

AI is coming for you: New Biometric Leadership in the era of Agentic AI

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Disclaimer

The views and opinions presented here represent those of the speaker and should not be considered to represent any companies or organizations.

Agenda

- **Agentic AI is coming**
- **What is Agentic AI?**
- **Why Agentic AI in Biometric Leadership?**
- **Agentic AI Implementation Leadership (System, Process & People)**
- **Leading into the future**
- **Discussion**



**As a Child, have you ever dreamed
that something was coming at you?**



Nowadays, Just like our Childhood dream, something big, unstoppable is coming our way.



Agentic AI

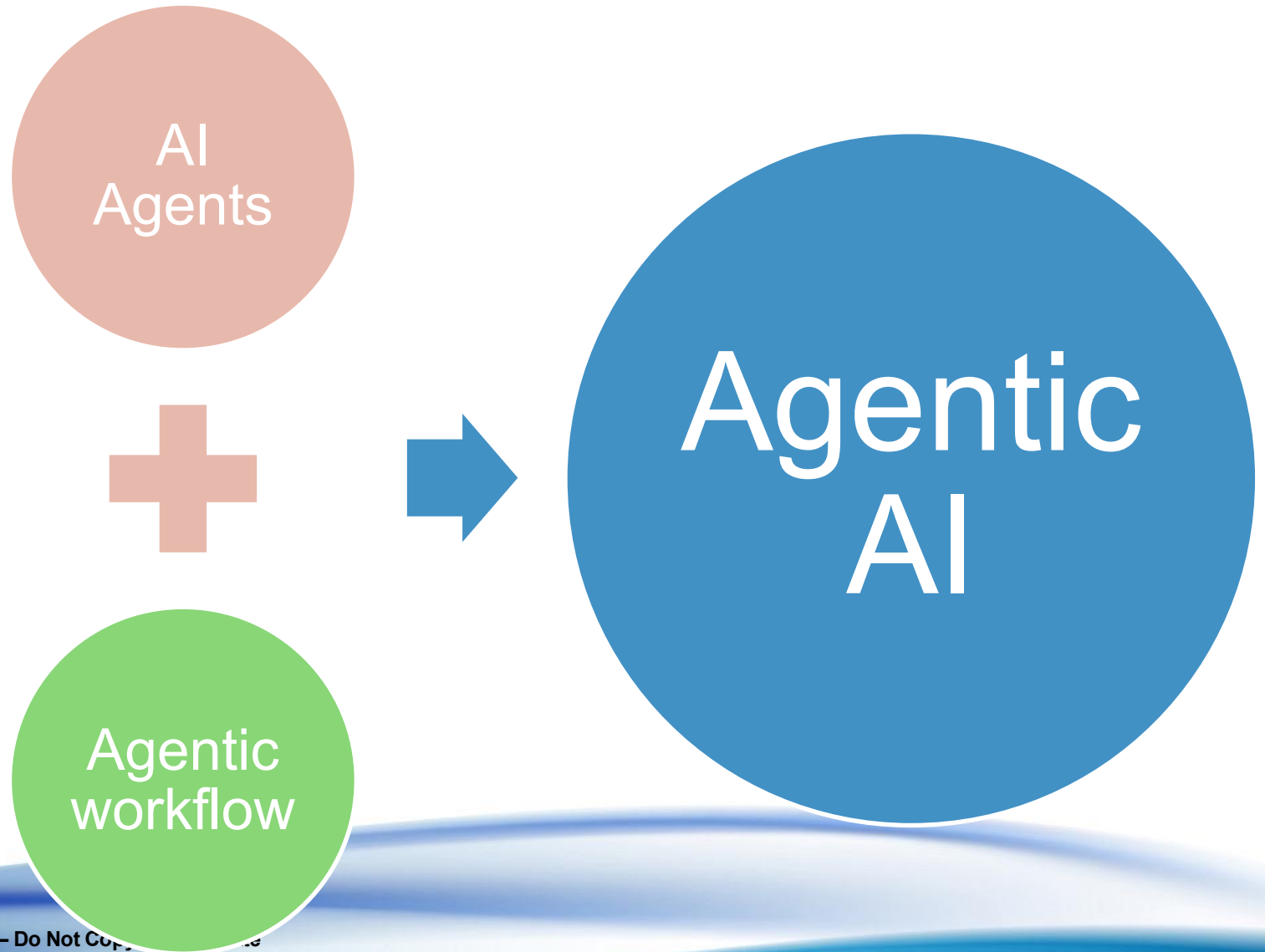
If Agentic AI is coming,

- How can we lead this big and unstoppable wave?
- What kind of leadership do we need to practice?



What is Agentic AI?

Agentic AI refers to an **AI paradigm** in which **autonomous AI Agents** actively pursue goals and execute tasks through **Agentic workflows**.



AI Agent in action (1)

The screenshot displays an AI agent interface. On the left is a file explorer with a dark theme, showing a list of files and folders. The file "SDTM Metadata v1.6.07.xlsx" is highlighted with a green underline. The main area on the right shows a chat window. A red hand-drawn circle highlights the first message: "SDTM Metadata v1.6.07.xlsx" Can you generate SDTM R code for DM, VS and AE and execute the DM codes as well. Below this, the AI agent's response is visible: "I'll generate SDTM R code for DM, VS, and AE domains from the metadata file, and then execute the DM code. Let me start by generating all three domains:". This response is followed by a status bar showing "Approved: sdtm_generate_multi_sheet_to_files". At the bottom of the chat area, there are three buttons: "Generate dm", "Generate vs", and "Generate ae", each with a circular progress indicator and the text "Generating code...". Below the buttons, there is a blue text overlay with a list of three items: "Human prepared input", "AI Agent planed", and "AI Agent executed code development". The word "planed" is misspelled. The background of the interface is dark grey.

EXPLORER

File Folder

- Archived
- JS_codes
- prompts
- Python_Codes
- R_Codes
- raw

Sample All TFL v1.3.pdf

SDTM additional request v1.1.d...

SDTM Metadata v1.6.07 - Cop...

SDTM Metadata v1.6.07 - Cop...

SDTM Metadata v1.6.07.xlsx

SDTM Prompt Example.docx

"SDTM Metadata v1.6.07.xlsx" Can you generate SDTM R code for DM, VS and AE and execute the DM codes as well.

I'll generate SDTM R code for DM, VS, and AE domains from the metadata file, and then execute the DM code.

Let me start by generating all three domains:

Approved: sdtm_generate_multi_sheet_to_files

Generate dm
Generating code...

Generate vs
Generating code...

Generate ae
Generating code...

- Human prepared input
- AI Agent planed
- AI Agent executed code development

AI Agent in action (2)

```
s_2026-03-25_0...  dm_2026-03-25_0... x
c:\Users\rohit\clinvia.com\clinvia.com - Documents\Project\CodeZen\SDTM Generation App\dm_2026-03-25_00-18-26-590.R
14 # calculates age, derives reference dates, and merges subject-level data to
   generate the
15 # SDTM DM dataset. The derivations include:
16 # - Subject identifiers (USUBJID, SUBJID)
17 # - Reference dates from exposure and disposition data
18 # - Age calculation based on birth date and informed consent date
19 # - Treatment arm assignments from randomization data
20 # - Death information from disposition data
21 #
22 #####
23
24 # This section loads required R packages for the codes
25 library(haven)
26 library(dplyr)
27 library(labelled)
28 library(tidyr)
29
30 # This section defines paths for raw data input and SDTM data output
31 # This code Get the current Windows username
32 user <- Sys.getenv("USERNAME")
33
34 # This codes define paths for raw data input and SDTM data output. Use this as a
   default unless input and output data path has been provided.
35 raw_path <- file.path("C:/Users", user, "clinvia.com/clinvia.com - Documents/Project/
   Data/pilot/raw")
36 sdtm_out_path <- file.path("C:/Users", user, "clinvia.com/clinvia.com - Documents/
   Project/CodeZen/SDTM Generation App/R_codes/Generated_code/out")
37
38 # This will set up working directory path
39 work_dir_path <- file.path("C:/Users", user, "clinvia.com/clinvia.com - Documents/
   Project/CodeZen/SDTM Generation App/R_codes/Generated_Code")
```

SDTM Metadata File: 10/17/2018 Can you generate SDTM R code for DM, VS and AE and execute the DM codes as well.

I'll generate SDTM R code for DM, VS, and AE domains from the metadata file, and then execute the DM code.

Let me start by generating all three domains:

Approved: sdtm_generate_multi_sheet_to_files

✓ Generated dm

dm_2026-03-25_00-18-26...

✓ Generated vs

vs_2026-03-25_00-18-26...

✓ Generated ae

ae_2026-03-25_00-18-26...

All three R code files have been generated. Now let me read the R skill documentation and then execute the DM code:

Read file Allow Esc Deny

Show Command

12:19 AM

- Human in a loop

Waiting for permission ***

Waiting for AI response...

AI Agent in action (3)

vs_2026-03-25_0... dm_2026-03-25_0... ae_2026-03-25_0... x

C:\Users\rohit\clinvia.com\clinvia.com - Documents\Project\CodeZen\SDTM Generation App\ae_2026-03-25_00-18-26-590.R

```
1 #####
2 # Program:      ae.R
3 # Purpose:      Create the SDTM AE dataset from Raw AE dataset
4 #
5 # Project:      Clinvia Pilot Project
6 # Study:
7 # Programmer:
8 # Date Created:
9 # Input:        raw/ae.sas7bdat, sdtm_out/dm.sas7bdat
10 # Output:       sdtm_out/ae.xpt, sdtm_out/suppaexpt
11 #
12 # Description:
13 # This program reads RAW AE dataset, performs data derivations,
14 # converts date formats, and merges with DM data to generate the
15 # SDTM AE dataset. The derivations include:
16 # - Converting date variables from MMDDYYYY to YYYY-MM-DD format
17 # - Creating sequence numbers by subject
18 # - Deriving treatment emergent flag as supplemental qualifier
19 # - Adding USUBJID from DM dataset
20 #
21 #####
```

Approved: Run command

The DM code has an error - it references `REPENDTC_rm` which doesn't exist. Let me read the generated code and fix it:

Approved: Read file

I see the issue - the code has a bug where it tries to use `REPENDTC_rm` but the `disp` dataframe already has `REPENDTC`, so when joining with `expo` (which doesn't have `REPENDTC`), the suffix isn't applied correctly. Also, the code is duplicated. Let me fix this:

Approved: Edit file

The code is duplicated. Let me rewrite the entire file with the fix and remove the duplication:

Approved: Write file

Now let me execute the fixed DM code:

- AI Agent found the issues in DM codes.
- AI Agent fixed the codes.
- AI Agent re-ran the codes.

AI Agent in action (4)

```
vs_2026-03-25_0...  dm_2026-03-25_0...  ae_2026-03-25_0... x
C:\Users\rohit\clinvia.com\clinvia.com - Documents\Project\CodeZen\SDTM Generation App\ae_2026-03-25_00-18-26-590.R

1 #####
2 # Program:      ae.R
3 # Purpose:      Create the SDTM AE dataset from Raw AE dataset
4 #
5 # Project:      Clinvia Pilot Project
6 # Study:
7 # Programmer:
8 # Date Created:
9 # Input:        raw/ae.sas7bdat, sdtm_out/dm.sas7bdat
10 # Output:       sdtm_out/ae.xpt, sdtm_out/suppaexpt
11 #
12 # Description:
13 # This program reads RAW AE dataset, performs data derivations,
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15 # SDTM AE dataset. The derivations include:
16 #   - Converting date variables from MMDDYY to YYYY-MM-DD format
17 #   - Creating sequence numbers by subject
18 #   - Deriving treatment emergent flag as supplemental qualifier
19 #   - Adding USUBJID from DM dataset
20 #
21 #####
22
23 # This section loads required R packages for the codes
24 library(haven)
25 library(dplyr)
26 library(labelled)
27 library(tidyr)
28
```

VS (Vital Signs)	vs_2026-03-25_00-18-26-590.R	✓ Generated
AE (Adverse Events)	ae_2026-03-25_00-18-26-590.R	✓ Generated

DM Execution Results:

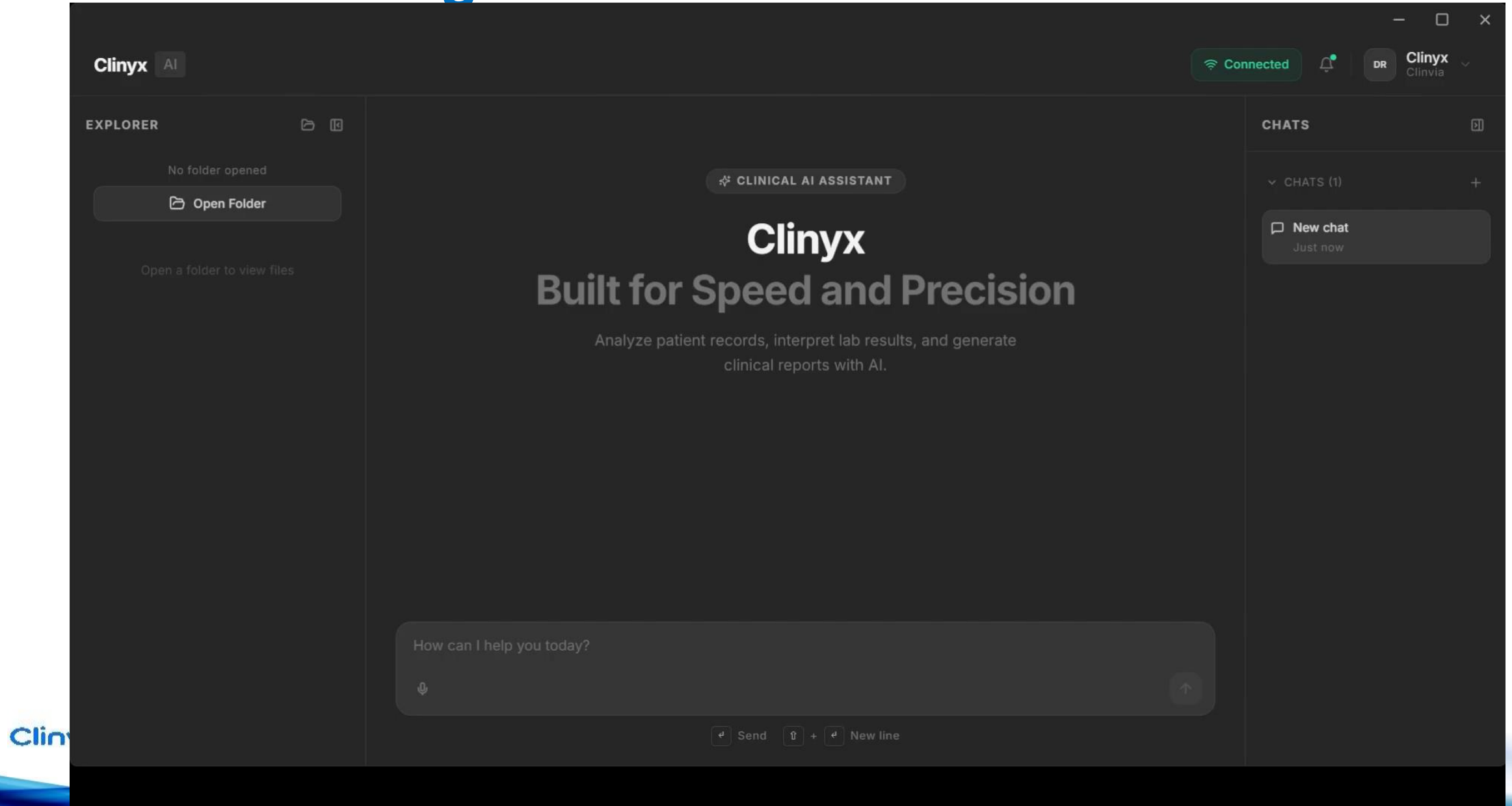
- **Status:** ✓ SUCCESS
- **R Version:** 4.5.1 (2025-06-13)
- **Output:** dm.xpt created in R_codes/Generated_code/out/
- **Fix Applied:** Corrected the REPENDTC_rm variable reference issue (renamed to REPENDTC_disp for clarity)

Output Files in out/ folder:

- dm.xpt ✓ (freshly generated)
- dm.sas7bdat
- ds.xpt
- lb.xpt
- suppaexpt

AI completed works
AI summarized its
action

AI Agent in action demo

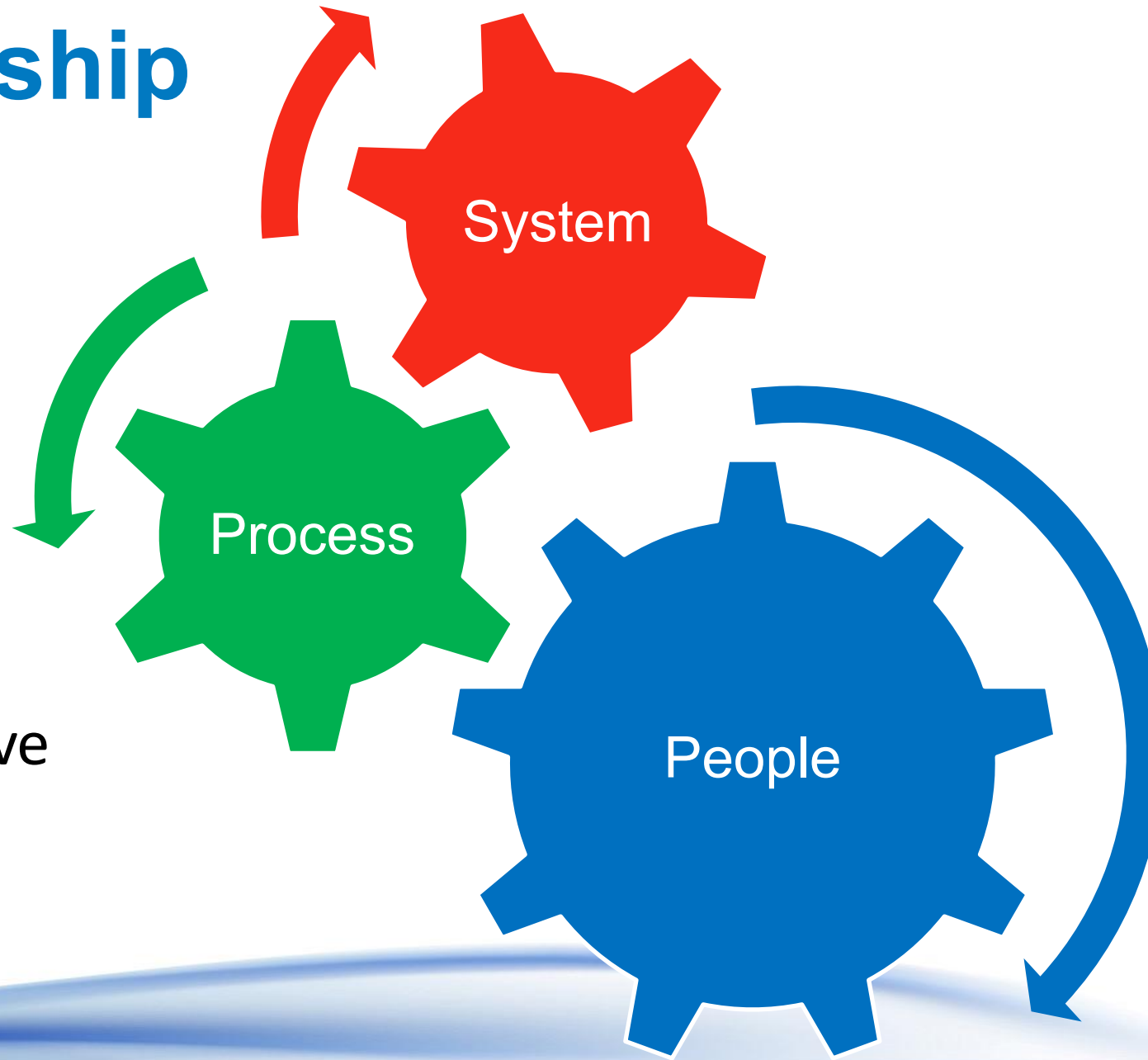


Definition of Leadership

Leadership is defined as

“the ability
to cultivate the environment,
guide the process,
empower people

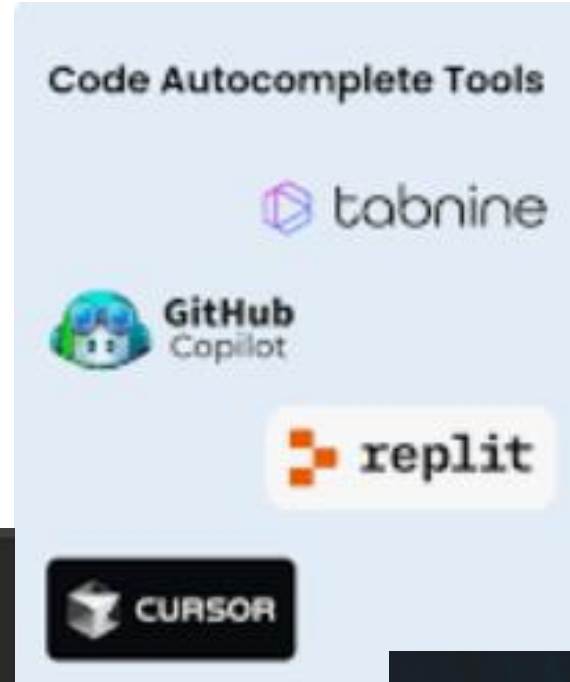
to achieve a shared vision and drive
common goals”



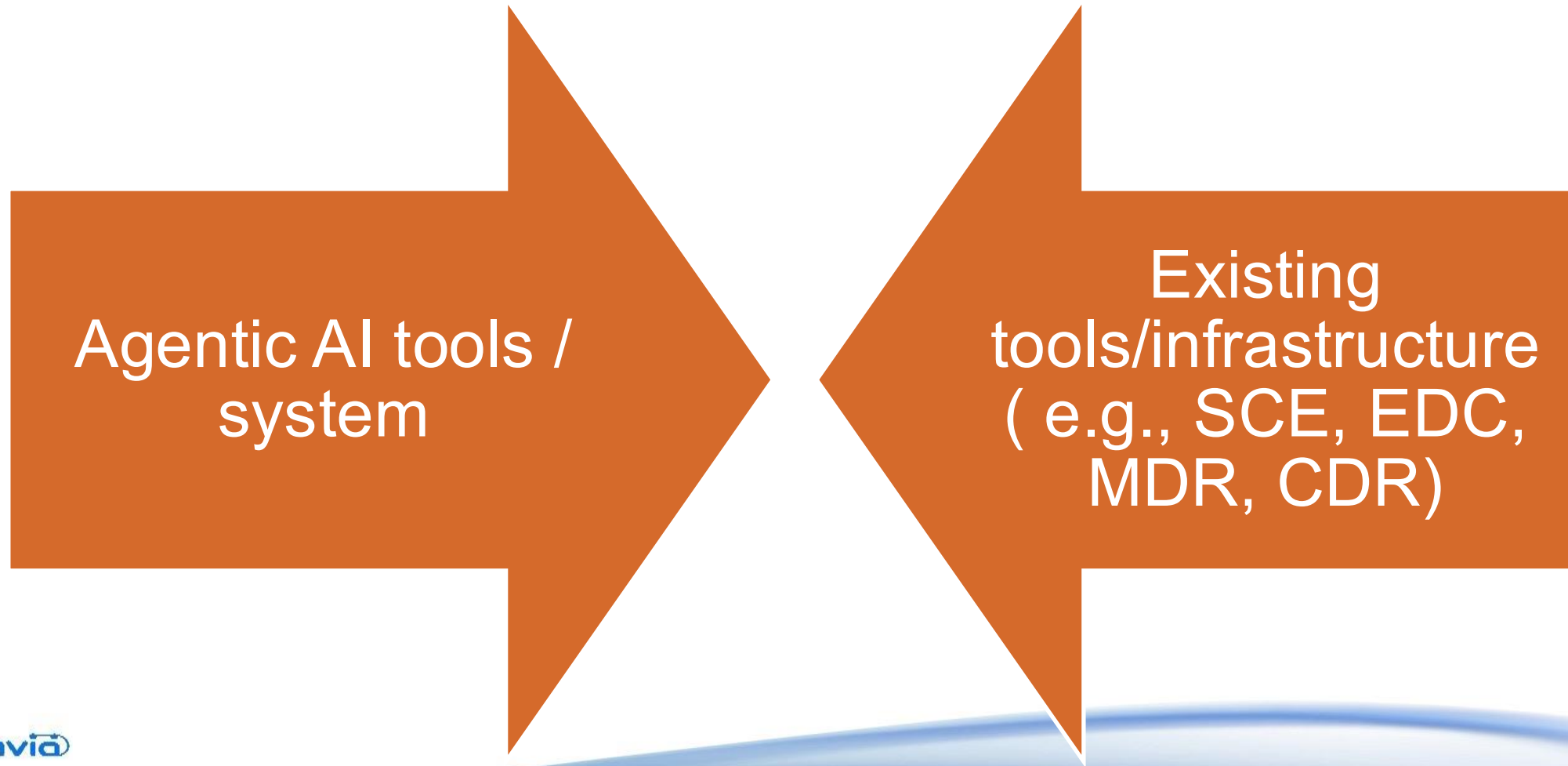
Agentic AI Tools / Systems in Biometrics

- Identifying Agentic AI tools
- Integrating with existing infrastructure
- Validation framework
- Compliance and Integrity

Agentic AI Tools / Systems



Integration with existing infrastructure



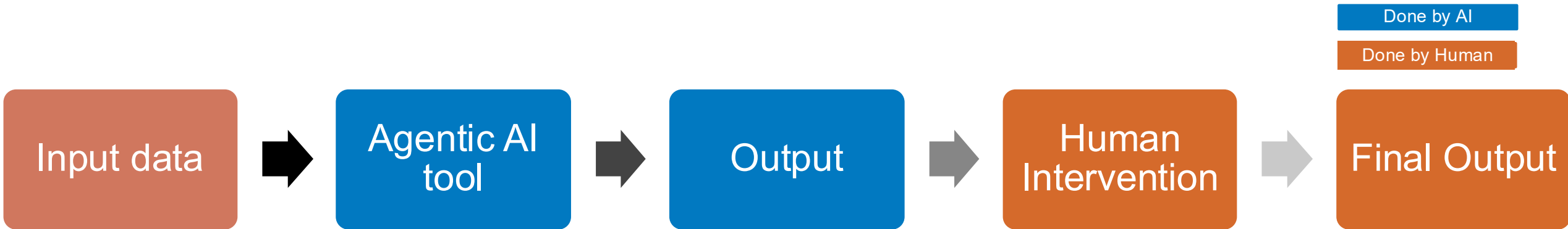
Where Agentic AI could be used???



Non GxP
Environment

GxP
Environment

Agentic AI outputs – mitigation / validation process

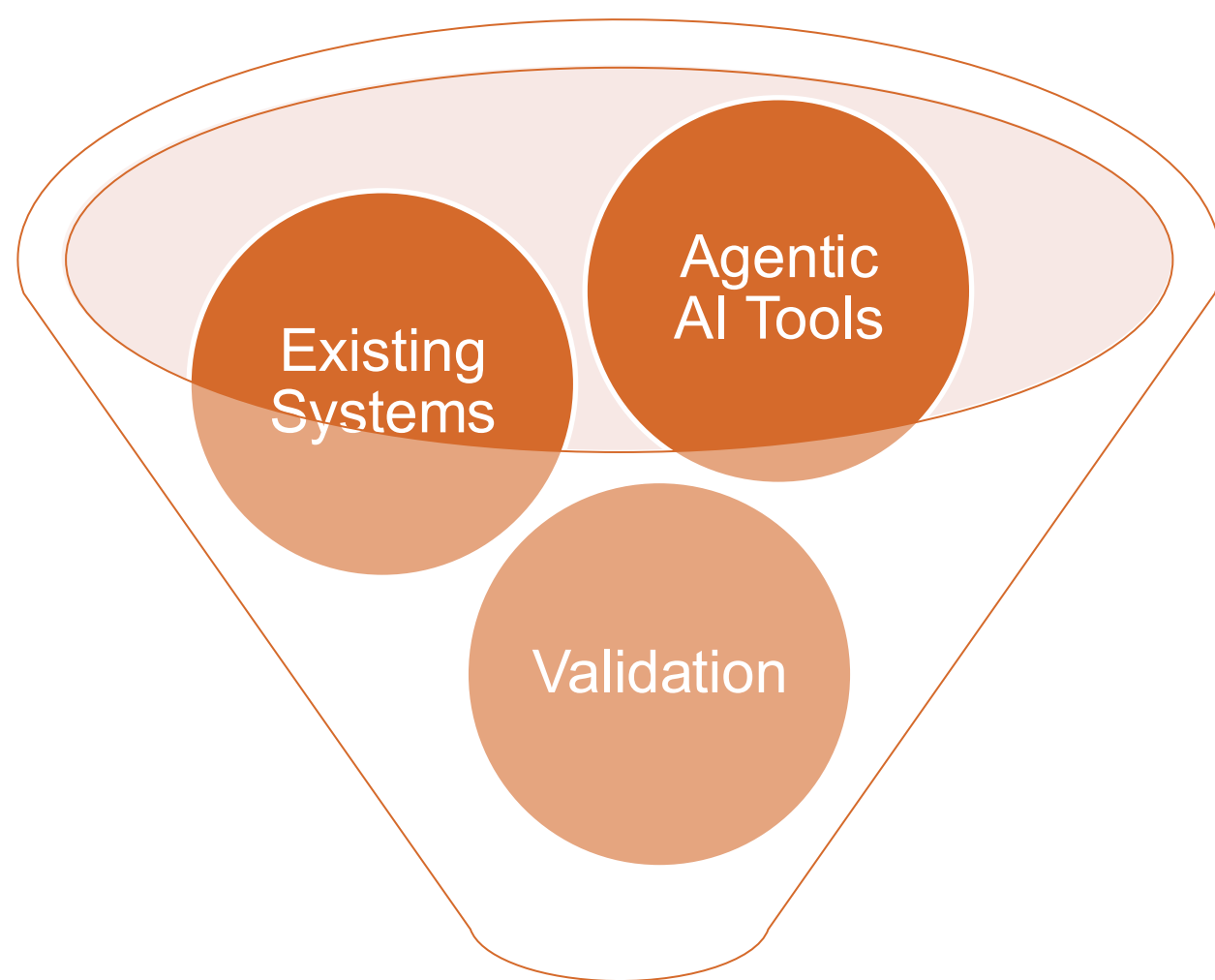


The output of Agentic AI is
not the final result,
but the beginning of new process.

Validation framework

- **Regulatory Importance:** Agentic AI outputs must meet the **same quality standards** as traditionally produced results.
- **Biometrics Leadership Role:** Must establish rigorous, **risk based validation protocols/systems** tailored for Agentic AI implementation.
- **Framework Components:**
 - Risk-based validation planning
 - Verification of AI-generated output accuracy
 - Application of GxP / GAMP 5 principles
 - Comprehensive documentation (requirement, process, test scripts, reports)
 - Version control and audit trails

Agentic AI integrated, compliant Biometric ecosystem roadmap



Ecosystem with traceability,
accuracy, consistency, and
compliance

Agentic AI Process Roadmap

- Validation & QC
- End to End Current Process Redesign
- Human & AI Collaboration
- Regulatory Strategy

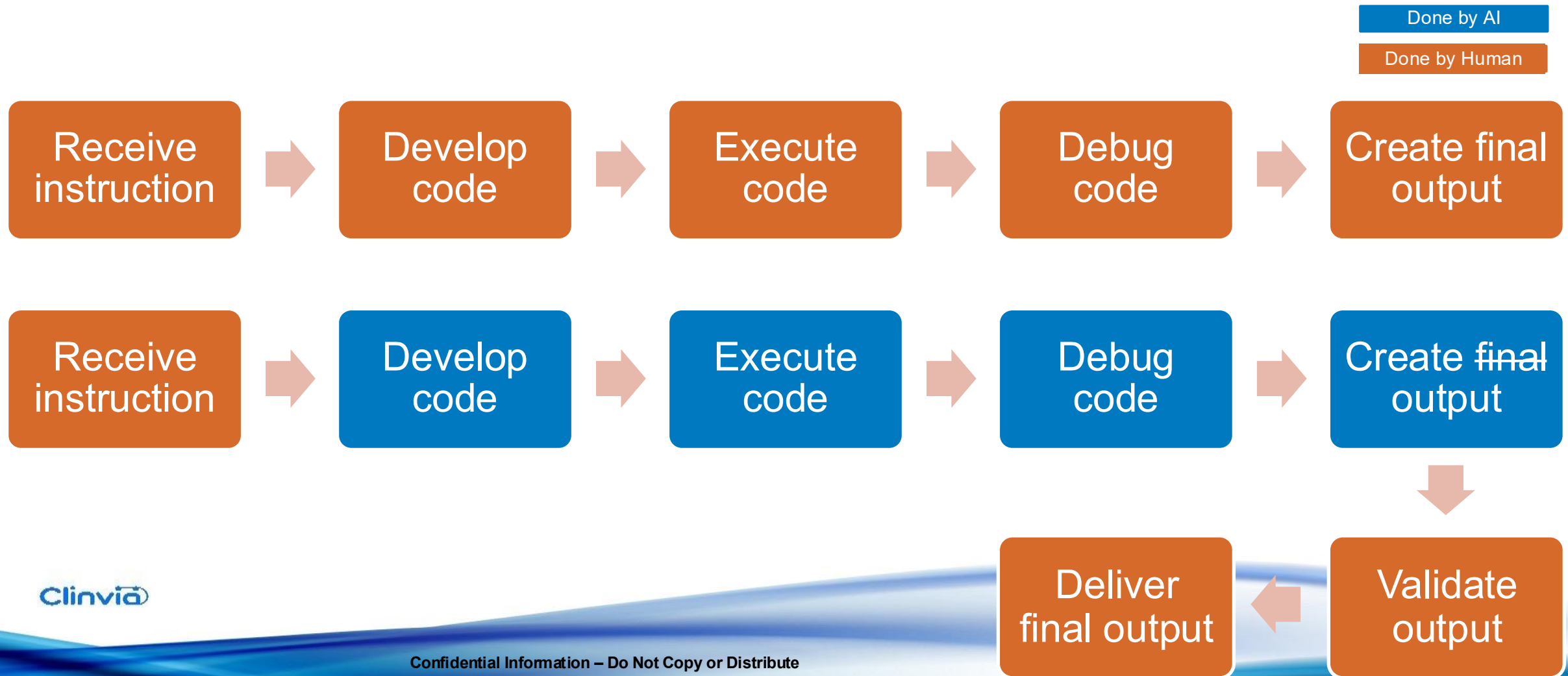
**Agentic AI is like a very smart,
capable, recently graduated intern/new
hire.**



What will we do with the outputs from an intern's work?



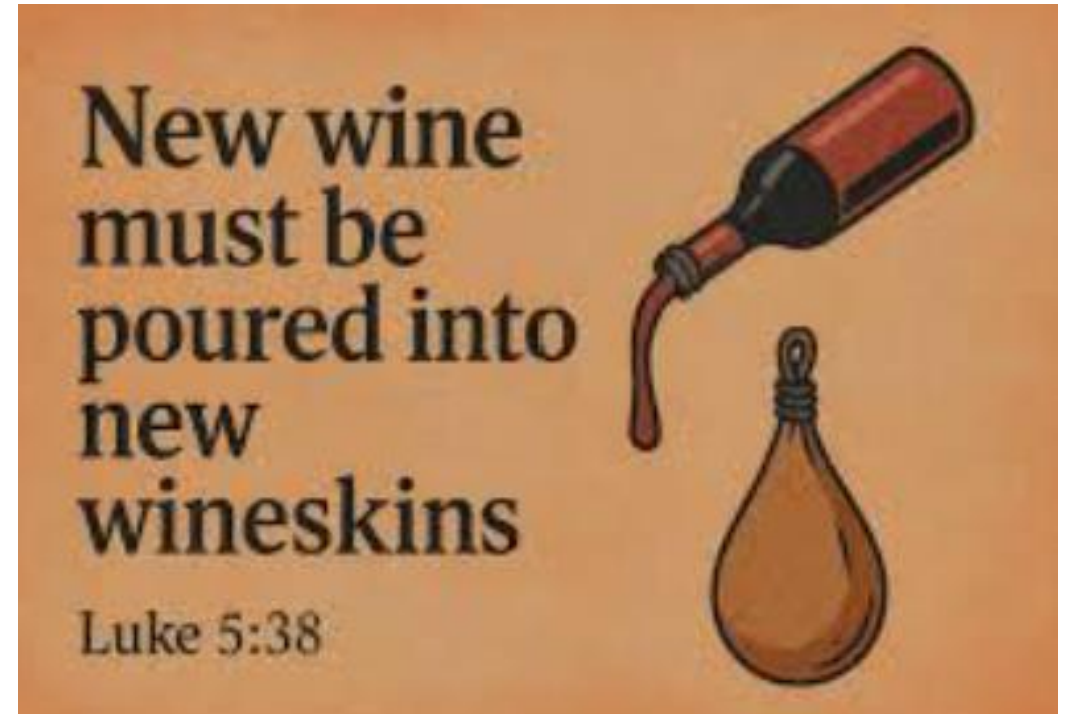
Biometrics Programming workflow using AI Agents with human involvement – **Agentic AI workflow**



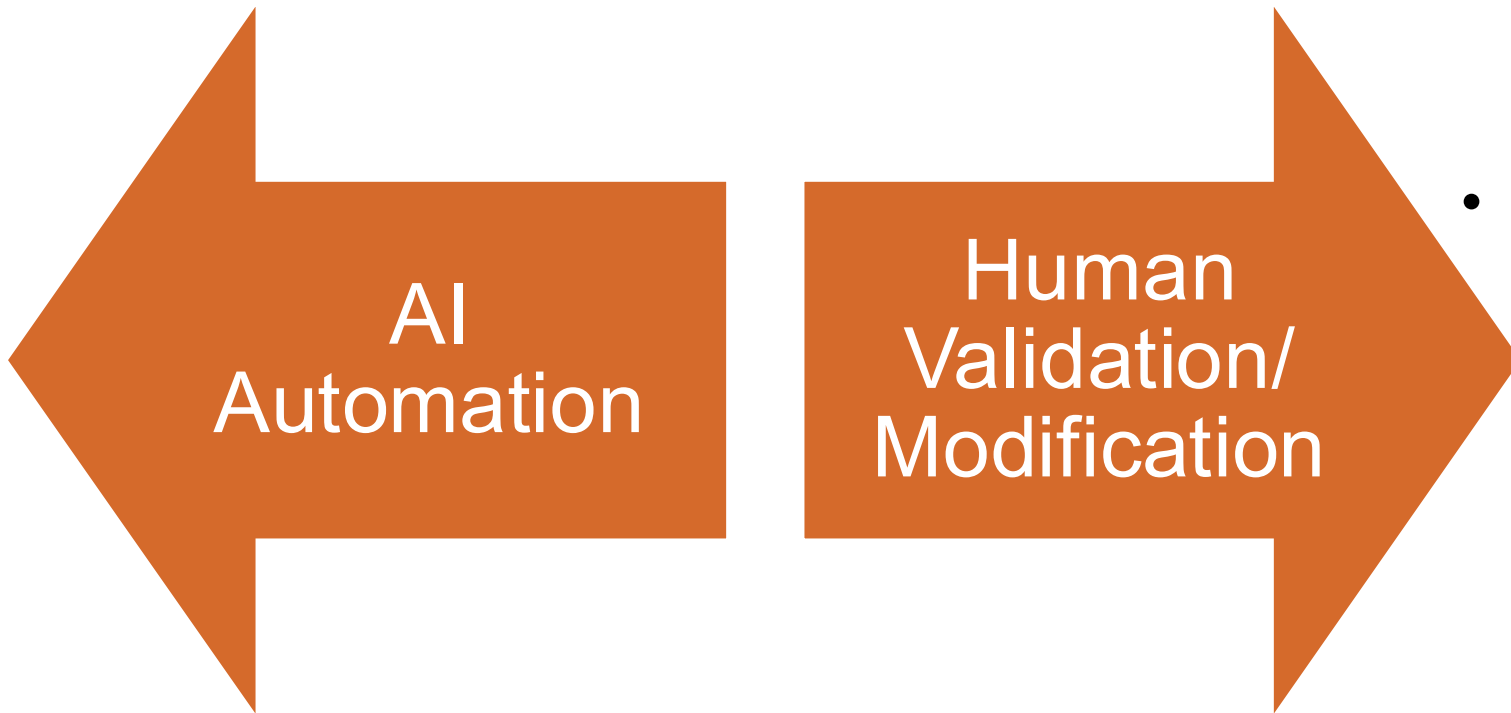
End-to-End Process Redesign with Agentic AI Integration

- **Comprehensive Review**: Biometrics leadership should review the entire biometric process
- **Identify Opportunities**: Focus on high-impact areas where Agentic AI can be integrated to add value.
- **New Agentic workflow**: Apply a holistic approach to streamline processes and reduce inefficiencies.

Goal: **Improve overall efficiency and effectiveness** of biometric workflows through Agentic AI integration.



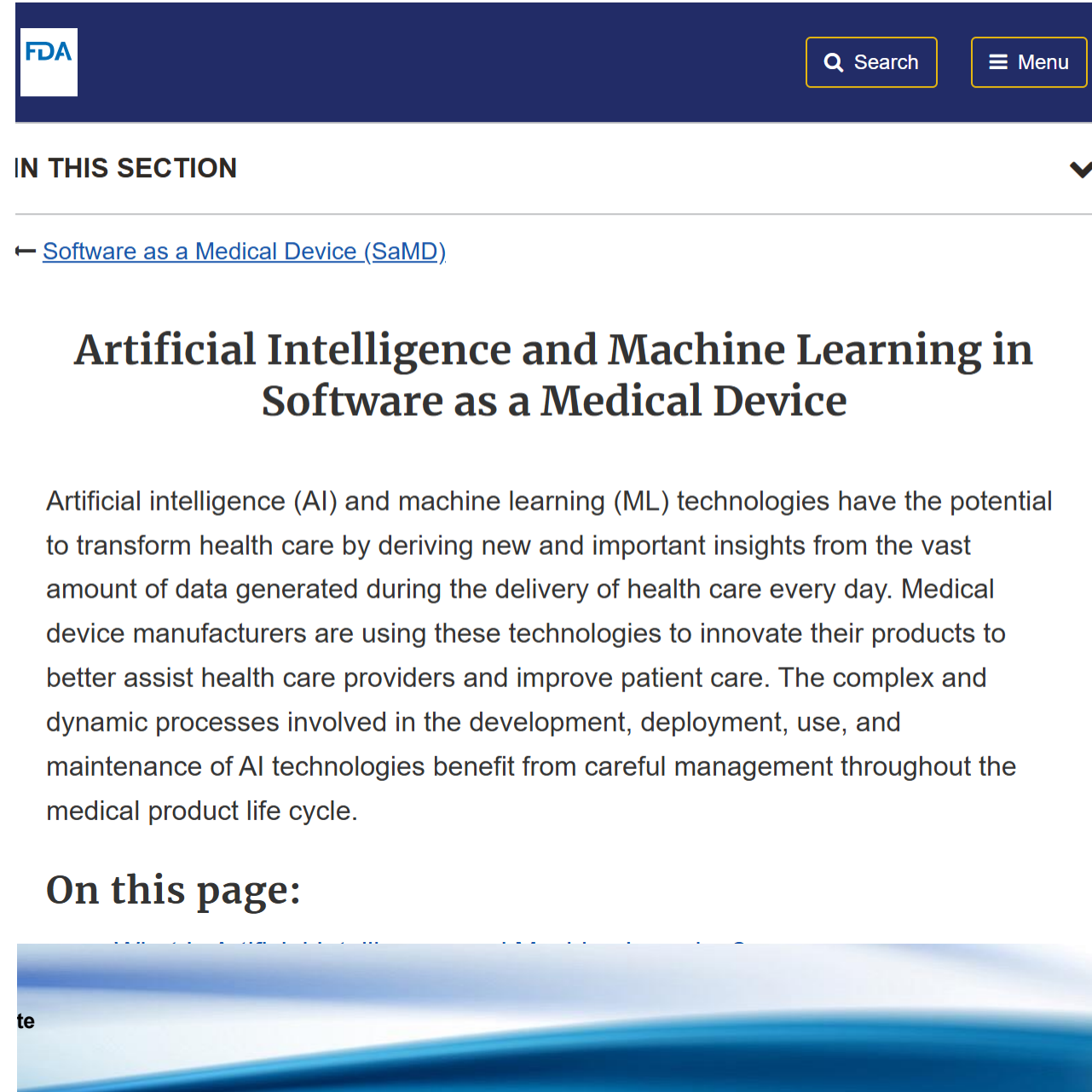
Human vs AI Collaboration Strategy



- Clear delineation
 - AI-driven activities
 - Human-driven activities
- AI roles
 - **Assistant**: e.g., generating initial code or report templates
 - **Autonomous Operator**: e.g., handling routine quality checks or standardized visualizations
- Human intervention- required to ensure **oversight and accountability.**

Regulatory Strategy

- **Forward-thinking leadership**
 - Expecting evolving **regulatory requirements**
 - **Engaging** proactively with authorities.
- **Key strategies:**
 - Preparing comprehensive documentation of **validation** approaches
 - Developing **SOPs, Working Instructions, and Guidelines** for Agentic process.
 - **Validating software packages** used by AI tools to ensure regulatory compliance (e.g., R or Python packages)



The screenshot shows the top navigation bar of the FDA website with the FDA logo, a search bar, and a menu button. Below the navigation bar, the section 'IN THIS SECTION' is visible, followed by a link to 'Software as a Medical Device (SaMD)'. The main heading of the page is 'Artificial Intelligence and Machine Learning in Software as a Medical Device'. The introductory paragraph discusses the potential of AI and ML technologies to transform health care by deriving new insights from vast amounts of data generated during the delivery of health care every day. It mentions that medical device manufacturers are using these technologies to innovate their products to better assist health care providers and improve patient care. The paragraph also notes that the complex and dynamic processes involved in the development, deployment, use, and maintenance of AI technologies benefit from careful management throughout the medical product life cycle. At the bottom of the page, there is a blue gradient banner with the text 'te' visible on the left side.

FDA

Search Menu

IN THIS SECTION

← [Software as a Medical Device \(SaMD\)](#)

Artificial Intelligence and Machine Learning in Software as a Medical Device

Artificial intelligence (AI) and machine learning (ML) technologies have the potential to transform health care by deriving new and important insights from the vast amount of data generated during the delivery of health care every day. Medical device manufacturers are using these technologies to innovate their products to better assist health care providers and improve patient care. The complex and dynamic processes involved in the development, deployment, use, and maintenance of AI technologies benefit from careful management throughout the medical product life cycle.

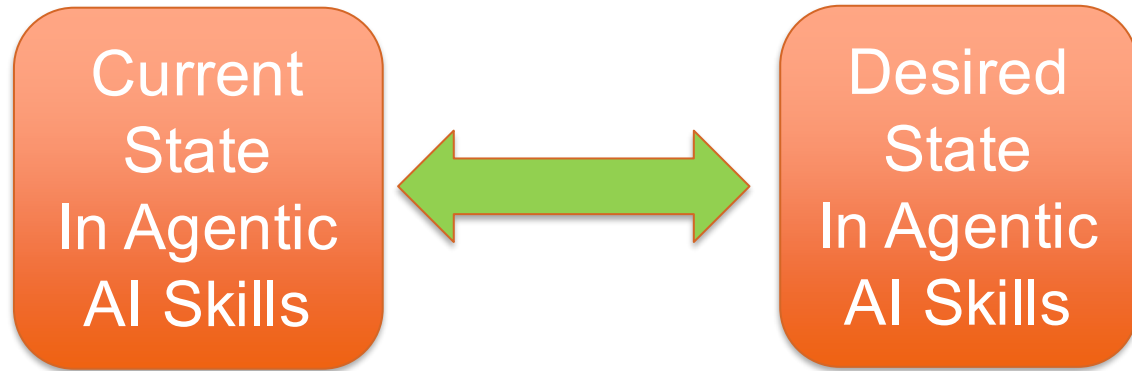
On this page:

te

People Empowerment

- Capability Building
- Culture Transformation
- Cross functional Collaboration

Comprehensive Capability Building



Assessment

- Existing skill gaps
- Implement targeted training initiatives.

- Focus areas for capability building:
 - Technical proficiency with Agentic AI tools (e.g., ChatGPT, Copilot)
 - Prompt engineering
 - Validation skills for AI-generated outputs
- A systematic approach ensures department-wide readiness for Agentic AI integration.

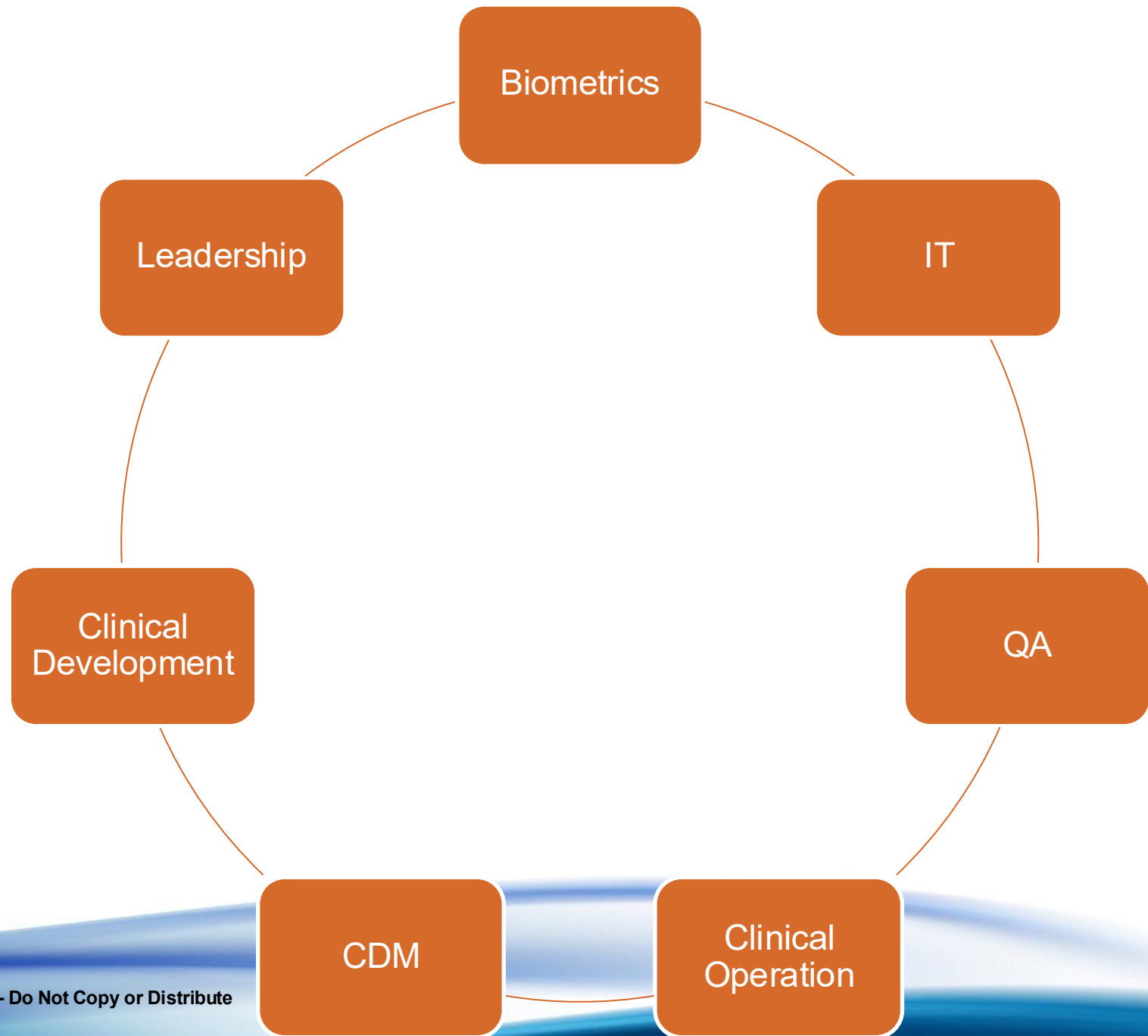
Culture Transformation

- Foster **psychological safety** to encourage experimentation with Agentic AI tools.
- Promote a mindset of **responsible innovation**—where creativity thrives without compromising compliance.
- Goals : To ensure continued commitment to **regulatory compliance** while embracing AI change.



Cross-functional Collaboration

- Goals : leading Agentic AI implementation by addressing the needs of other functions



Leading into the future

- Dream come true???
- The opportunity to grow

In a dream, something is coming at you – You are growing.



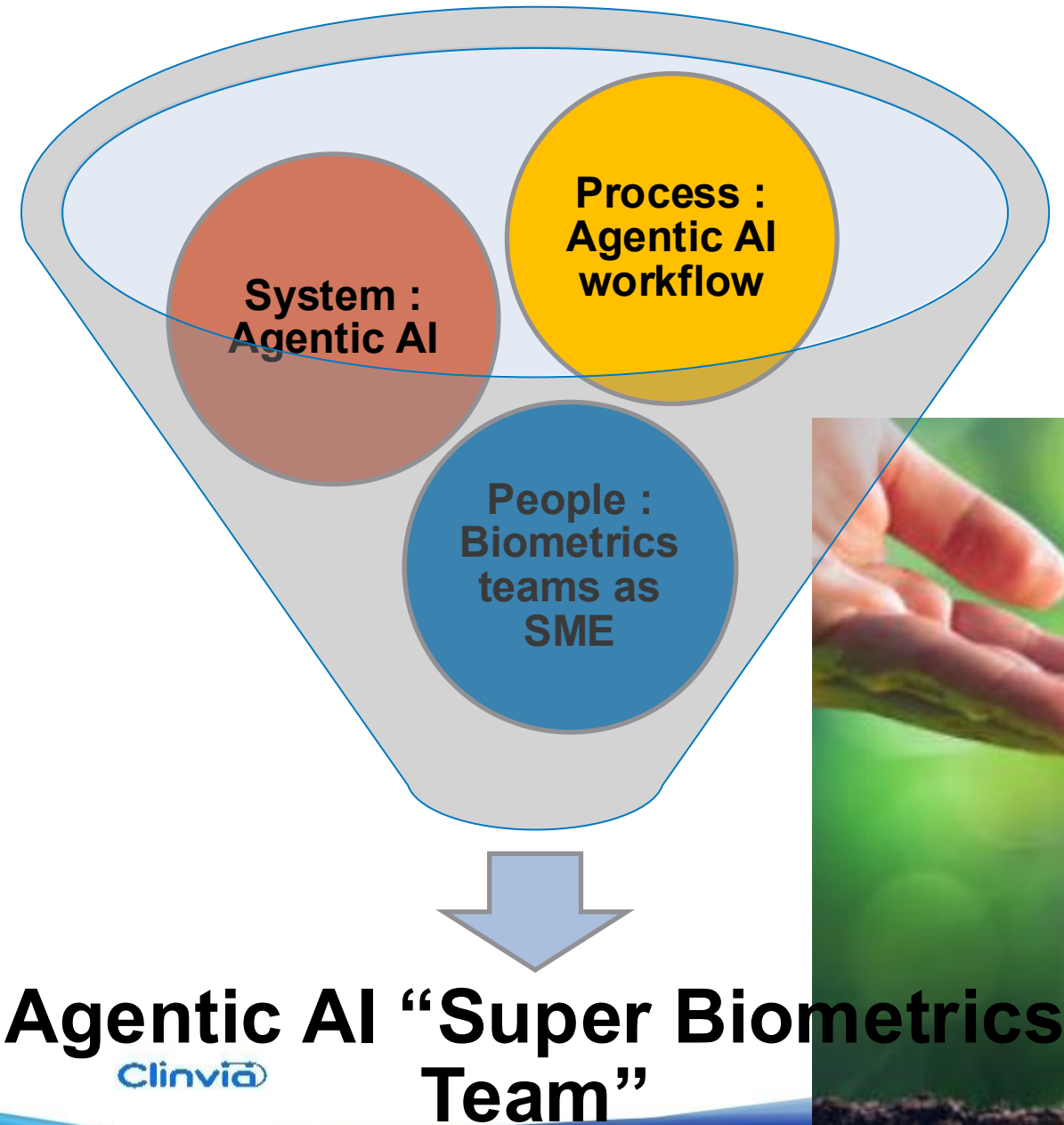
ChatGPT Users vs Non-Users Comparison in Boston Consulting

- Results of ChatGPT Users
 - finished **12.2%** more tasks on average
 - completed tasks **25.1%** more quickly
 - produced **40%** higher quality results

Re-imagine how much we could improve with Agentic AI?



Growing with Agentic AI into “Super Biometric Team”



Confidential Inform



ANY QUESTIONS



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