Port R ay CTO-db

A Clinical Trial Outcome Meta Database for Informed Decision Making

Chenna Keshava Reddy Sannala
Cytel Statistical Software & Services Pvt. Ltd.

Disclaimer

The opinions expressed in this presentation and on the following slides are solely those of the presenter and not necessarily those of Cytel

This presentation uses simulated data for visualization purpose

Agenda

- Meta data & its sources in clinical trial context
- Need for structured database
- Introducing Clinical Trial Outcome database (CTO-db)
- Portraying applications of integrating visualization capabilities of R to CTO-db

Meta data of clinical trials

What?

- Descriptive and inferential statistics of clinical trial data at trial, arm, treatment or subgroup level

About?

- Efficacy and/or safety of interventions, Trial design and subject characters

Meta data of clinical trials


CLINICAL THERAPEUTICS/NEW TECHNOLOGY

838-P

Leadership for Healthy Lifestyle (LHL) Pilot Intervention: BMI and Fitness Outcomes

DEBORAH YOUNG-HYMAN, HELEN BLOCKER-ADAMS, MARLO VERNON, Augusta, GA

LHL is a 16 week after school intervention teaching middle school youth leadership skills in the areas of nutrition, fitness, critical thinking & problem solving. Sessions contain 45 minutes of focus on improving personal best performance in strength, flexibility and cardiovascular fitness. Among other activities, youth practice leadership skills by rotating leadership during the fitness sessions which are supervised by a certified fitness coach. Youth also chose weekly outside activities to improve fitness.

Of the 39 students (10-14y, 69% AA, 54% F) completing baseline (B), 24 completed final (E) evaluations (62% retention). Mean attendance = 9.5/20 sessions (range 2-15). Youth were weighed, measured, completed the Sit and Reach (flexibility) and Harvard Step Test (heart rate)and had fat measured via calipers.

Mean age and gender CDC BMI remained stable over 16 wks (12.7 vs. 12.5, t= 1.05, p<.3). Tricep and subscapular fat decreased slightly in the expected direction (12.8 vs. 11.8mm, t=1.25, p<.22; 12.1 vs. 10.5mm, t=1.33, p<.20). Ending heart rate decreased slightly from B to E (103 vs. 98, t=1.76, p<.10). Flexibility significantly improved from B to E (21.1 vs. 31 inches, t=-2.5, p<.03).

This school-based empowerment approach produced small but encouraging improvements in fitness and fitness, demonstrating acceptable attendance and a high rate of retention. Highly structured non-sports team interventions that teach leadership as well as fitness skills may show weight gain in this age group and improve cardiovascular health. Such programs need to be tested in other middle schools to further establish feasibility and efficacy. Longer intervention periods could be expected to improve health outcomes.

Supported By: Georgia Regents University

835-P

Executive Dysfunction in Type 2 Diabetes: The Role of High Blood Pressure and Body Mass Index

MOISE-DENIS K. JEAN, OLUSOLA AJILORE, Chicago, IL

This study determines variables that play a role in executive dysfunction in patients with Type 2 diabetes. This cross-sectional study uses data from a neuroimaging study focused on depression and diabetes. Data was collected from 47 healthy control (HC) and 63 subjects with Type 2 diabetes (T2D).

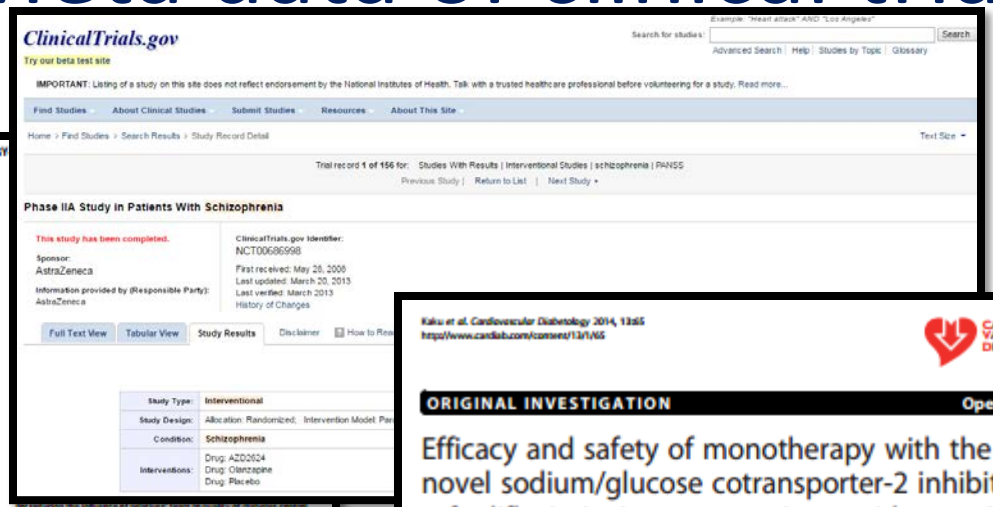
To measure cognition, neuropsychological tests were administered. Tests were calculated into z-scores and analyzed by SPSS through t-tests, chi-square, and ANOVA. Compared to HC, T2D had significantly worse cognitive z-scores (HC: 0.0791 +/- 0.5722, T2D: -0.4630 +/- 0.8348, p<0.001). No demographic difference existed other than age. HC had higher scores even after controlling for age(p<0.001).

As expected, T2D had higher hemoglobin A1c (p<0.001). In addition, T2D had higher systolic blood pressure(SBP)(p=0.001), BMI(p<0.001), HDL cholesterol(p<0.001), C-reactive protein(p=0.039), and triglycerides(p=0.041). When controlled individually, executive function scores between groups were still significantly different, but when controlling for both BMI and SBP were the scores statistically similar(p=0.059).

In line with literature, Type 2 diabetes is associated with executive dysfunction. This impairment is most likely related to hypertension and obesity in these patients. These results indicate that proper management of these risk factors may mitigate cognitive impairment associated with type 2 diabetes.

Supported By: NIMH

For author disclosure information, see page A743.


ClinicalTrials.gov

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Trial record 1 of 156 for: Studies With Results | Interventional Studies | schizophrenia | PANSS

Previous Study | Return to List | Next Study

Phase IIA Study in Patients With Schizophrenia

This study has been completed.

Sponsor: AstraZeneca

Information provided by (Responsible Party): AstraZeneca

ClinicalTrials.gov Identifier: NCT00686998

First received: May 26, 2008
Last updated: March 20, 2013
Last verified: March 2013
History of Changes

Full Text View | Tabular View | Study Results | Disclaimer | How to Read

Study Type:	Interventional
Study Design:	Allocation: Randomized; Intervention Model: Par
Condition:	Schizophrenia
Interventions:	Drug: AZD2624 Drug: Olanzapine Drug: Placebo

CLINICAL THERAPEUTICS/NEW TECHNOLOGY—GLUCOSE MONITORING AND SENSING

Guided Audio Tour: Advances in Glucose Monitoring (Posters 833-P to 840-P), see page 12.

833-P

A Randomized Trial on Home Telemonitoring for the Management of Metabolic and Cardiovascular Risk in Patients with Type 2 Diabetes

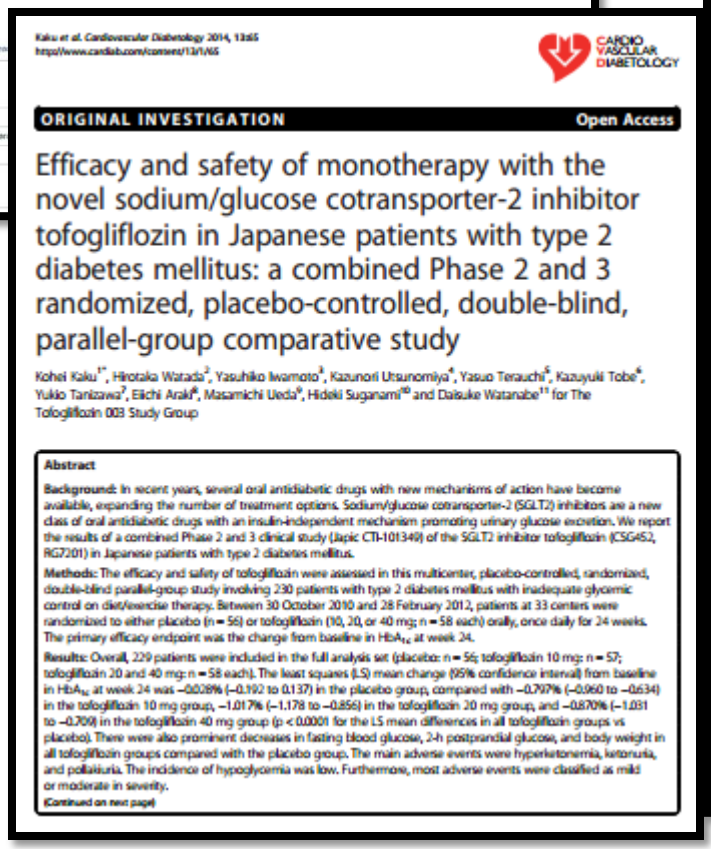
ANTONIO NICOLUCCI, STEFANIA CERCONE, ALBERTO CHIRATTI, FABRIZIO MUSCAS, GIANFRANCO GENSINI, Sesto Mona Imbaro, Italy, Rome, Italy, Florence, Italy

The opportunity to utilize telemedicine systems combining home monitoring with remote educational interventions promoting self-care and treatment compliance represents an appealing innovation. The primary aim of this randomized trial was to evaluate whether a home telehealth system (HTS) enabling the patient to monitor body weight, blood glucose values and blood pressure values, associated with remote educational support and feedback to the general practitioner, can improve metabolic control and overall cardiovascular risk in individuals with T2DM, as compared to usual practice.

Overall, 29 general practitioners enrolled 382 patients, of whom 153 were assigned to the HTS group (114 received intervention) and 149 to the control group (135 received intervention). Over a period of 12 months, the use of HTS was associated with a statistically significant reduction in HbA1c levels as compared to the control group (estimated mean difference 0.33±0.1; p=0.001). No difference emerged as for body weight, blood pressure, and lipid profile. The proportion of patients reaching the target of HbA1c <7.0 was higher in the HTS group after 6 (33.3% vs. 18.7%; p=0.0001) and 12 months (28.1% vs. 18.5%; p=0.01). In terms of quality of life, as measured with the SF-36 Health Survey, between group comparison showed significant differences in favor of the HTS group as for physical functioning (p=0.01), role limitations due to emotional problems (p=0.03), mental health (p=0.005), and mental component summary score (p=0.03). As for resource utilization, the two groups did not significantly differ in terms of hospital admissions and home visits, while a lower number of specialist visits was reported in the telemedicine group (incidence rate ratio 0.72; 95%CI 0.51-1.01; p=0.06). In conclusion, the use of HTS was associated with better metabolic control and quality of life and lower resource utilization. No impact was documented on blood pressure, lipid profile and body weight.

Supported By: Merci Strap & Zahne Corp.

Guided Audio Tour poster | ADA-Funded Research


Kaku et al. Cardiovascular Diabetology 2014, 13:65
http://www.cardiab.com/content/13/1/65

CARDIOVASCULAR DIABETOLOGY

ORIGINAL INVESTIGATION Open Access

Efficacy and safety of monotherapy with the novel sodium/glucose cotransporter-2 inhibitor tofogliflozin in Japanese patients with type 2 diabetes mellitus: a combined Phase 2 and 3 randomized, placebo-controlled, double-blind, parallel-group comparative study

Kohei Kaku[1*], Hirotaka Watada[2], Yasuhiko Iwamoto[3], Kazunori Utsunomiya[4], Yasuo Terauchi[5], Kazuyuki Tobe[6], Yukio Tanizawa[7], Eiichi Araki[8], Masamichi Ueda[9], Hideki Suganami[10] and Daisuke Watanabe[11] for The Tofogliflozin 003 Study Group

Abstract

Background: In recent years, several oral antidiabetic drugs with new mechanisms of action have become available, expanding the number of treatment options. Sodium/glucose cotransporter-2 (SGLT2) inhibitors are a new class of oral antidiabetic drugs with an insulin-independent mechanism promoting urinary glucose excretion. We report the results of a combined Phase 2 and 3 clinical study (Japic CTI-101349) of the SGLT2 inhibitor tofogliflozin (CSG452, RG7201) in Japanese patients with type 2 diabetes mellitus.

Methods: The efficacy and safety of tofogliflozin were assessed in this multicenter, placebo-controlled, randomized, double-blind parallel-group study involving 230 patients with type 2 diabetes mellitus with inadequate glycemic control on diet/exercise therapy. Between 30 October 2010 and 28 February 2012, patients at 33 centers were randomized to either placebo (n = 56) or tofogliflozin (10, 20, or 40 mg; n = 58 each) orally, once daily for 24 weeks. The primary efficacy endpoint was the change from baseline in HbA_{1c} at week 24.

Results: Overall, 229 patients were included in the full analysis set (placebo: n = 56; tofogliflozin 10 mg: n = 57; tofogliflozin 20 and 40 mg: n = 58 each). The least squares (LS) mean change (95% confidence interval) from baseline in HbA_{1c} at week 24 was −0.08% (−0.192 to 0.137) in the placebo group, compared with −0.797% (−0.960 to −0.634) in the tofogliflozin 10 mg group, −1.017% (−1.178 to −0.856) in the tofogliflozin 20 mg group, and −0.870% (−1.031 to −0.709) in the tofogliflozin 40 mg group ($p < 0.0001$ for the LS mean differences in all tofogliflozin groups vs placebo). There were also prominent decreases in fasting blood glucose, 2-h postprandial glucose, and body weight in all tofogliflozin groups compared with the placebo group. The main adverse events were hyperketonemia, ketonuria, and pollakiuria. The incidence of hypoglycemia was low. Furthermore, most adverse events were classified as mild or moderate in severity.

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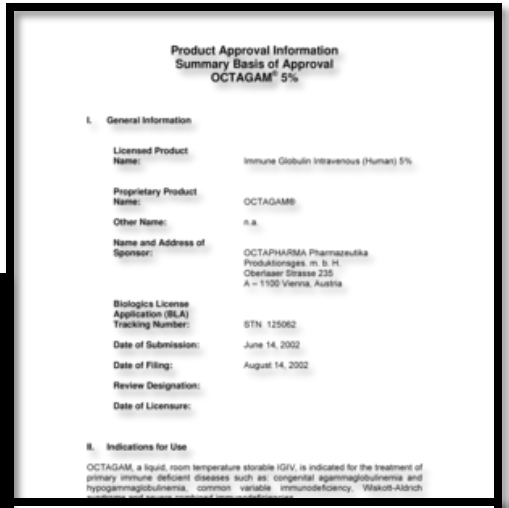
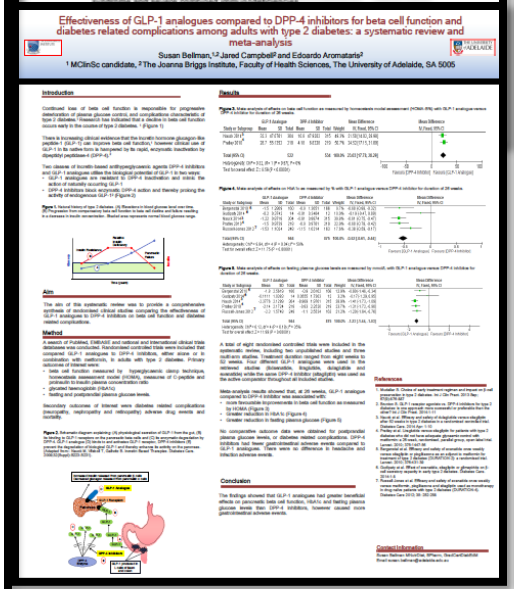

Product Approval Information
Summary Basis of Approval
OCTAGAM® 5%

I. General Information

Licensed Product Name:	Immune Globulin Intravenous (Human) 5%
Proprietary Product Name:	OCTAGAM®
Other Name:	n.a.
Name and Address of Sponsor:	OCTAPHARMA Pharmazeutika Produktionsges. m. b. H. Oberlaaer Strasse 235 A – 1100 Vienna, Austria
Biologics License Application (BLA) Tracking Number:	STN: 125062
Date of Submission:	June 14, 2002
Date of Filing:	August 14, 2002
Review Designation:	
Date of Licensure:	

II. Indications for Use

OCTAGAM, a liquid, room temperature storable IGIV, is indicated for the treatment of primary immune deficient diseases such as: congenital agammaglobulinemia and hypogammaglobulinemia, common variable immunodeficiency, Wiskott-Aldrich


Effectiveness of GLP-1 analogues compared to DPP-4 inhibitors for beta cell function and diabetes related complications among adults with type 2 diabetes: a systematic review and meta-analysis

Susan Bellman[1,2], Jared Campbell[2] and Edoardo Aromataris[2]

[1] MClinSc candidate, [2] The Joanna Briggs Institute, Faculty of Health Sciences, The University of Adelaide, SA 5005

Introduction

Results

Aim

Method

Conclusion

References

17-JUN-2017

PhUSE SDE Hyderabad 2017

Need for structured database

- To make data user friendly
- To be able to filter out to the level of requirement
- Will be a one stop as source of truth

Structure of CTO-db

- Levels of data
  - Source, Trial, Arms, Treatments, Demographics & Assessments (Efficacy/Safety)
- Quality is guided by
  - Efficient process of data extraction & QC
  - Therapeutic area expertise
  - Knowledge of statistics

Strengths of CTO-db

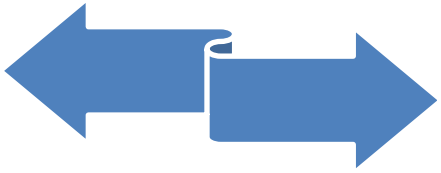
- Robust structure
- Individual level data can also be appended
- Comprehensive data coverage
- Reproducible and high quality outputs
- Scalable to user requirements

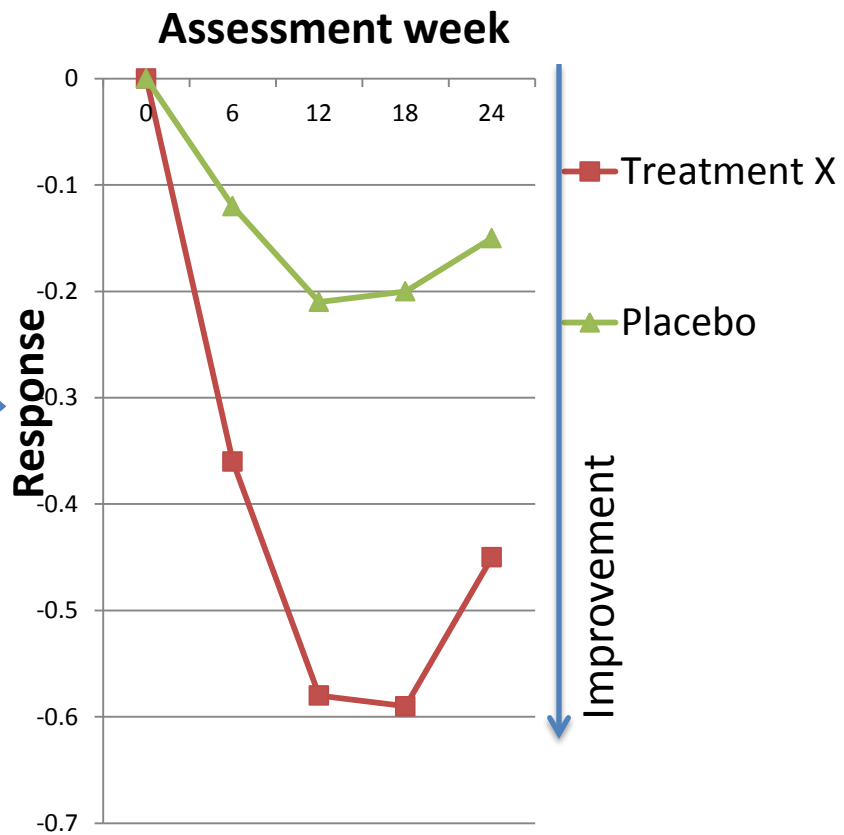
Applications of CTO-db

- Broader understanding of therapy area
- Trends in clinical research
- Competitive advantage
- Input for trial planning
- Active/Placebo response

Structured database Vs Visualization

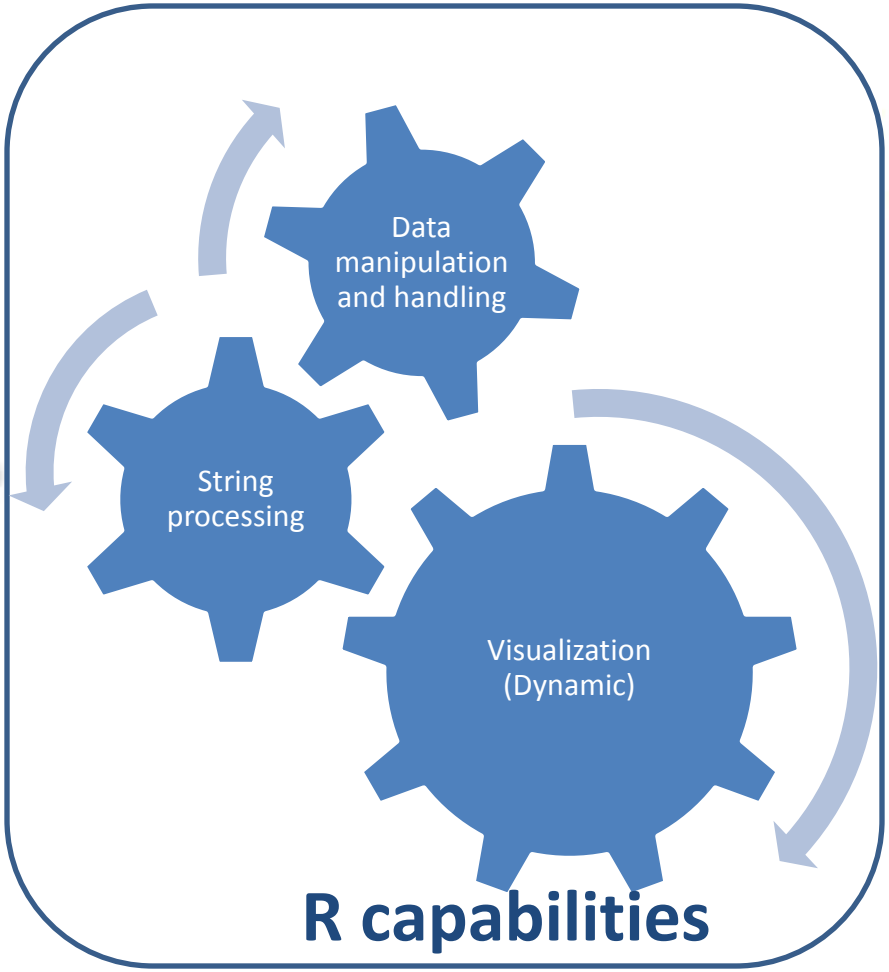
Assessment Time (week)	Treatment	Response
0	Treatment X	0
6	Treatment X	-0.36
12	Treatment X	-0.58
18	Treatment X	-0.59
24	Treatment X	-0.45
0	Placebo	0
6	Placebo	-0.12
12	Placebo	-0.21
18	Placebo	-0.2
24	Placebo	-0.15





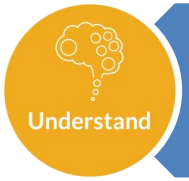
Integrating R capabilities to CTO-db

Database



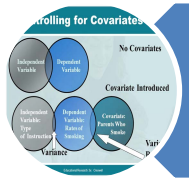
Spotfire

Visual Aggregate Analysis



Understanding Dataset

Identifying underlying trends and patterns

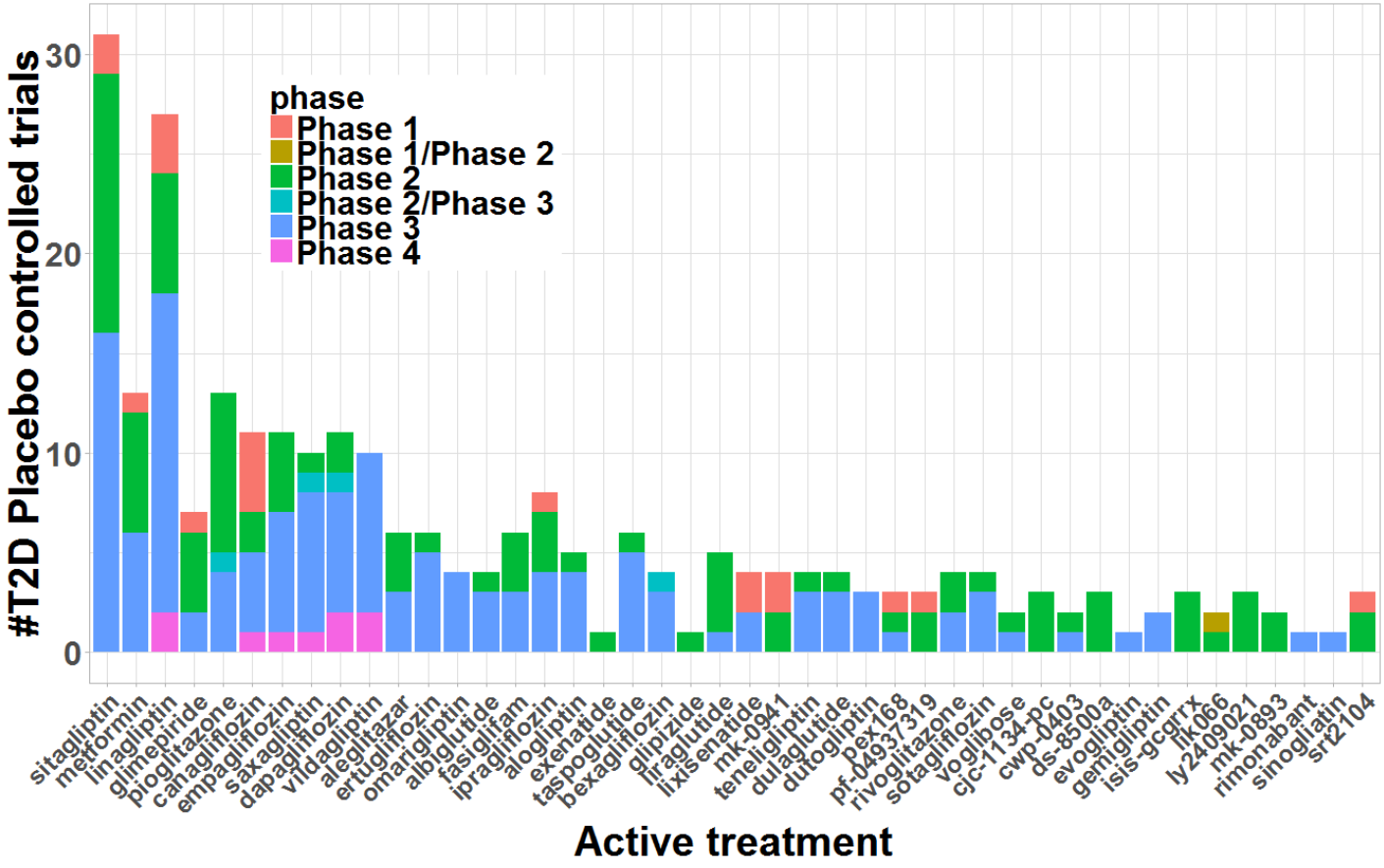


Identifying potential covariates for model based meta-analysis (MBMA)

Identifying possible correlations between covariates

Portraying applications

- Understanding Dataset
- Identifying underlying trends and patterns
- Identifying potential covariates for MBMA
- Correlations between covariates



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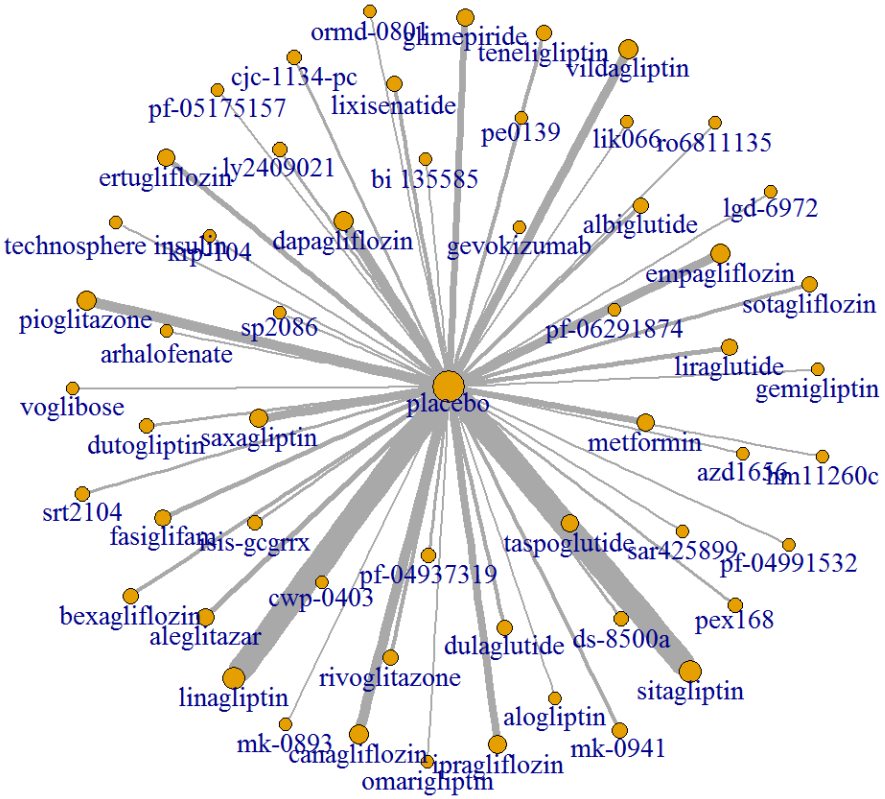

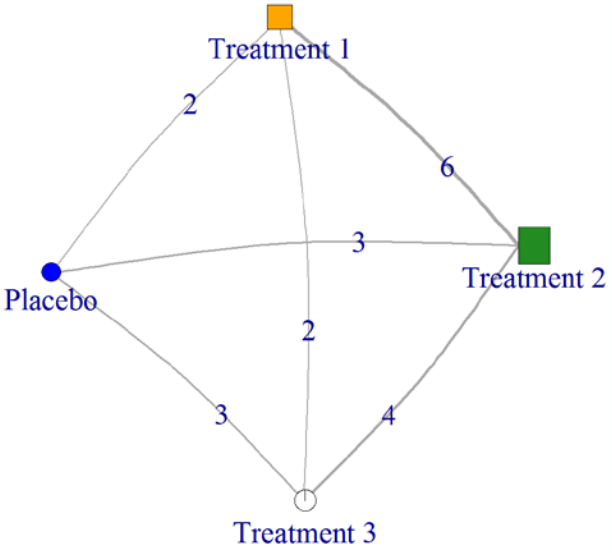

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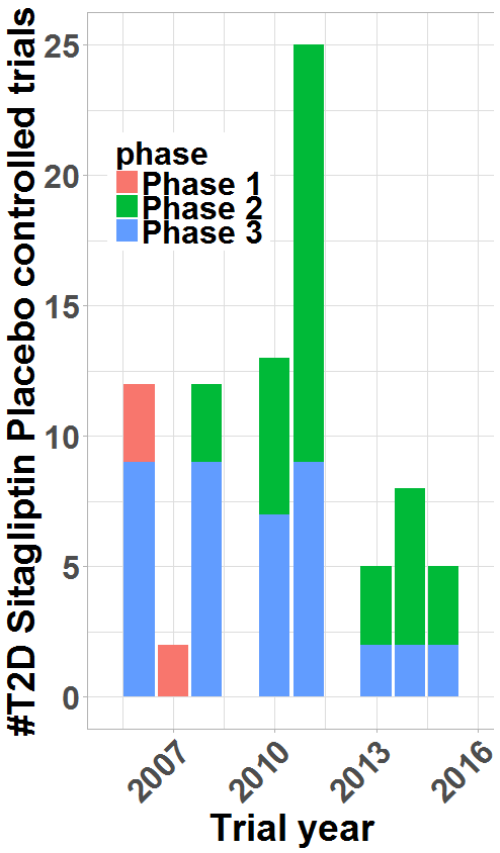

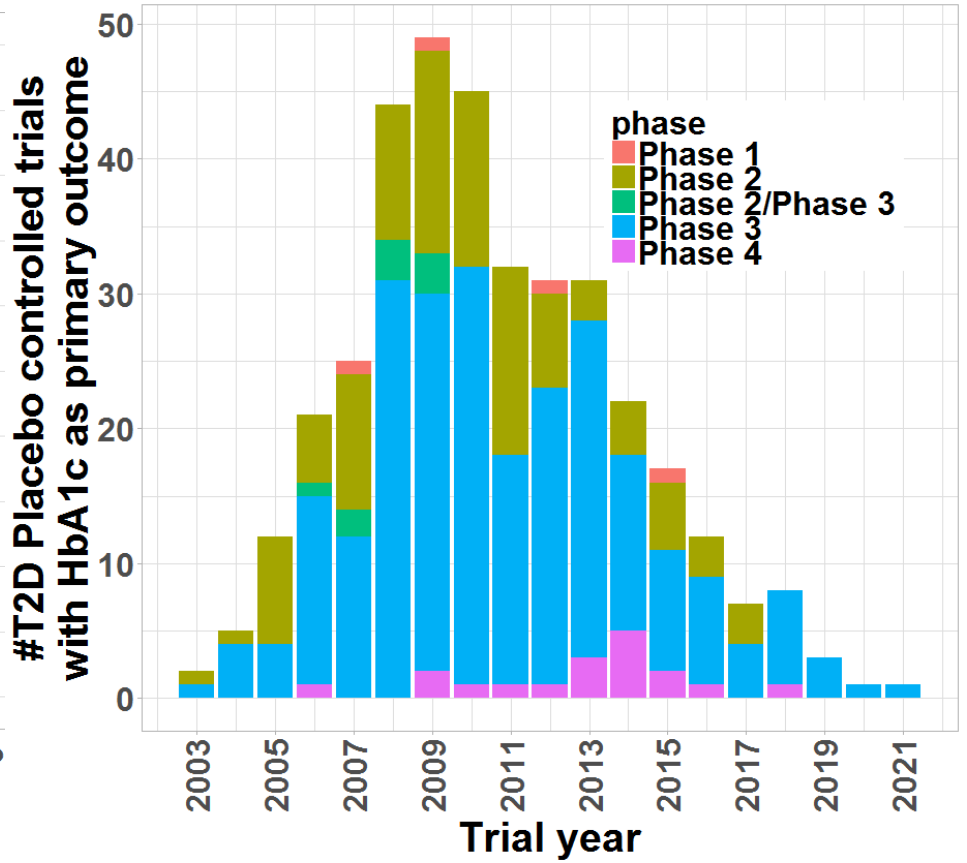

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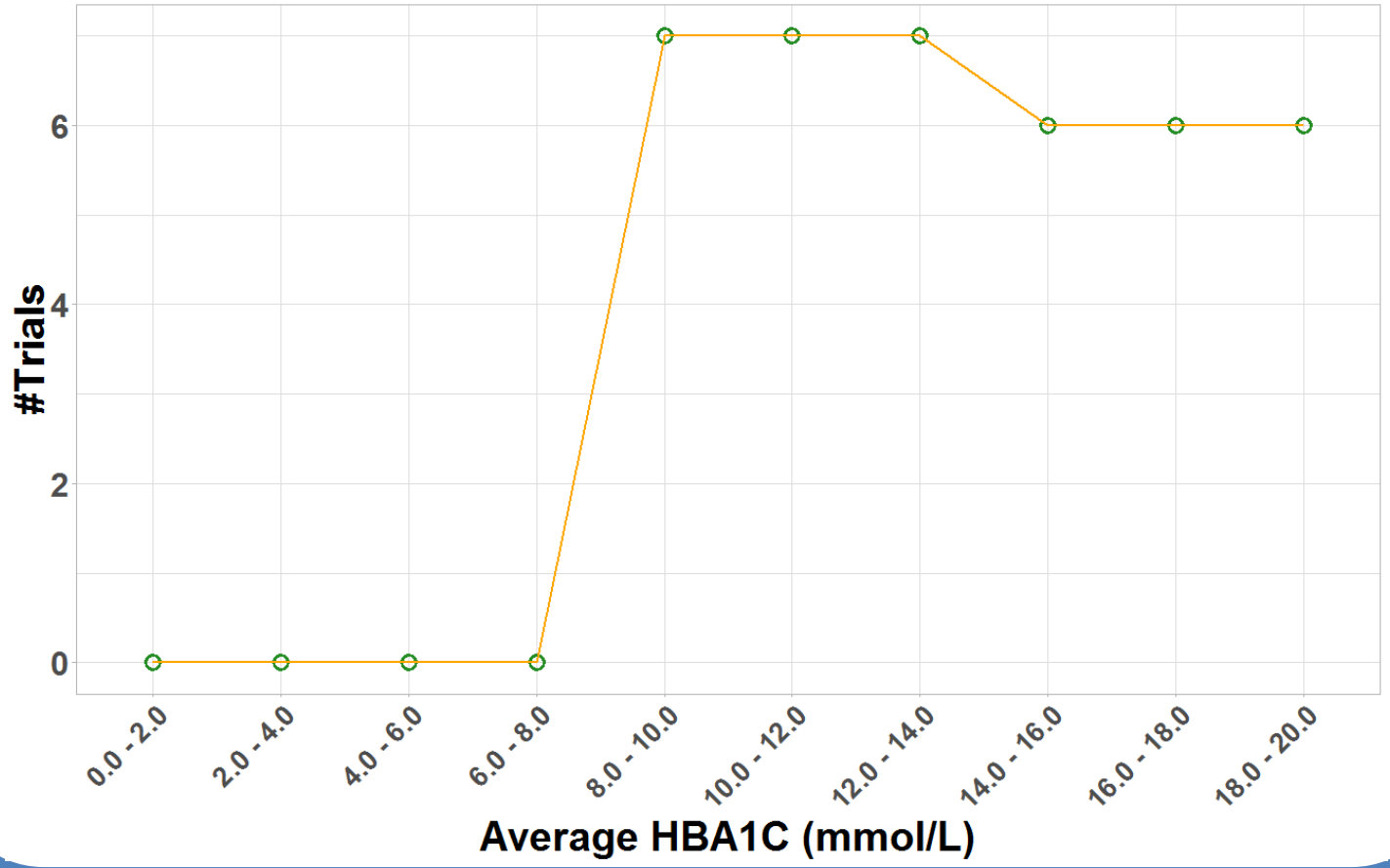

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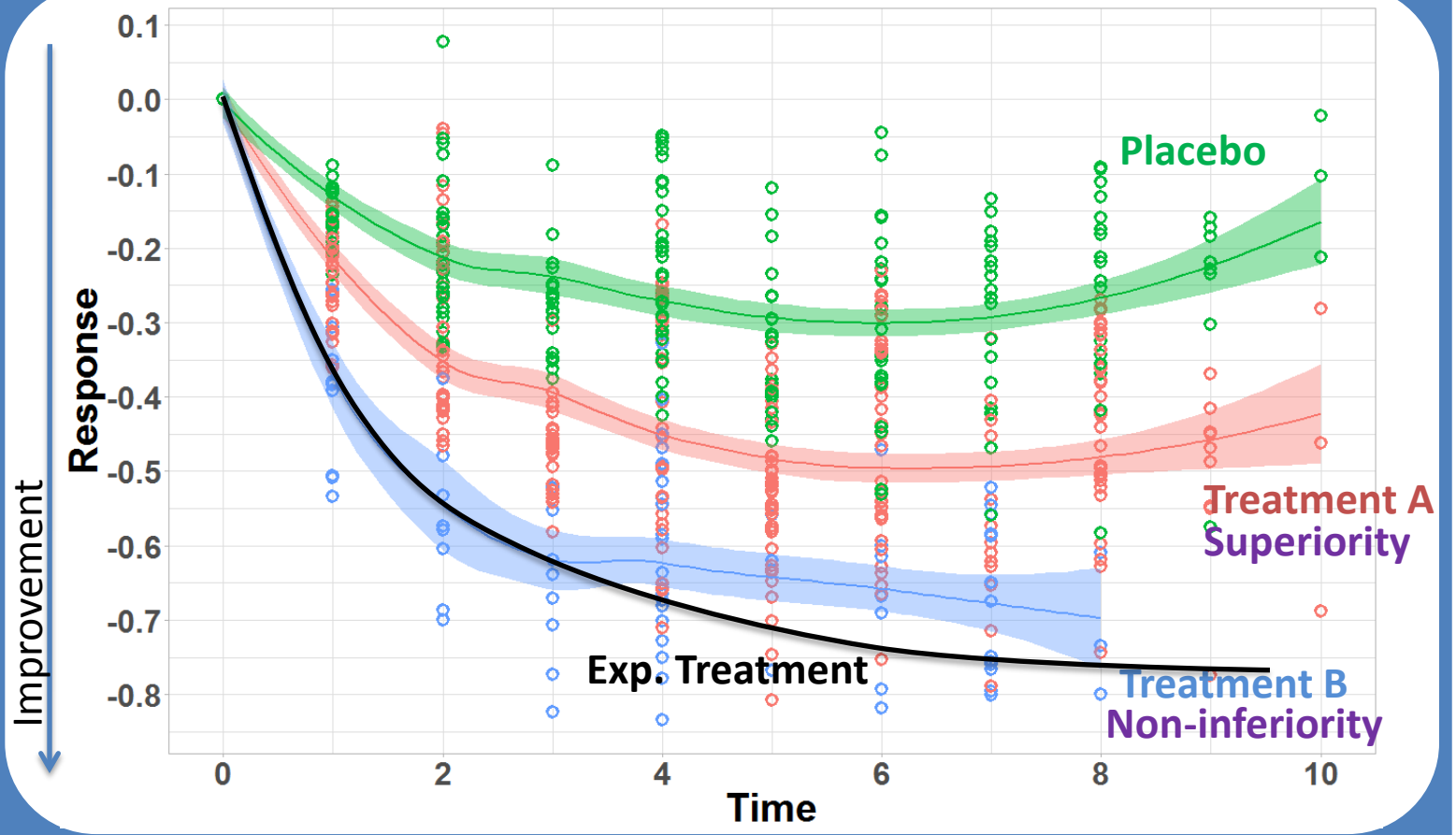

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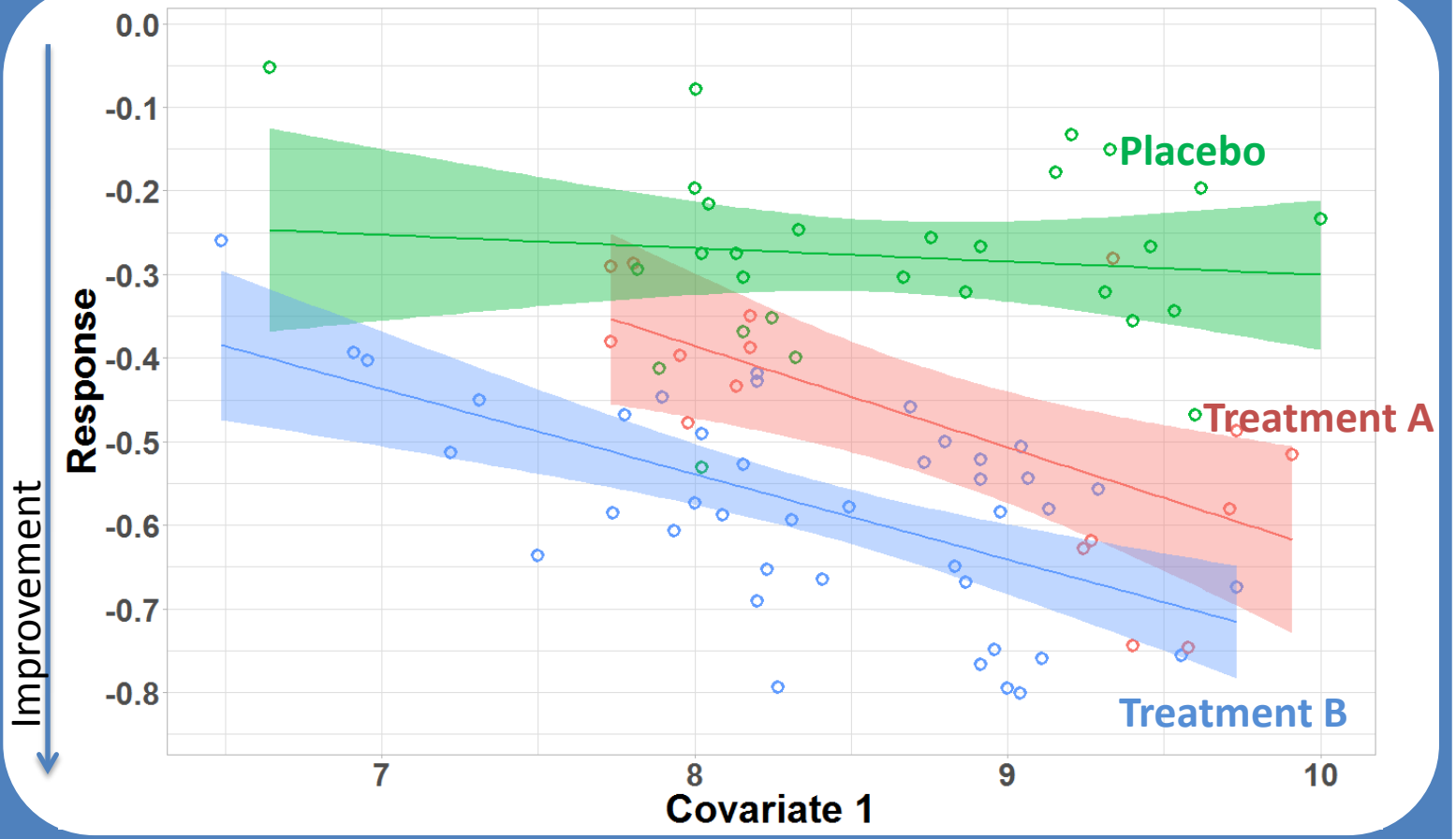

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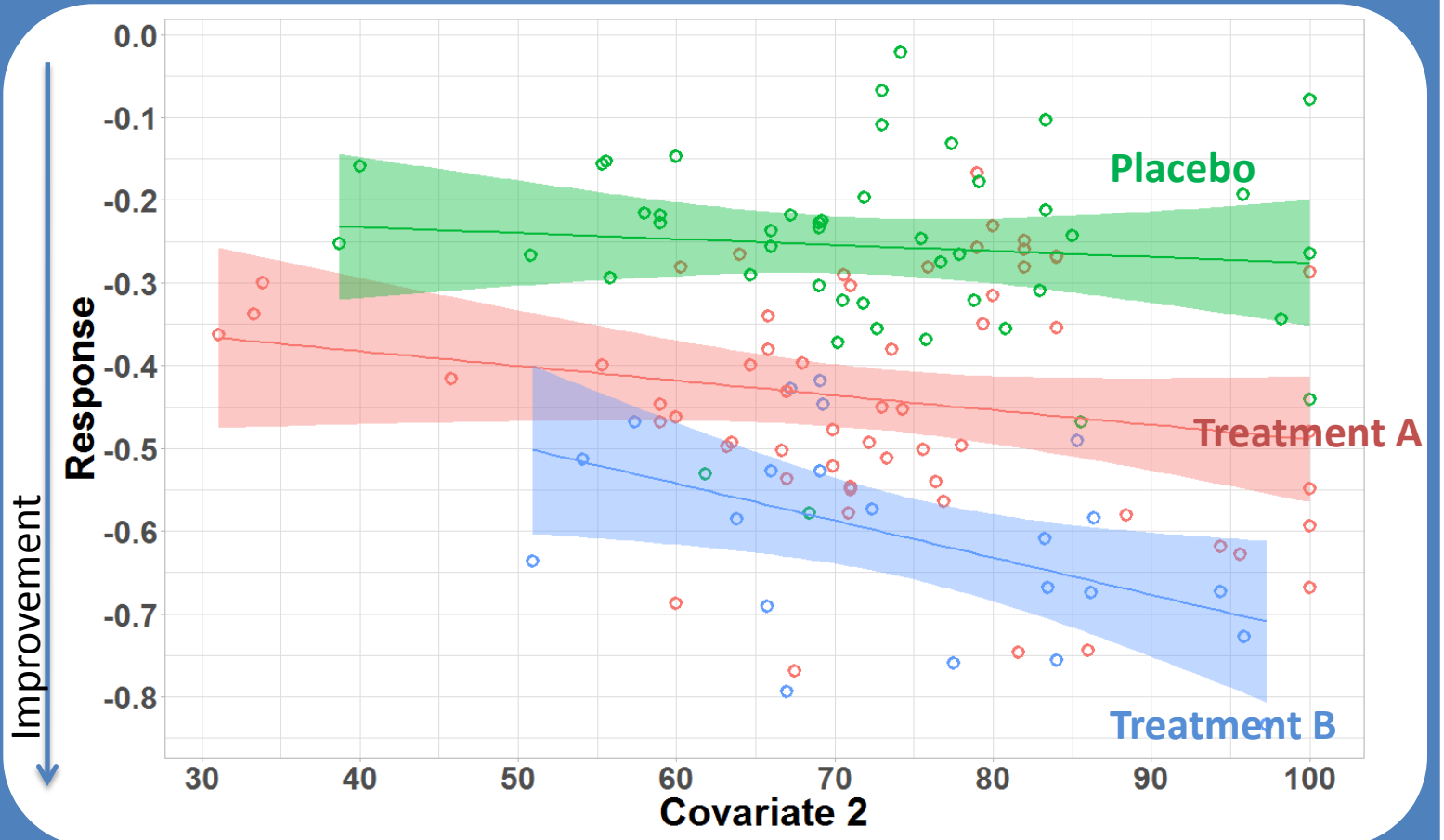

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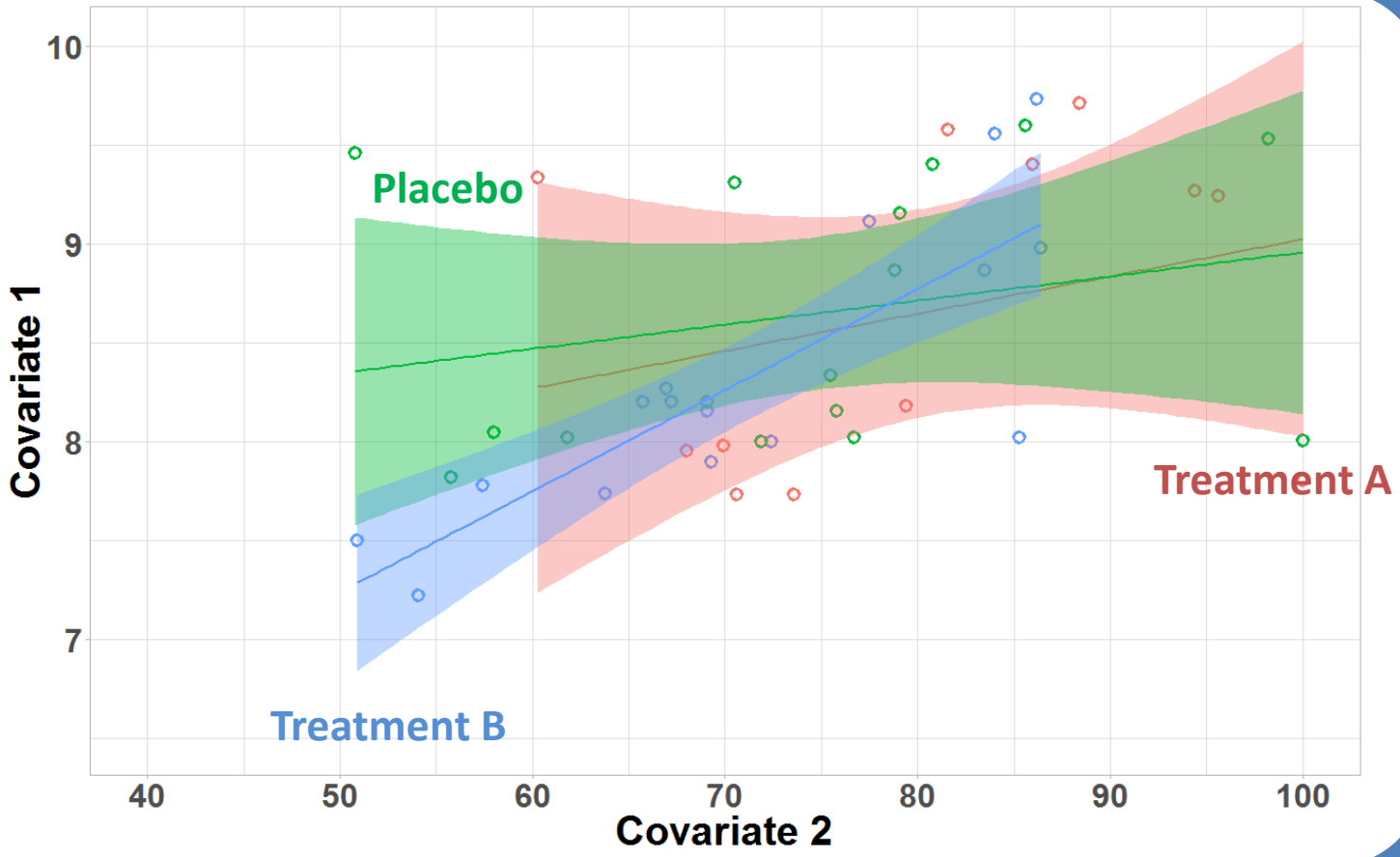

Thank you

Contact Author: Chennakeshavareddy Sannala
Chennakeshavareddy.Sannala@cytel.com