

The logo for GU RUS features the text "GU" in a dark blue, rounded sans-serif font, followed by a stylized graphic element consisting of three vertical bars of increasing height in green, light blue, and dark blue, and then the text "RUS" in the same dark blue, rounded sans-serif font.

GU RUS

Biostatisticians and Programmers: The Ultimate Tag Team or Friendly Fire?



AGENDA

1. Introduction
2. Examples of scenarios
3. Take home message
4. Q/A

Collaboration

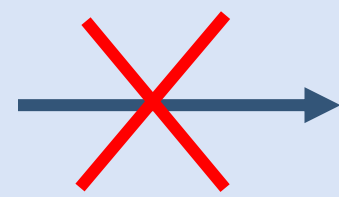


Questions

- How to get a collaboration between Statistical Programmers and Biostatisticians, that will bring to compromise and not the fight ?
- It is assumed that statistical programmers and biostatisticians work together in harmony. But is it always this way?
- The practice shows that it's not that easy and simple and there are lots of collision points.

How to optimize the collaboration to get more efficient teamwork?

Protocol & SAP inconsistency



ISSUE: The Protocol specifies 6 reasons resulting to SAE, including OVERDOSE. But only 5 of them are reflected in both the SAP and TFL Shell output.

CONSEQUENCES:

- Ambiguity in Implementation
- Constant Clarification Loops with Biostatistician
- Time-consuming Rework
- Delays in Deliverables



RESOLUTION: Programmer should always challenge Biostatisticians and raise identified inconsistencies to avoid further complications. Biostatistician should have made a more careful review

Comprehensible Shell view

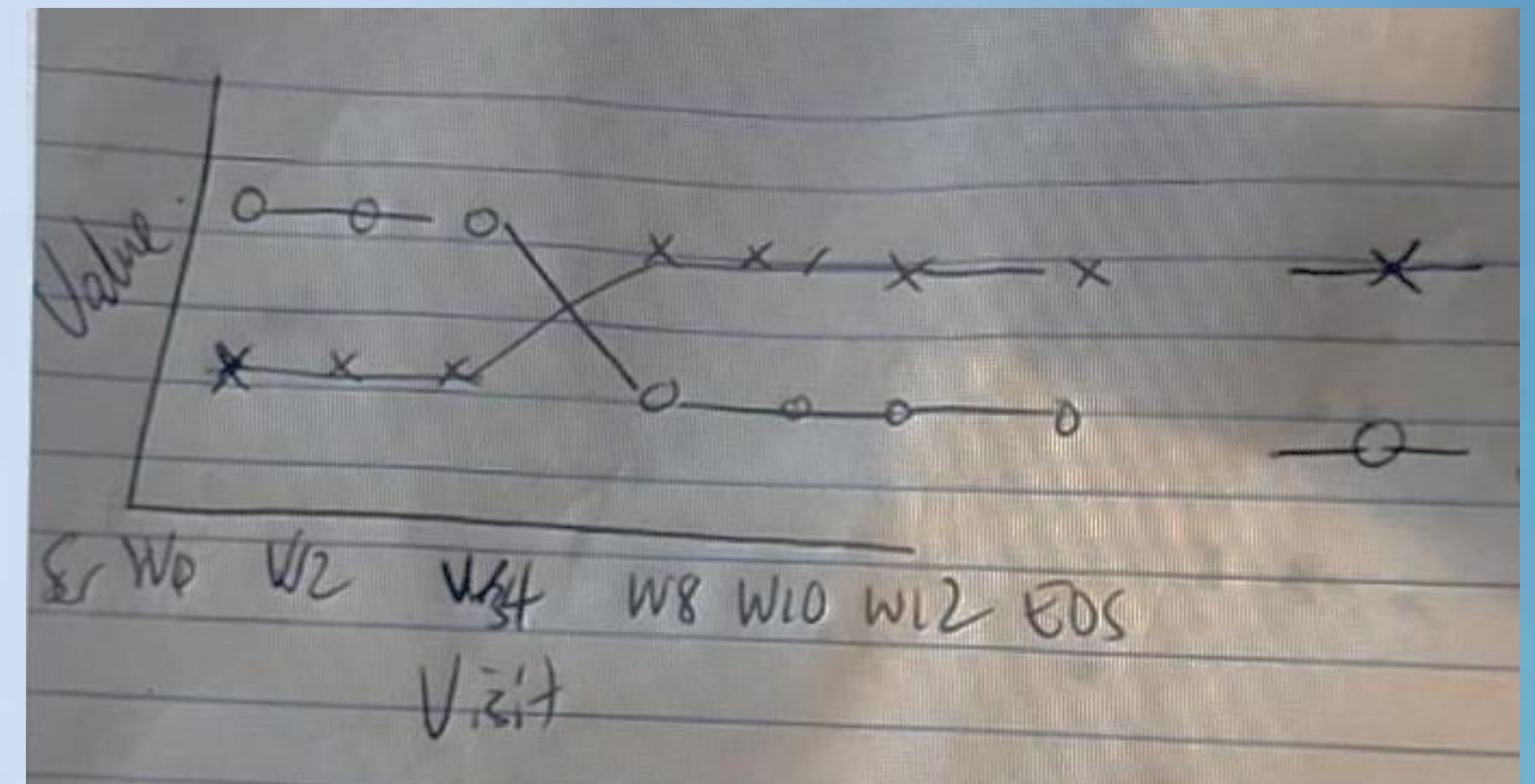
ISSUE: Sometimes the TLF shell may be ambiguous, contain inaccuracies, or require substantial time and effort to develop.

CONSEQUENCES:

- Shell is not in a good shape
- Increased Risk of Programming Errors
- Inconsistent Outputs

RESOLUTION:

- Design Clear and Functional Shells
- Validate with Reference Examples
- Leverage Available Tools and Resources



Challenging Biostatisticians

ISSUE: Incomplete footnotes in the Shell.

CONSEQUENCES:

- Misinterpretation of Results
- Inconsistencies Across Outputs
- Frequent Need for Clarification from Biostatistician

Add specific cases as a footnote to explain inconsistency between visit counts



Add all covariates of the model as a footnote from SAP



For parameters that will be only presented at Baseline add an asterisk (*) with corresponding footnote



After Biostatistician's approval Shell was updated

Additional CDISC guidelines

ISSUE: Lack of experience in data standardization and insufficient knowledge of CDISC guidelines.

CONSEQUENCES:

- Non-Compliant Data Structures
- Misinterpretation of Efficacy or Safety Endpoints
- Reduced Credibility of Programming Team



RSSTRESC	RSSTRESN
0	0
1	1
2	2
3	3
4	4
5	5

RESOLUTION: Biostatistician should familiarize the programming team with FDA-endorsed standards and regulatory guidelines.
Provide response-specific guidance to ensure consistent mapping of original results.

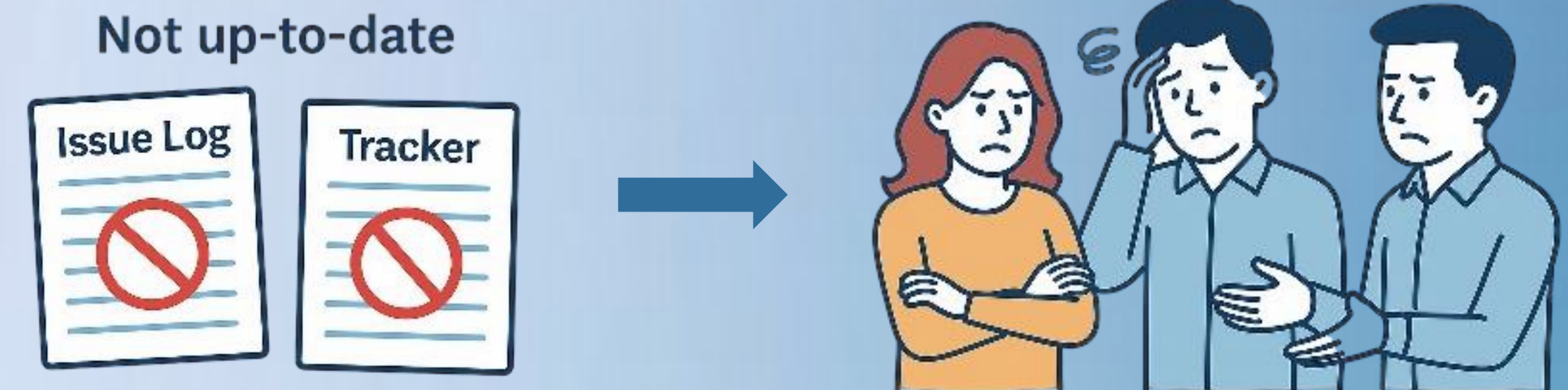
ECOG Performance Status

☐ 0 - FULLY ACTIVE
 ☐ 1 - RESTRICTED IN PHYSICALLY STRENUOUS ACTIVITY
 ☐ 2 - AMBULATORY AND CAPABLE OF ALL SELF CARE
 ☐ 3 - CAPABLE OF ONLY LIMITED SELF CARE
 ☐ 4 - COMPLETELY DISABLED
 ☐ 5 - DEAD

CRF: ECOG collection page

Unrefreshed Tracker & Issue Log

ISSUE: Programmer shares outputs without prior review, or the associated tracker is not updated and doesn't reflect the current status of outputs.

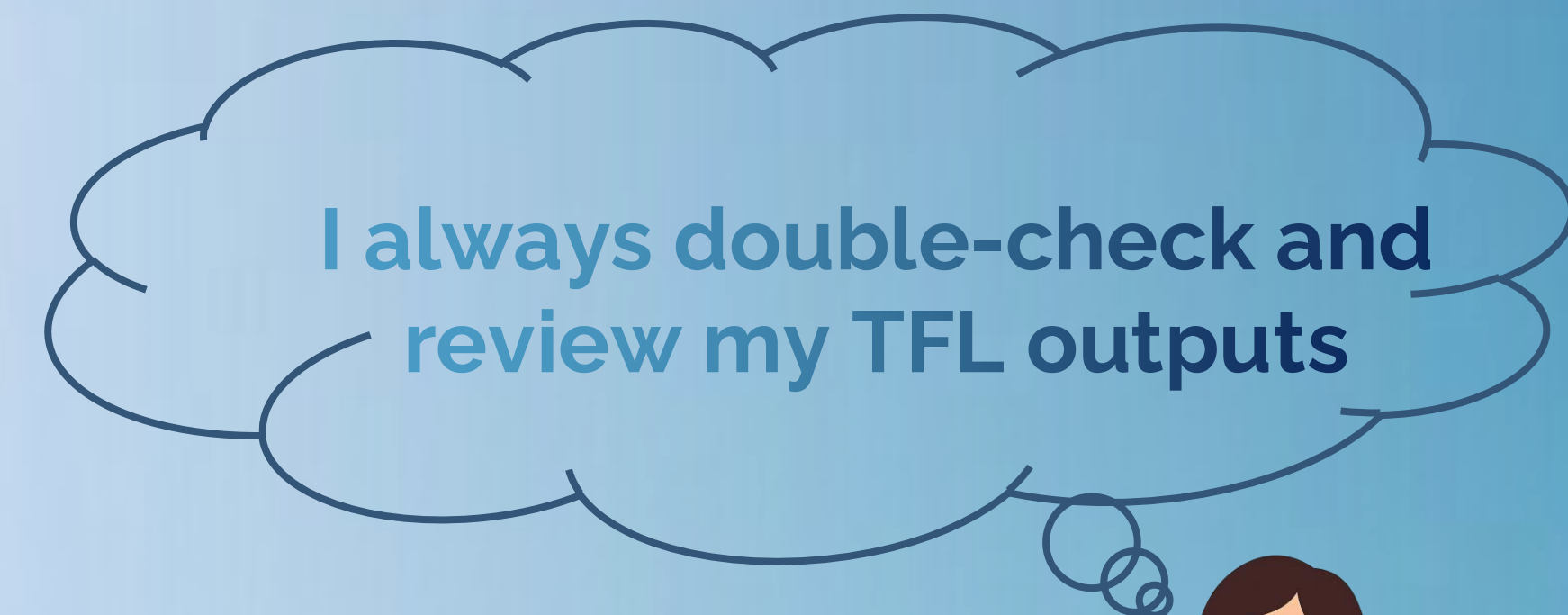


CONSEQUENCES:

- Redundant output review by Biostatistician
- Delay of timelines
- Miscommunication among team members
- Version control issues

RESOLUTION: Programmers should maintain a clean and up-to-date study tracker and issue log.

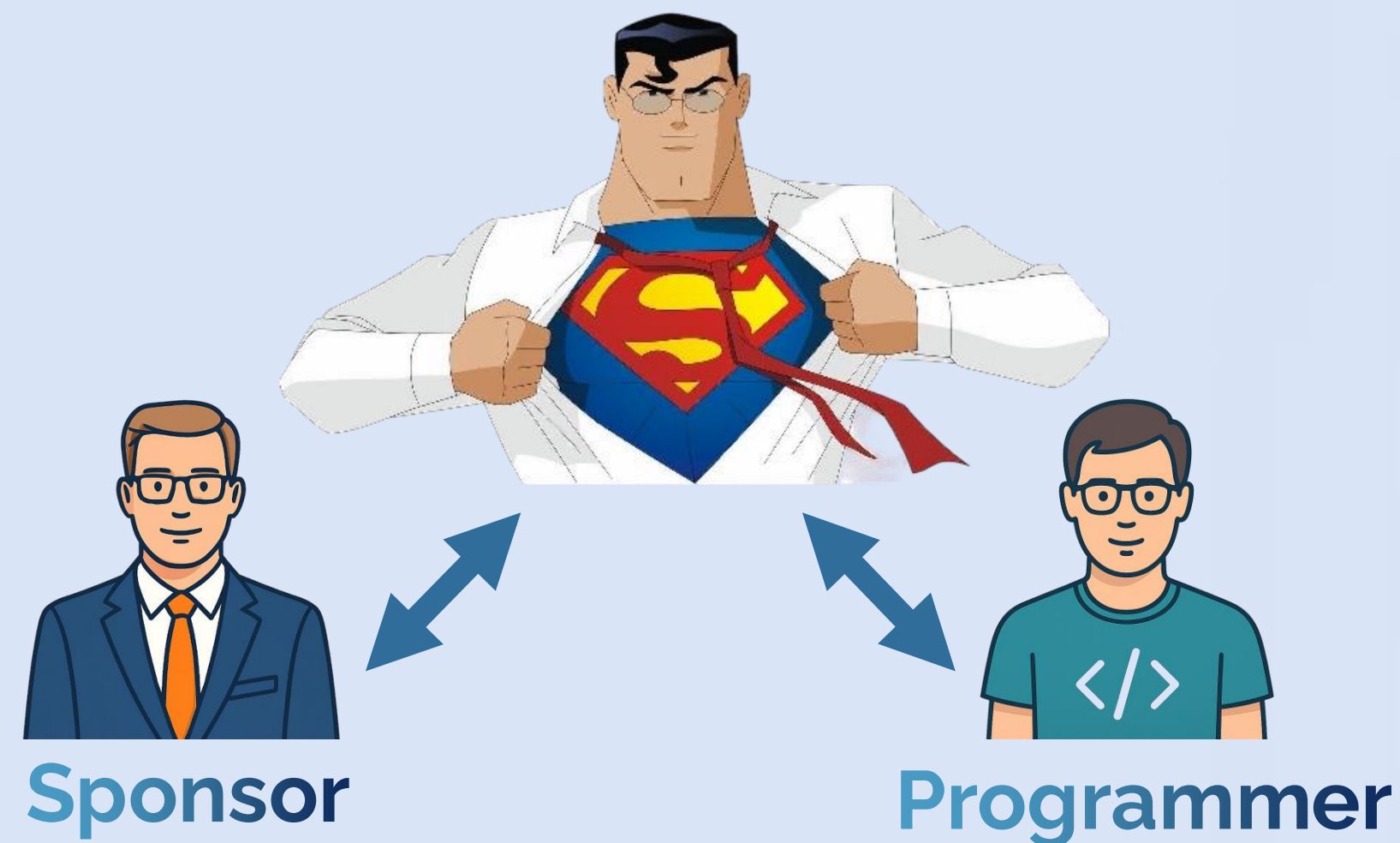
Review the outputs by paying attention on titles, footnotes and all display details.



Miscommunication with Stat

- Different channels of communication (email, Teams, etc.)
- Misunderstanding of SAP analysis/derivations
- Frequent analysis changes

- Information Overload
- Delays in Updates and Deliverables
- Lack of Accountability and Tracking
- Incorrect Implementation of Statistical Methods
- Risk of Errors and Rework



- Use a Single Point of Contact (e.g. LP)
- Set Regular Check-ins
- Make Explanations Clear and Simple
- Consider Alternative Points of View
- Proactively Address possible changes

Take home message

What can be done to optimize work interaction

1. Make sure programmers have a proper review of the study SAP/ Shells, and biostatisticians are involved during programming discussions. This aligns expectations early and prevents rework.
2. Weekly or milestone-based meetings help clarify evolving analysis needs and resolve technical questions before they become bottlenecks
3. Proactivity is a key factor

**Put yourself in another's shoes and
view each task from another's
perspective.**



THANK YOU

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Q/A Session