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Practical Search Tool for Regulatory Request Based on Past Knowledge

From Individual Experience to Reusable Knowledge: A Use Case at Daiichi-Sankyo

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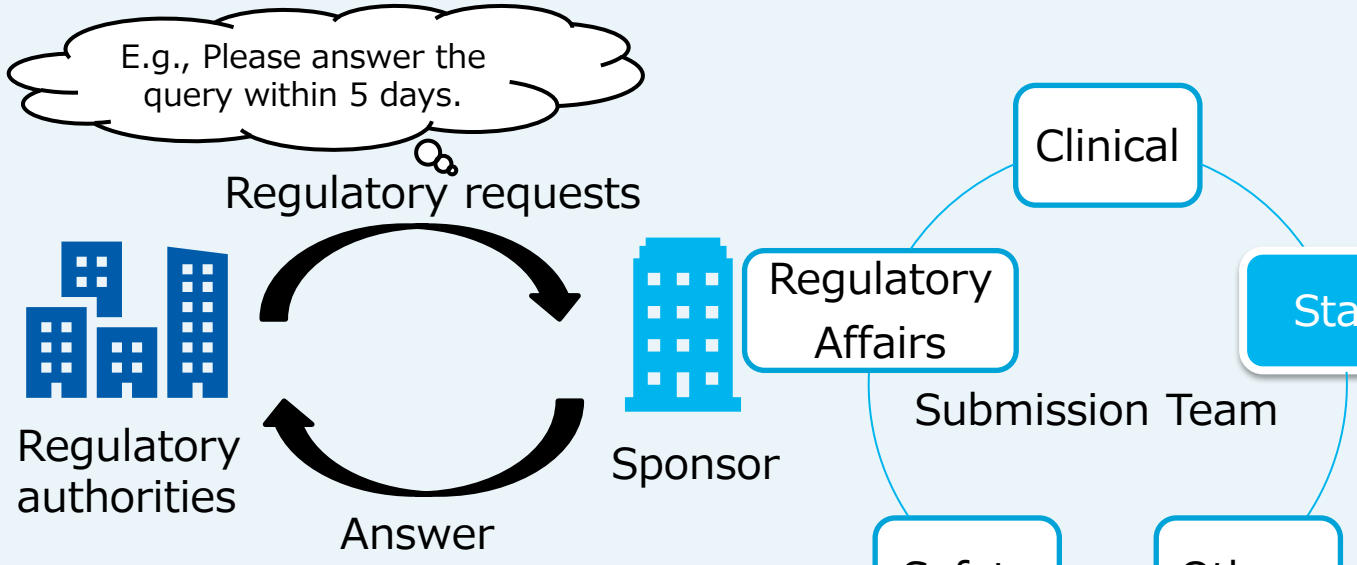
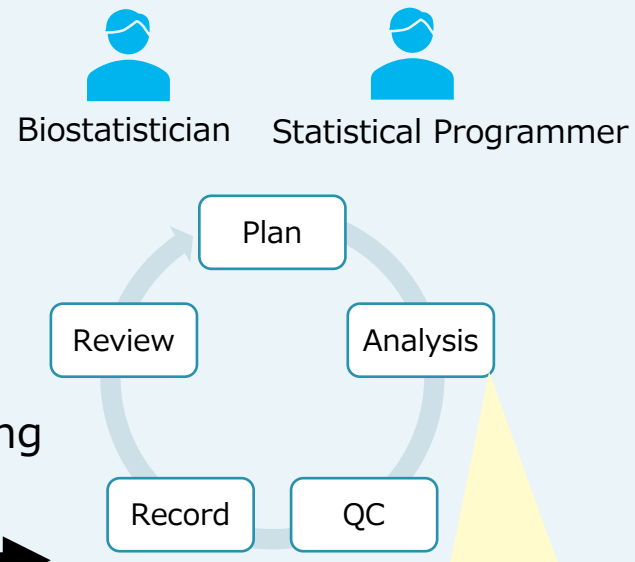
Introduction: Why We Started This Project

Preparing Responses to Regulatory Requests Are Challenging.

Situation under regulatory review





Past knowledge is not centralized

Tight timeline

High workload

We have a wealth of past knowledge,
but have not been able to use it efficiently.

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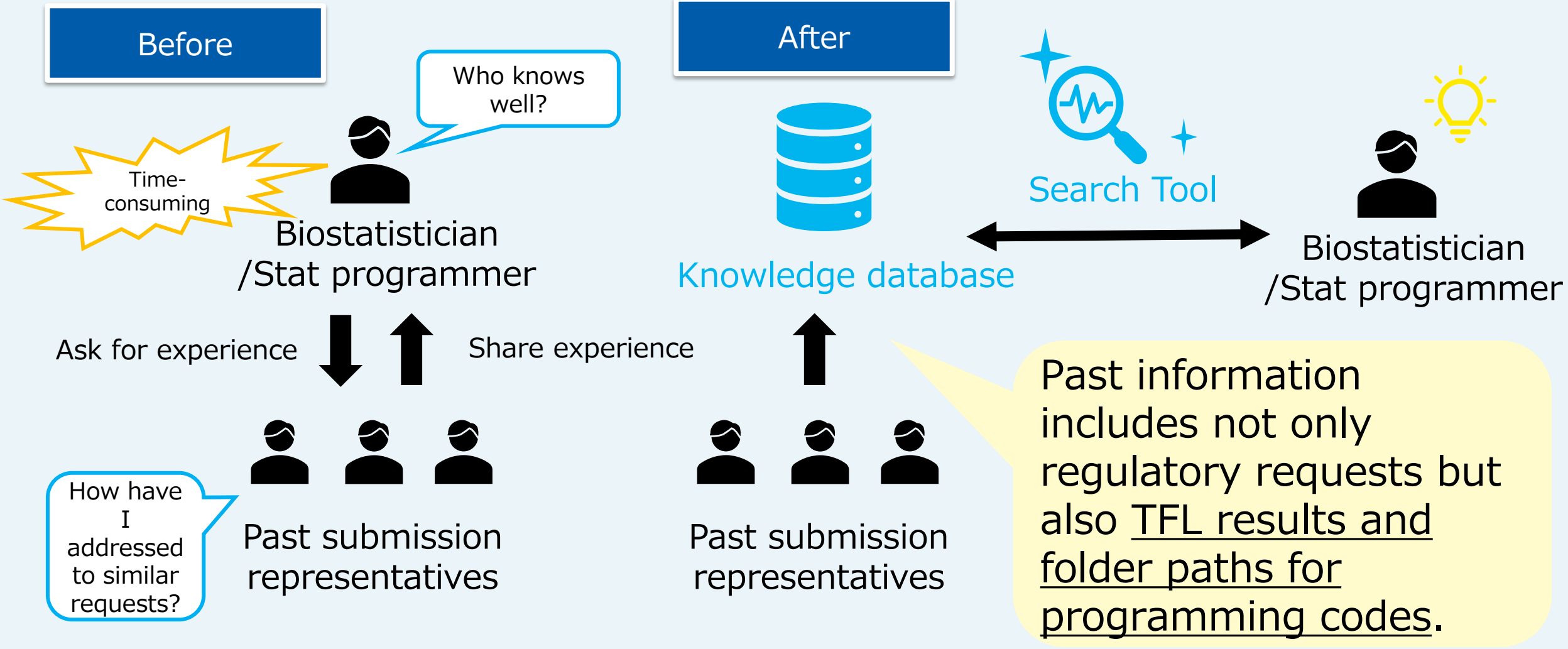
Our Goal: Make Past Knowledge Searchable and Reusable

From Oral Tradition to Shared Knowledge



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Expected Benefits:

How the Tool Supports Additional Analyses for Regulatory Requests

Faster Planning
Identify relevant analysis strategies earlier

Better Access to Knowledge
Find past cases without relying on individual experience

Greater Knowledge Reuse
Turn prior experience into reusable organizational knowledge

Confidence Building
Support less experienced users in initial analysis planning

Stat programmer can refer to past layouts or SAS code, and **Biostatistician** can refer to past analyses and considerations, without asking each past submission representative.
Target: **20–30% reduction** in resources required for regulatory request analyses, once sufficient data are accumulated.



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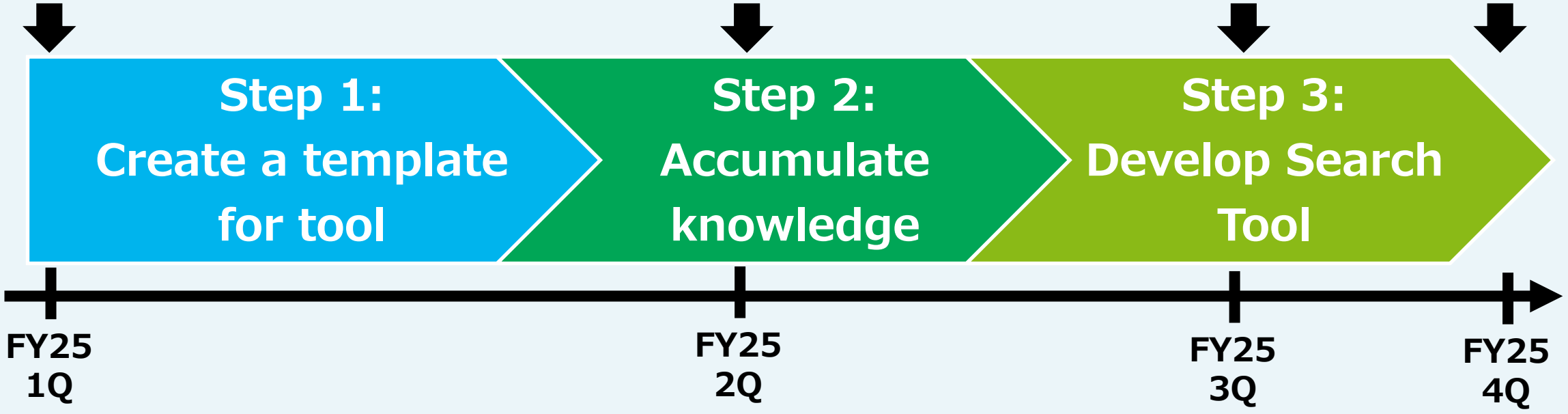
Method: Development Strategy
A Citizen-Developed Approach

- Learned lessons and planned next steps
- Collected feedback from Biostatistician and Stat programmer

- Reviewed internal and external activities
- Consulted with internal AI/ML team and administrators of similar tools

- Programming
- Conducted a user interface review

- Conducted testing and released Search Tool



Key principles: User Feedback, Cost-effectiveness, Idea Reuse

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Method: Data Flow for Search Tool

Input

New regulatory requests

Search Tool

Database

Regulatory requests

TFL name
PGM name
Footnote

RA tool (Veeva submission)

Working space for programming

Output

Past information for Regulatory requests
TFL information
Program name
Footnote
Document link



Programs for regulatory requests

Search quality depends on how well past knowledge is structured.

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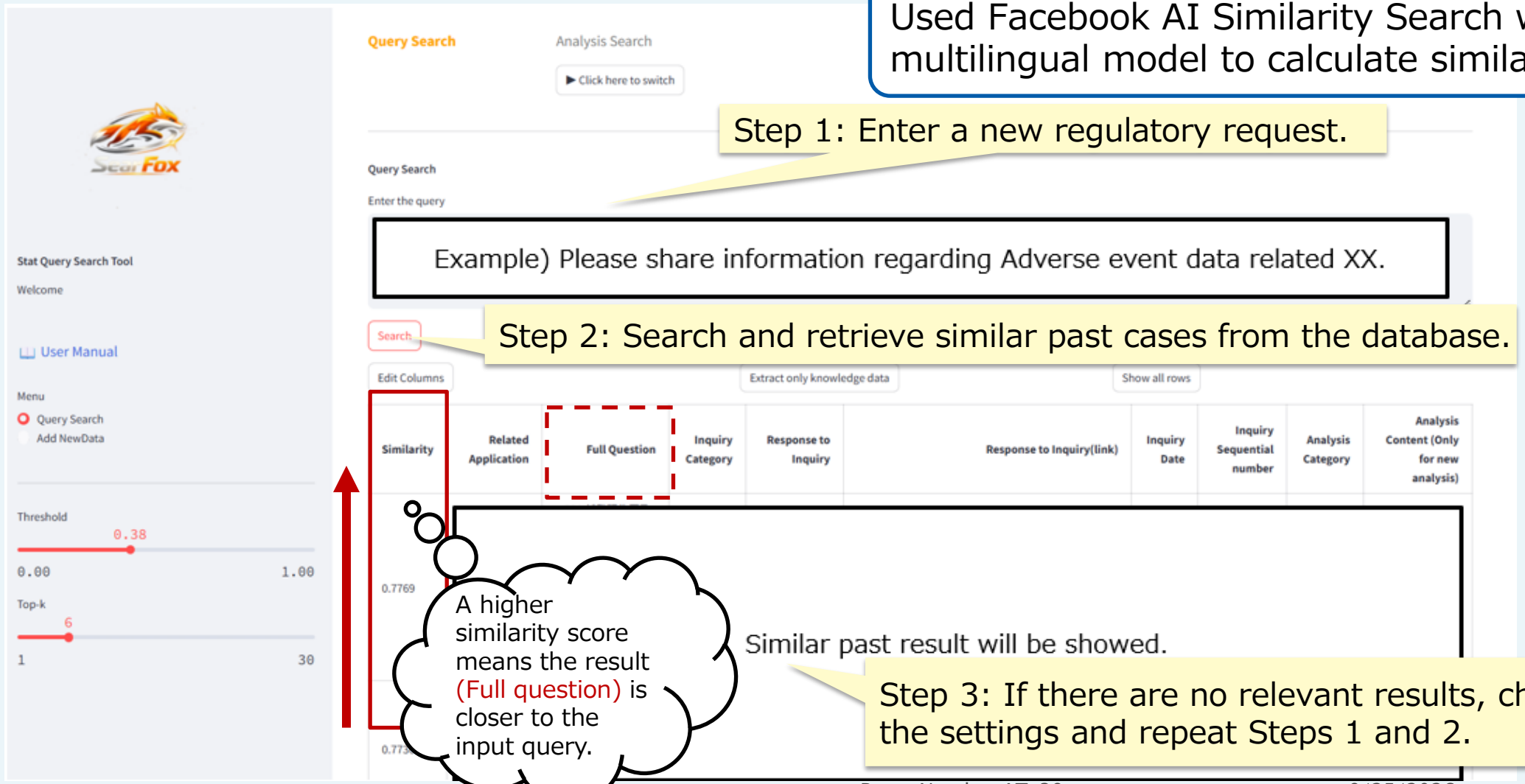
Method: Design and Specification

Used Facebook AI Similarity Search with a multilingual model to calculate similarity.



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Method: How Similarity Search Supports Users

Experience can provide valuable clues for new regulatory requests.



Expected to shorten the timeline for initial analysis planning

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Result: How the Search Tool Works (Example)

Query Search

Enter the query

[redacted]群において選択された薬剤別の部分集団について、BICR判定による PFS及び OSの Kaplan-Meier曲線をそれぞれ提示してください。

Search

Edit Columns | Extract only knowledge data | Show all rows

Similarity	Related Application	Full Question	Inquiry Category	Response to Inquiry	Response to Inquiry(link)	Inquiry Date	Inquiry Sequential number
0.9229	[redacted]	無作為化前に選択された薬剤ごとに、PFS 及びOS の結果の詳細（各群の中央値及びその95%CI、ハザード比及びその95%CI 並びにKaplan-Meier 曲線）をそれぞれ提示してください。	申請前照会事項	[redacted]	[redacted]	2023-12-22	照会事項4①
0.9179	[redacted]	[redacted]集団及び[redacted]集団における無作為化前に選択された薬剤別のPFS 及びOS の解析結果について、Kaplan-Meier 曲線を提示してください。	申請前照会事項	[redacted]	[redacted]	2024-07-12	照会事項3①

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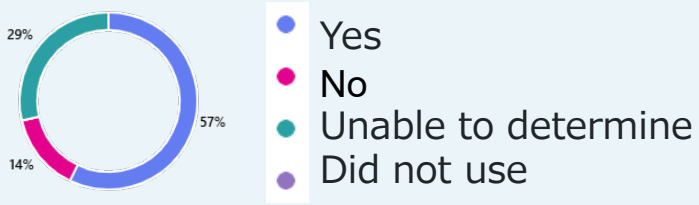
Result: Feedback From Users (Test Version)

n=8

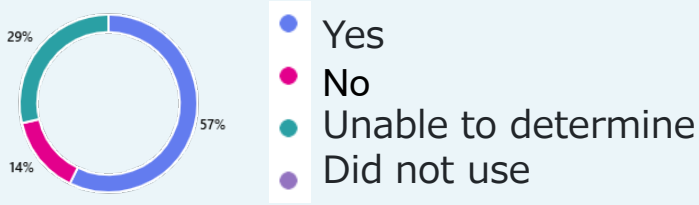
1. Please evaluate the usability of the tool.



2. With Query Search, did you get the results you expected?



3. With Analysis Search, did you get the results you expected?



Comments:

- I found a similar query and reused old programs for the actual regulatory requests.
- I expect this tool to improve efficiency in the preparation process in the near future.

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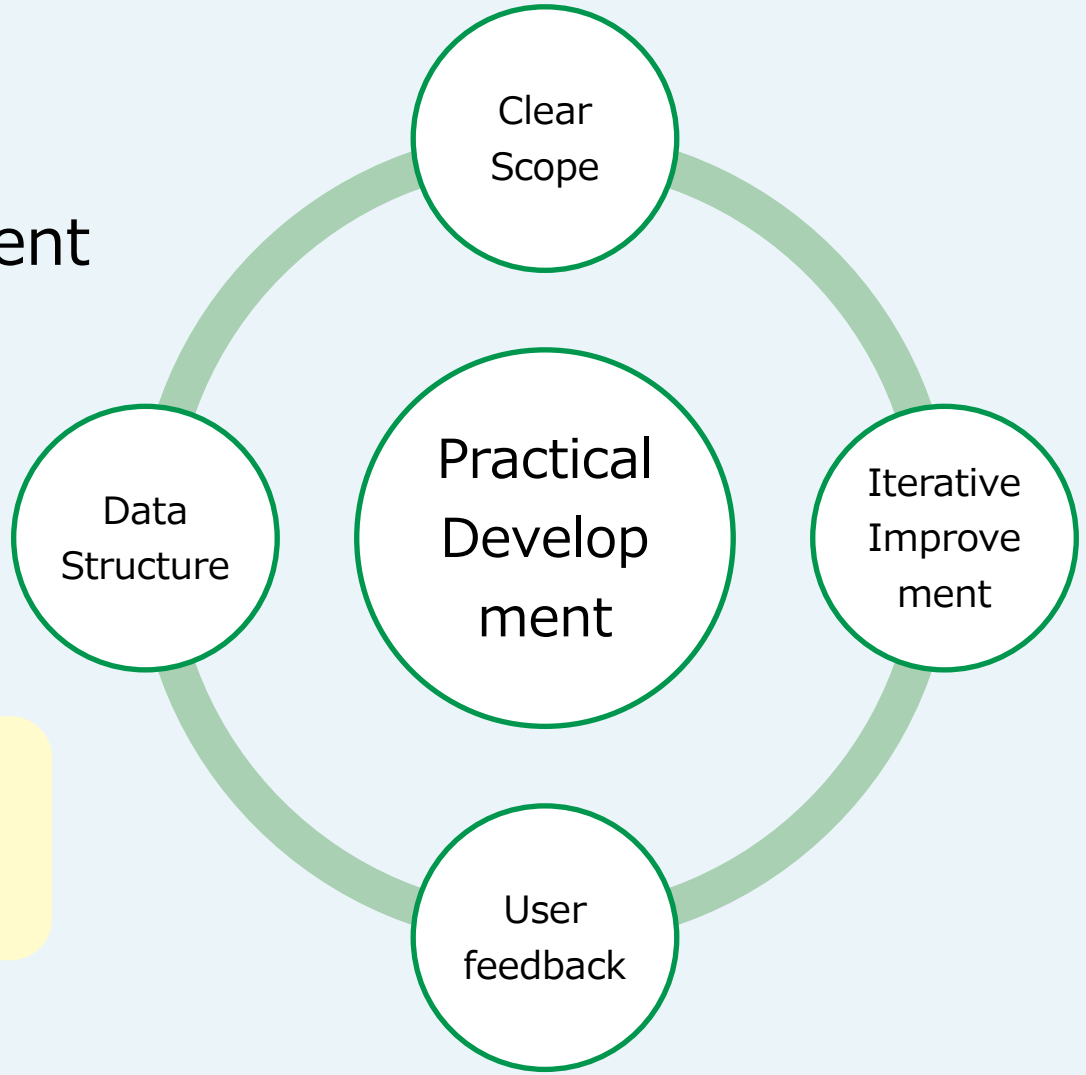
Discussion: What We Learned From This Development

1. Start with a real business problem
2. Structure knowledge before development
3. Involve users early and often
4. Release, learn, and improve iteratively



Close collaboration between biostatisticians and statistical programmers made this tool more beneficial.

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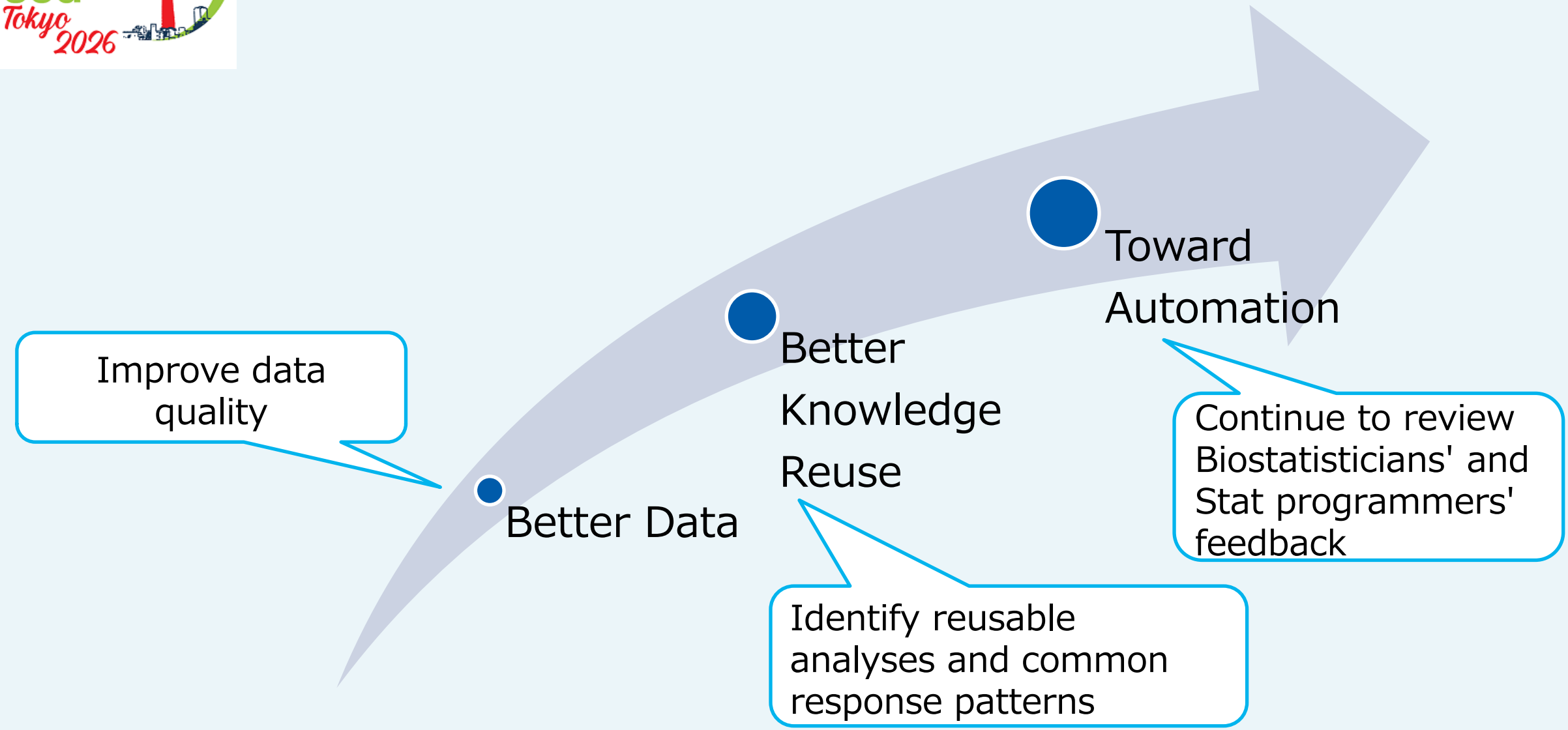
Discussion: Future Directions



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Discussion: Take-Home Messages

1. Past regulatory request experiences are valuable knowledge.
2. Similarity search can make this knowledge easier to find and reuse.
3. Better access to past knowledge can support faster and more consistent decision-making.

We are turning individual experience into reusable organizational knowledge.

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Thank You for Listening

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