Technology Facilitated Collaboration

From a statistician's point of view

Xiaoying Yang
Genentech

A Statistician Works Collaboratively

Clinical Scientist

Safety Scientist

Biomarker Scientist

Programmer

Medical Writer

Many Others

Collaboration with Programmers

OLD Way of Communication

Emails
Request sent and communicated via emails

Implementation
Programmers update code and specifications

Emails
Progress update communicated via emails

NEW Way of Communication

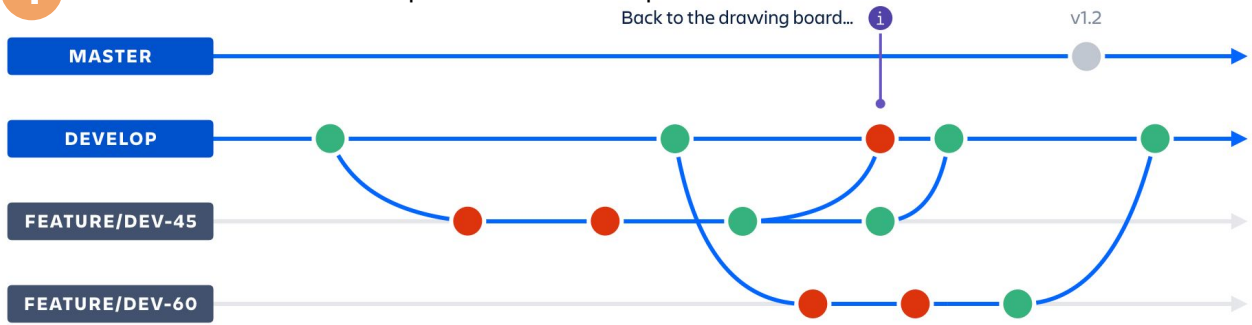
GitHub
Request created and managed on GitHub project board

GitHub
Communications occur within issues with pointer to code

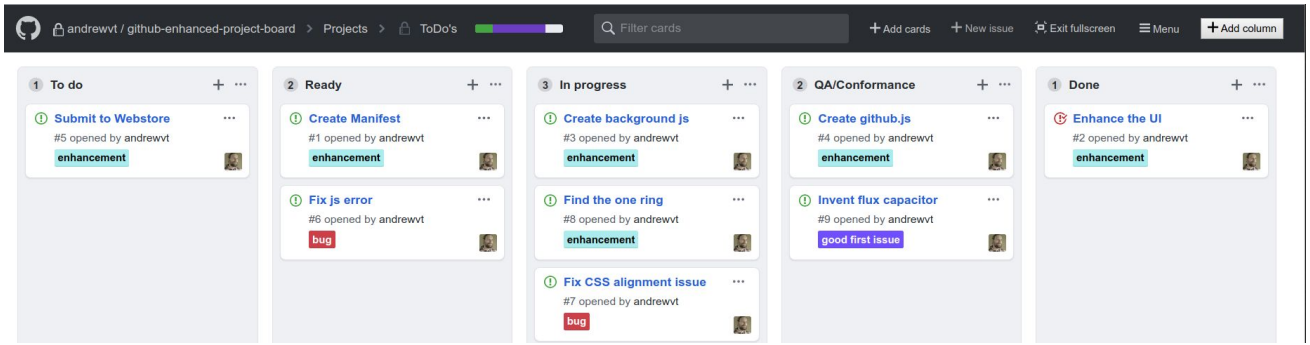
GitHub
Archived issues document discussion for future reference

An Example: GitHub Workflow

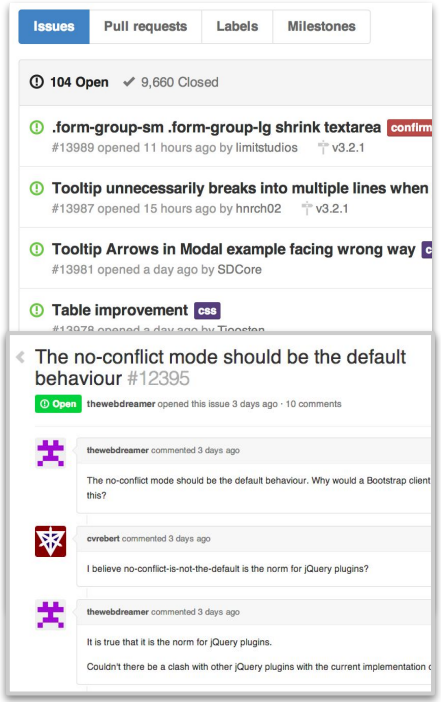
1 Branch structure to enable parallel code development



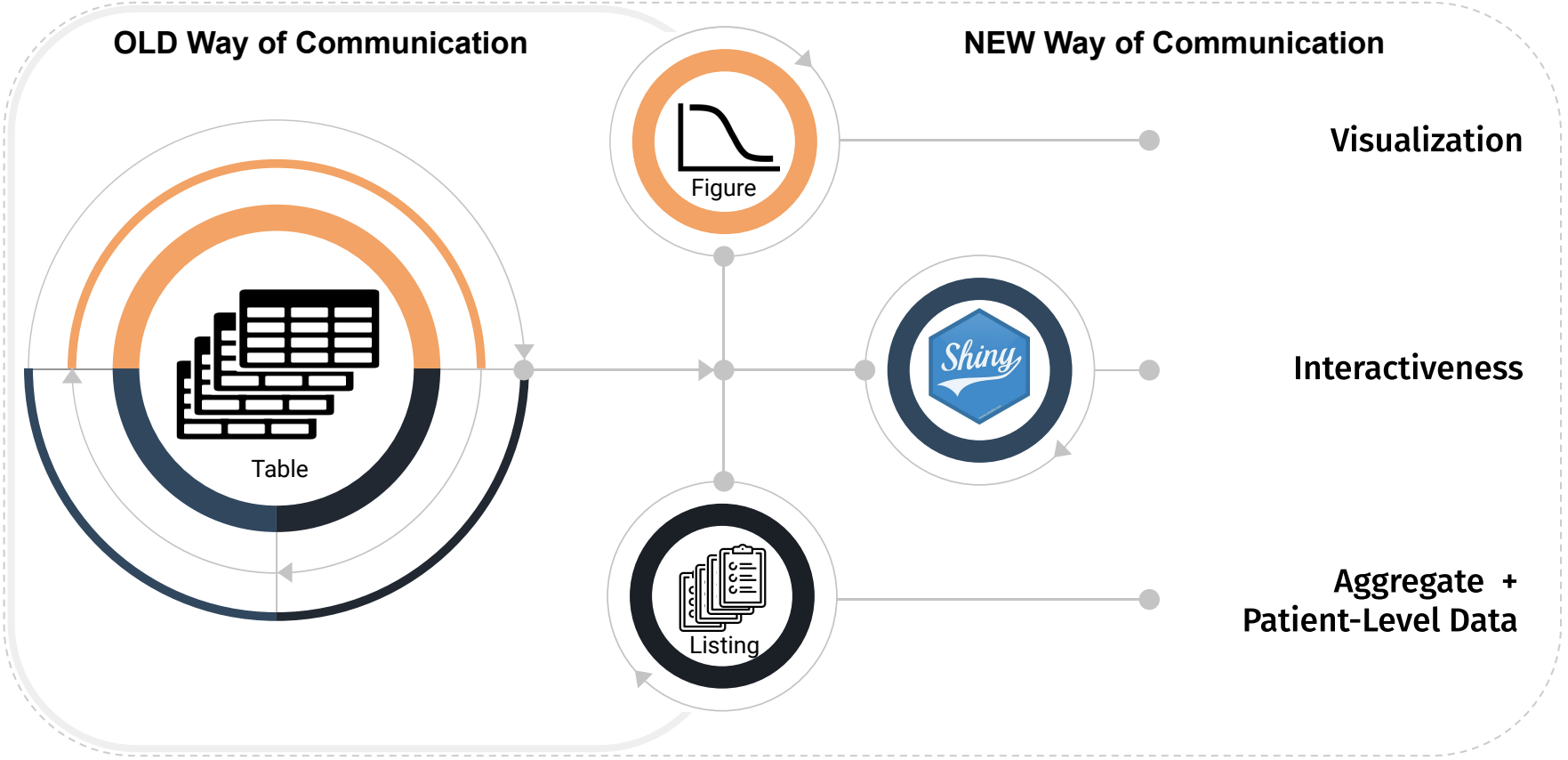
2 Project board to manage task and progress



3 Issue to track and document discussion



Collaborations with Scientists



An Example: Interactive Output Interface

Box Plot | Correlation Plot | Density Distribution Plot | Line Plot | Spaghetti Plot

User-customized visualization

ADLB Data Settings

Select Treatment Variable

ARM Description of Planned Arm

Select a Biomarker

ALT Alanine Aminotransferase Measure

Select an X-Axis Variable

ARM Planned Arm

Select a Y-Axis Variable

AVAL Analysis Value

Facet by

AVISITCD Analysis Visit Window C

Data Constraint

- None
- Screening
- Baseline

Plot Aesthetic Settings

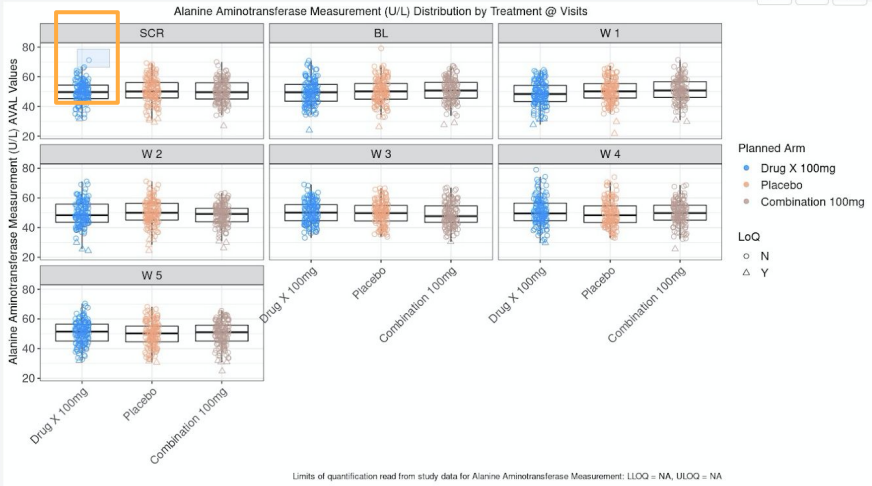
Plot settings

Show R code

Debug info

Imbedded code for reproducibility and debugging

Data point selection to explore outliers



Selected Data Points

Show 10 entries Search:

USUBJID	ARM	AVISITCD	PARAMCD	AVAL	LOQFL
AB12345-CHN-13-id-166	Drug X 100mg	SCR	ALT	71.1933	N

Showing 1 to 1 of 1 entries Previous 1 Next

Dataset	Obs	Subjects
ADSL	400/400	400/400
ADLB	8400/8400	400/400

Active Filter Variables

ADSL

ADLB

Add Filter Variables

ADSL

Select a variable

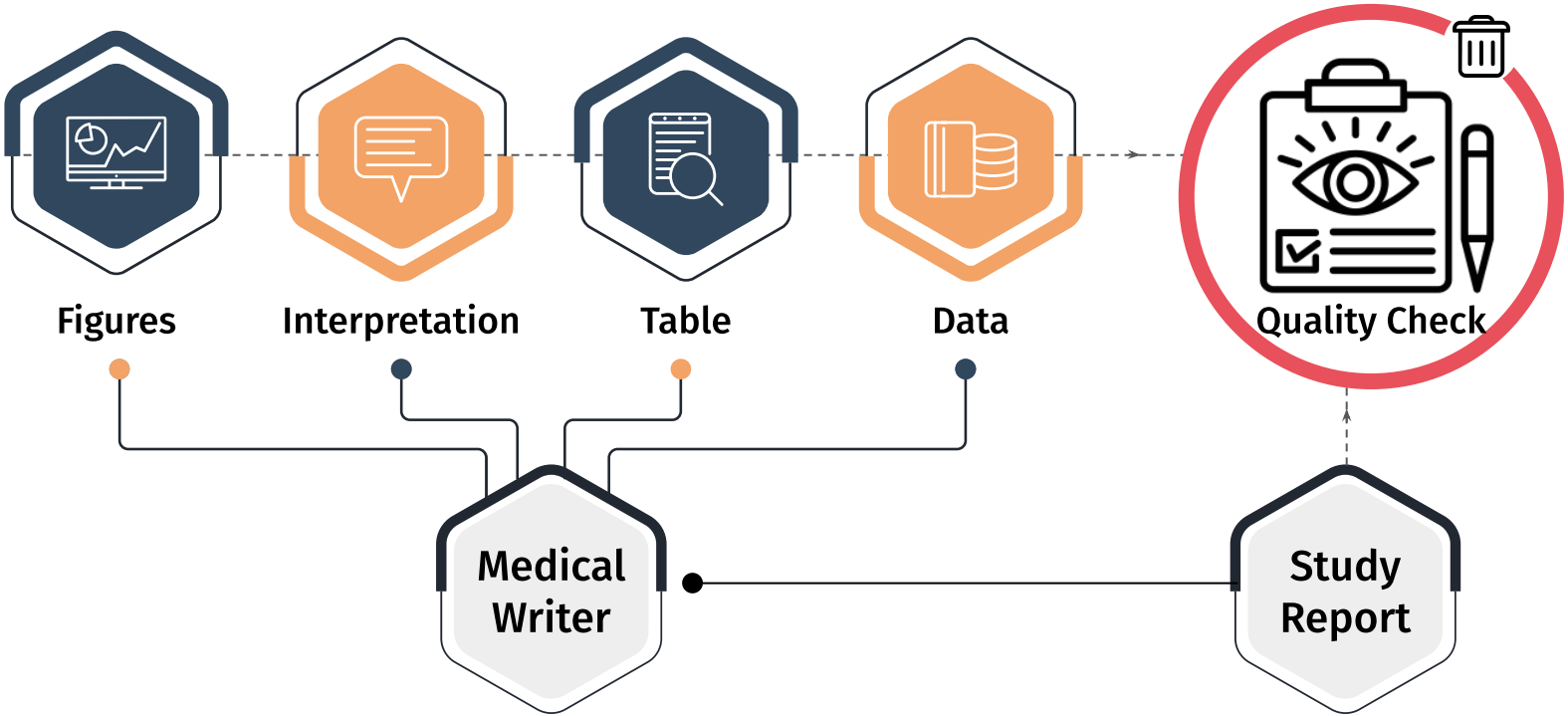
ADLB

Select a variable

Interactive filters for further data exploration

https://rstudio.com/resources/webinars/the-role-of-r-in-drug-discovery-research-and-development/

Collaborations with Medical Writers



An Example: Data-Dependent Writing

Table 9 Asthma Exacerbations During the 52-Week Double-Blind Treatment Period, mITT Population

All Patients

		Placebo	MSTT1041A 70 mg	MSTT1041A 210 mg	MSTT1041A 490 mg
N		127	127	126	122
Number of exacerbations per patient	0				
	1				
	2				
	3				
	4				
	5				
Total number of exacerbations					
Total follow-up time at risk (years)					
Exacerbation rate (per year)					
Unadjusted					
Adjusted					
Absolute rate difference (events/year), adjusted(MSTT1041A-placebo)					
Rate Ratio, adjusted(MSTT1041A/placebo)			0.63	0.78	0.57
95% CI			(0.44, 0.91)	(0.54, 1.12)	(0.39, 0.84)
p-value			0.0144	0.1838	0.0049
Percentage rate reduction, adjusted (MSTT1041A vs. placebo)			36.9%	21.9%	43%

Adjusted exacerbation rates and rate ratio are estimated from a Poisson regression model with over-dispersion adjusted for the following covariates and log(patient time at risk) as offset term: eosinophil level at visit 1 (<150, >=150 to <300, >=300 cells/ul), number of asthma exacerbations requiring the use of systemic corticosteroids within the 12 months prior to the study entry (1-2, >=3 events), total daily ICS dose at visit 1 (< 1000µg, >= 1000 µg of fluticasone propionate or equivalent), and geographic region (North America, Latin America, Central and Eastern Europe, Western Europe and Rest of World).

In the primary efficacy analysis, the highest (490 mg) and lowest (70 mg) doses of MSTT1041A showed a statistically significant reduction over placebo in the incidence of asthma exacerbations after 52 weeks of treatment. However, per the Type I error control strategy, only the highest dose of MSTT1041A met the primary endpoint.

The rate reduction versus placebo in asthma exacerbations after 52 weeks of treatment was 43% for MSTT1014A 490 mg (p=0.0049), 21.9% for MSTT1041A 210 mg (p=0.1838), and 36.9% for MSTT1041A 70 mg (p=0.0144) (Table 9).