I: D/C		
Didanosine (Pall)	II-III	Mkt	Mkt Japan		II: D/C	II: D/C	III Japan		
Didanosine	II-III	III	II	II: D/C		II: D/C	II		
Didanosine	II-III	III	III				III		
Indinavir (Viracept)	II-III	Mkt	Mkt			II: D/C	III		
Didanosine (Videx)	II-III	Mkt	Mkt		II: D/C	III: D/C	Mkt	II	

CUSTOMIZED
ANALYSES:
EXAMPLES



MOAs by Indication



CONCLUSION

FINAL THOUGHTS

- ◆ Standardized process using Bizint, Reference Rows, and VantagePoint has significantly increased CI efficiency & accuracy
- ◆ Cross-checking and consolidating information is still time consuming
- ◆ Ability to directly edit on Reference Rows would be optimal
- ◆ While VantagePoint visualizations are useful, ability to customize landscapes would further streamline CI process



Thank you

Any questions or comments?