

Real-time Interactive Dashboard for Clinical Trials

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Motivation

- There are numerous opportunities to improve the clinical trial monitoring, data visualization and analytics in the clinical development process, particularly in Phase 2 and 3 trials
- As a clinical statistician working in a small organization, I need a versatile data tool to more efficiently collaborate with the team

A versatile data tool

- ❑ Dashboard: host various clinical data and informative good-looking visuals
- ❑ Interactive: freely explore data by mouse click in the interface
- ❑ Real-time: “one click” ready whenever needed
- ❑ Programmable: generate advanced logic, formula, statistics
- ❑ Sharable: easy and secure access

A versatile data tool

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Microsoft Power BI can achieve the goal with following features:

- ✓ Raw data import
- ✓ Visuals options and extensions
- ✓ Interactive function (filter, measure, tooltip)
- ✓ DAX and Power Query
- ✓ Refresh and publish
- ✓ Others

AE Table and Listing

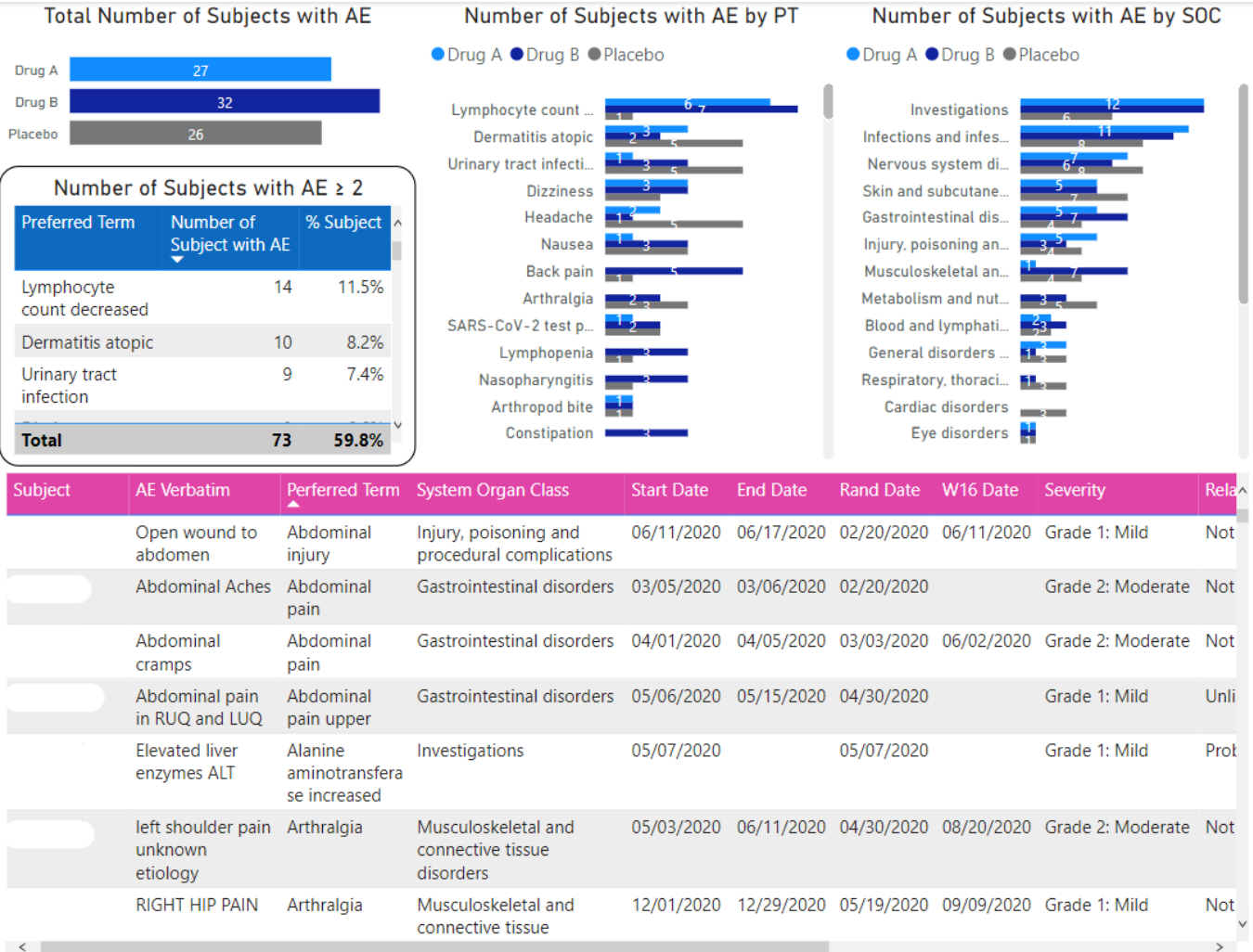
Table 14.3. Summary of Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Double Blind Treatment Period
Safety Set

System Organ Class	Drug A	Drug B	Placebo	Total
Preferred Term				
Subjects with any TEAE, n (%)	19 (40.4)	31 (66.0)	22 (47.8)	72 (51.4)
Blood and lymphatic system disorders				
Lymphopenia	3 (6.4)	2 (4.3)	1 (2.2)	6 (4.3)
Iron deficiency anaemia	0 (0.0)	2 (4.3)	0 (0.0)	2 (1.4)
Leukopenia	1 (2.1)	0 (0.0)	0 (0.0)	1 (0.7)
Thrombocytopenia	1 (2.1)	0 (0.0)	0 (0.0)	1 (0.7)
Coagulopathy	0 (0.0)	0 (0.0)	1 (2.2)	1 (0.7)
Ear and labyrinth disorders				
Excessive cerumen production	2 (4.3)	0 (0.0)	0 (0.0)	2 (1.4)
Meniere's disease	1 (2.1)	0 (0.0)	0 (0.0)	1 (0.7)
Eye disorders				
Dry eye	1 (2.1)	1 (2.1)	0 (0.0)	2 (1.4)
Eyelid cyst	0 (0.0)	1 (2.1)	0 (0.0)	1 (0.7)
	1 (2.1)	0 (0.0)	0 (0.0)	1 (0.7)

Listing 16. Adverse Events
Full Analysis Set

Subject ID	Study Period/ AE #	MedDRA SOC Term/ MedDRA Preferred Term	Treatment-emergent? [1]/ Onset Date (Day) - SAE: End Date (Day) [2] Criteria?	Outcome/ CTCAE Severity [3]	Relationship to Study Treatment/ Action taken with Study Treatment	Treatment of Event	TME	TME Category/ Subcategory
	DB/1	Infections and infestations/ Influenza/ (Influenza B infection)	Yes/ 11FEB2020 (8) - 16FEB2020 (13)	No	Recovered/R esolved/ Grade 2	None	No	
	OLE/1	Infections and infestations/ Gastroenteritis viral/ (Viral Gastroenteritis)	Yes/ 22OCT2020 (332) - 26OCT2020 (336)	No	Recovered/R esolved/ Grade 1	None	No	

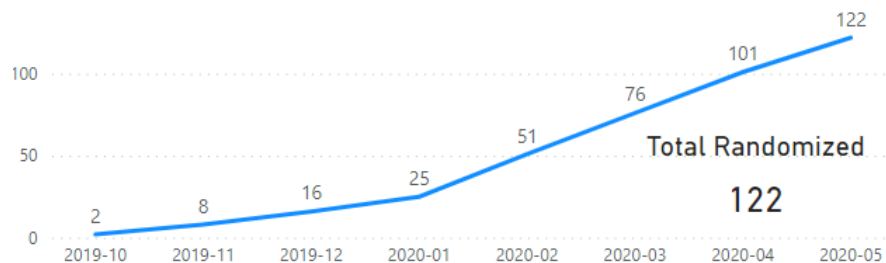
Dashboard



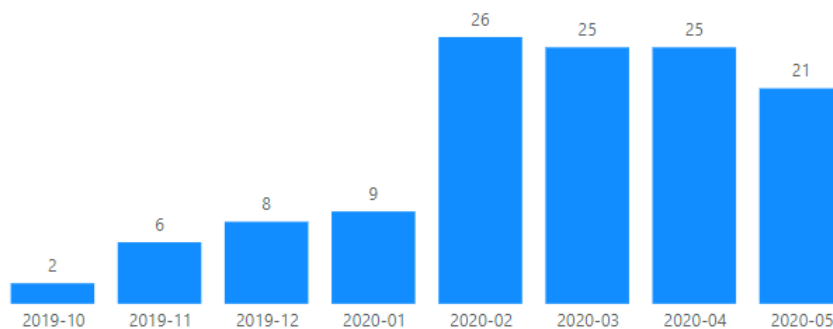
Subject	AE Verbatim	Perferred Term	System Organ Class	Start Date	End Date	Rand Date	W16 Date	Severity	Rela
	Open wound to abdomen	Abdominal injury	Injury, poisoning and procedural complications	06/11/2020	06/17/2020	02/20/2020	06/11/2020	Grade 1: Mild	Not
	Abdominal Aches	Abdominal pain	Gastrointestinal disorders	03/05/2020	03/06/2020	02/20/2020		Grade 2: Moderate	Not
	Abdominal cramps	Abdominal pain	Gastrointestinal disorders	04/01/2020	04/05/2020	03/03/2020	06/02/2020	Grade 2: Moderate	Not
	Abdominal pain in RUQ and LUQ	Abdominal pain upper	Gastrointestinal disorders	05/06/2020	05/15/2020	04/30/2020		Grade 1: Mild	Unli
	Elevated liver enzymes ALT	Alanine aminotransfera se increased	Investigations	05/07/2020		05/07/2020		Grade 1: Mild	Prot
	left shoulder pain unknown etiology	Arthralgia	Musculoskeletal and connective tissue disorders	05/03/2020	06/11/2020	04/30/2020	08/20/2020	Grade 2: Moderate	Not
	RIGHT HIP PAIN	Arthralgia	Musculoskeletal and connective tissue	12/01/2020	12/29/2020	05/19/2020	09/09/2020	Grade 1: Mild	Not

Enrollment and Status

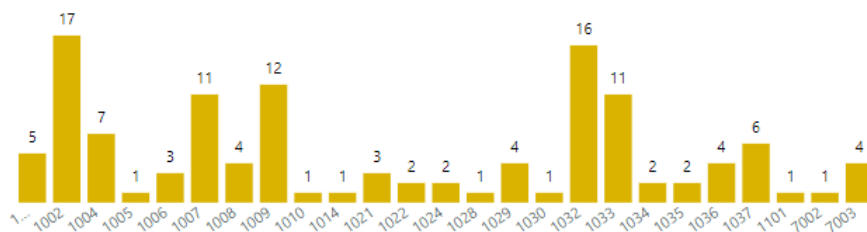
Cumulative Randomization Over Time



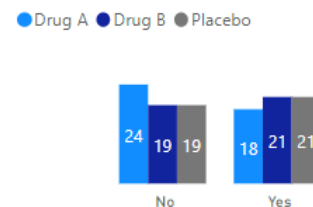
Monthly Randomization Over Time



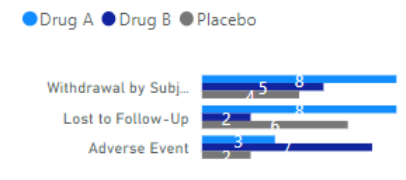
Randomization by Site



Study Completion



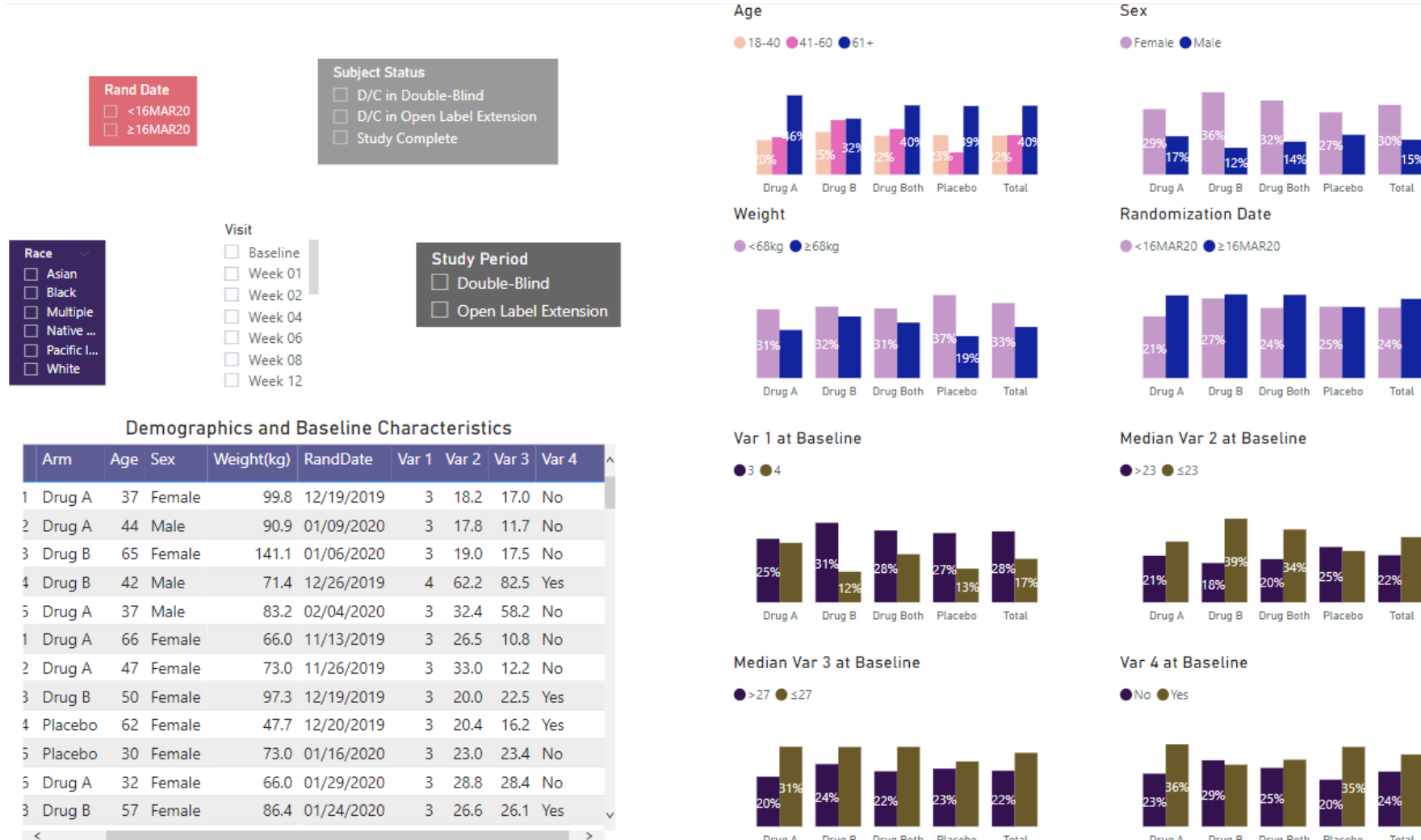
Primary Reason for Study Discontinuation



Study and Treatment Completion Status

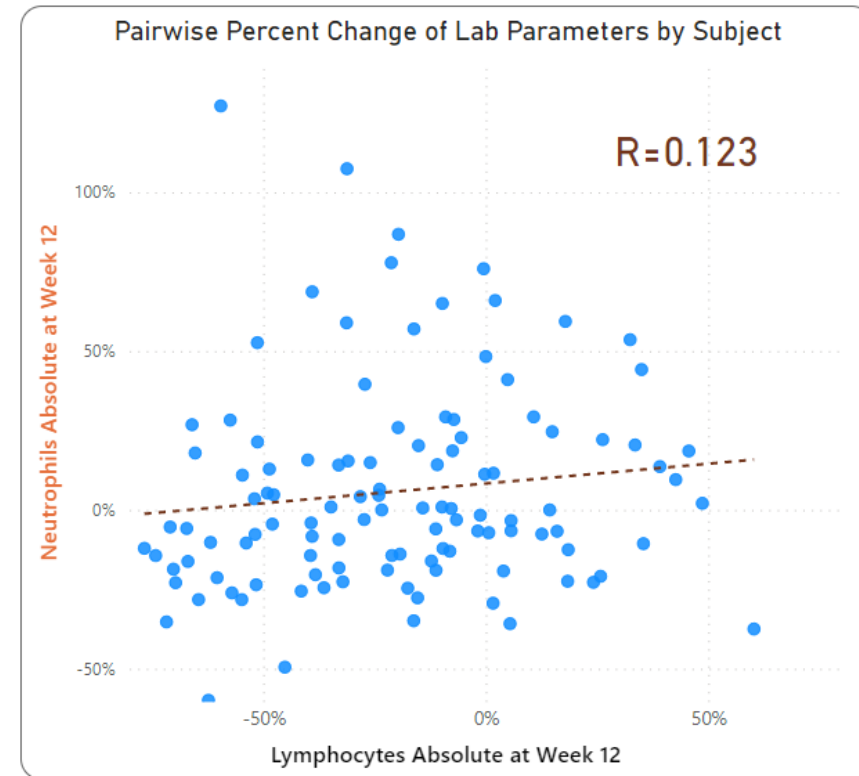
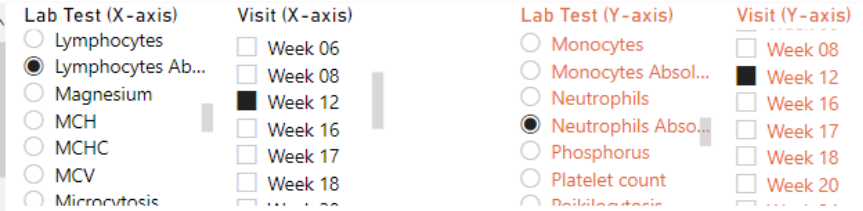
Study Complete	Primary Reason	Treatment Complete	Primary Reason	Last Visit	Last Visit Date	Last Visit Date
No	Failure to meet continuation criteria	No	Failure to meet continuation criteria	Week 16	20/03/16	20/03/16
No	Withdrawal by Subject	No	Withdrawal by Subject	Week 72	20/08/21	20/08/21
Yes		Yes		Week 72	21/04/28	21/04/28
No	Other	No	Other	Week 08	20/02/19	20/02/19
No	Lost to Follow-Up	No	Lost To Follow-up	Week 12	20/04/27	20/04/27
Yes		Yes		Week 72	21/03/04	21/03/04
Yes		Yes		Week 72	21/03/16	21/03/16
Yes		Yes		Week 72	21/04/08	21/04/08
Yes		Yes		Week 72	21/04/06	21/04/06
Yes		Yes		Week 72	21/05/06	21/05/06
Yes		Yes		Week 72	21/05/10	21/05/10

Subgroup Analysis



Exploratory Analysis

Lab Test (X)	Visit (X)	% Change (X)	Subject	% Change (Y)	Visit (Y)	Lab Test (Y)
Lymphocytes Absolute	Week 12	-62%		-60%	Week 12	Neutrophils Absolute
Lymphocytes Absolute	Week 12	-23%		0%	Week 12	Neutrophils Absolute
Lymphocytes Absolute	Week 12	-70%		-23%	Week 12	Neutrophils Absolute
Lymphocytes Absolute	Week 12	-52%		4%	Week 12	Neutrophils Absolute
Lymphocytes Absolute	Week 12	-27%		40%	Week 12	Neutrophils Absolute
Lymphocytes Absolute	Week 12	-0%		76%	Week 12	Neutrophils Absolute
Lymphocytes Absolute	Week 12	-11%		14%	Week 12	Neutrophils Absolute
Lymphocytes Absolute	Week 12	-11%		-19%	Week 12	Neutrophils Absolute
Lymphocytes Absolute	Week 12	-0%		11%	Week 12	Neutrophils Absolute
Lymphocytes Absolute	Week 12	-7%		-3%	Week 12	Neutrophils Absolute
Lymphocytes Absolute	Week 12	-9%		29%	Week 12	Neutrophils Absolute
Lymphocytes Absolute	Week 12	-10%		1%	Week 12	Neutrophils Absolute
Lymphocytes Absolute	Week 12	-1%		-2%	Week 12	Neutrophils Absolute
Lymphocytes Absolute	Week 12	-49%		5%	Week 12	Neutrophils Absolute
Lymphocytes Absolute	Week 12	-24%		7%	Week 12	Neutrophils Absolute
Lymphocytes Absolute	Week 12	-33%		-18%	Week 12	Neutrophils Absolute
Lymphocytes	Week 12	-10%		-12%	Week 12	Neutrophils



Demo
