



d-wise™

Accelerate to the Speed of Life

SimSCE: Building an SCE City to Enable Future Clinical Computing Needs

Agenda

- SimCity: What was it and how did it work?
- Industry Perspective and Current Roadblocks
- Is there another option?
- How is Modularity (SimSCE) Different than the Past
- SimSCE Journey

Sim City... Building and Configuring..



What was SimCity?

- Open Ended City Building Video Game
- First released in 1989
- Player rapidly builds a city on a patch of undeveloped land adding:
 - Roads
 - Building types
 - Tax rates, budget, and social policies
 - Simulated People - "Sims"



Industry Perspective, Current Roadblocks, and a 3rd Option



Industry Vision

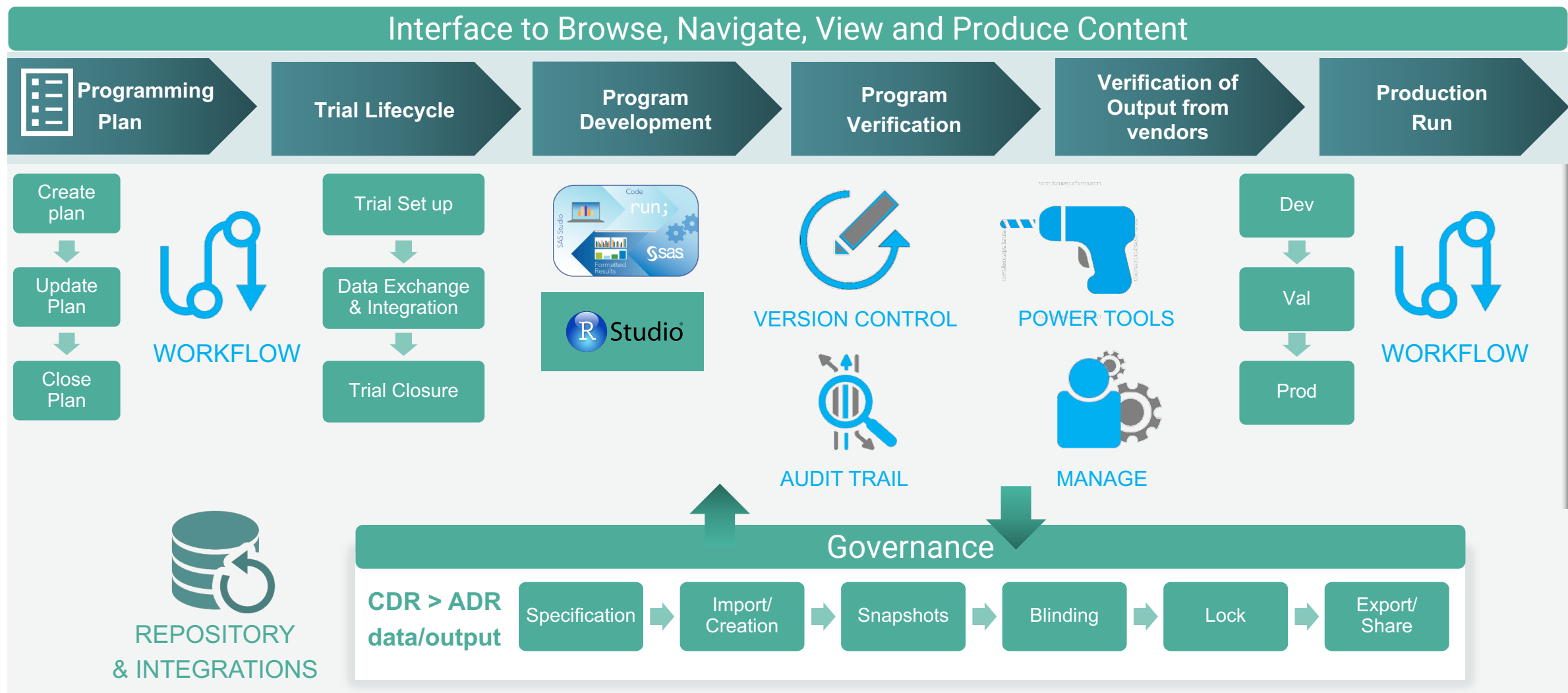
Sponsors are seeking strategic input and a solution to transform from a traditional reactive 'SCE' to an intelligent, intuitive clinical analytics framework with focus on the meaning of data and not the transformations along the way

d-wise perspective ➡ an enabled future state includes the following features and benefits:

- ✓ **Fit for Purpose UX:** right tool and experience for the business need
- ✓ **Enabled Elasticity:** consume compute based on demand
- ✓ **Efficiency and Automation:** optimized business process promoting first time quality
- ✓ **Human Capital Focused:** maximize and integrate talent across the organization and align to trends in workforce skills
- ✓ **Compliance:** systemized validation process



Clinical Data Workflow: Raw Data to Clinical Study Report



Today's Challenge

- Unintuitive
- Steep learning curve
- Siloed

Usability



- Performance Challenges
- Validation Burden

Scalability



- Rigid Process
- Access to the right tool
- Nuanced business needs

Flexibility



- Access and controls gaps
- Data integrity risks

Compliance



- Lack of robust proof path
- Challenges reproducing results

Traceability



SimSCE – The Third Way

Produce Statistical Analyses (With Control & Efficiency)

❶ COTS

+Quick Build

-Limited configuration

+Shared cost

-Limited control of roadmap

❷ Custom-build

-Slow build

+Unlimited customisation

-Expensive costs: build / own

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❸ Another Option?

Pre-built core components

Efficient & Economic

Custom-built UX / UI

+Fit-for-purpose & adopt at customer's pace

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-Slow build

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**How is Modularity Different
then the Past?**



What is Modularity?



What is a Good Module?



Recent Enablers?



Who Supports Open Source?



Good Process Brings Value Too



SimSCE Journey



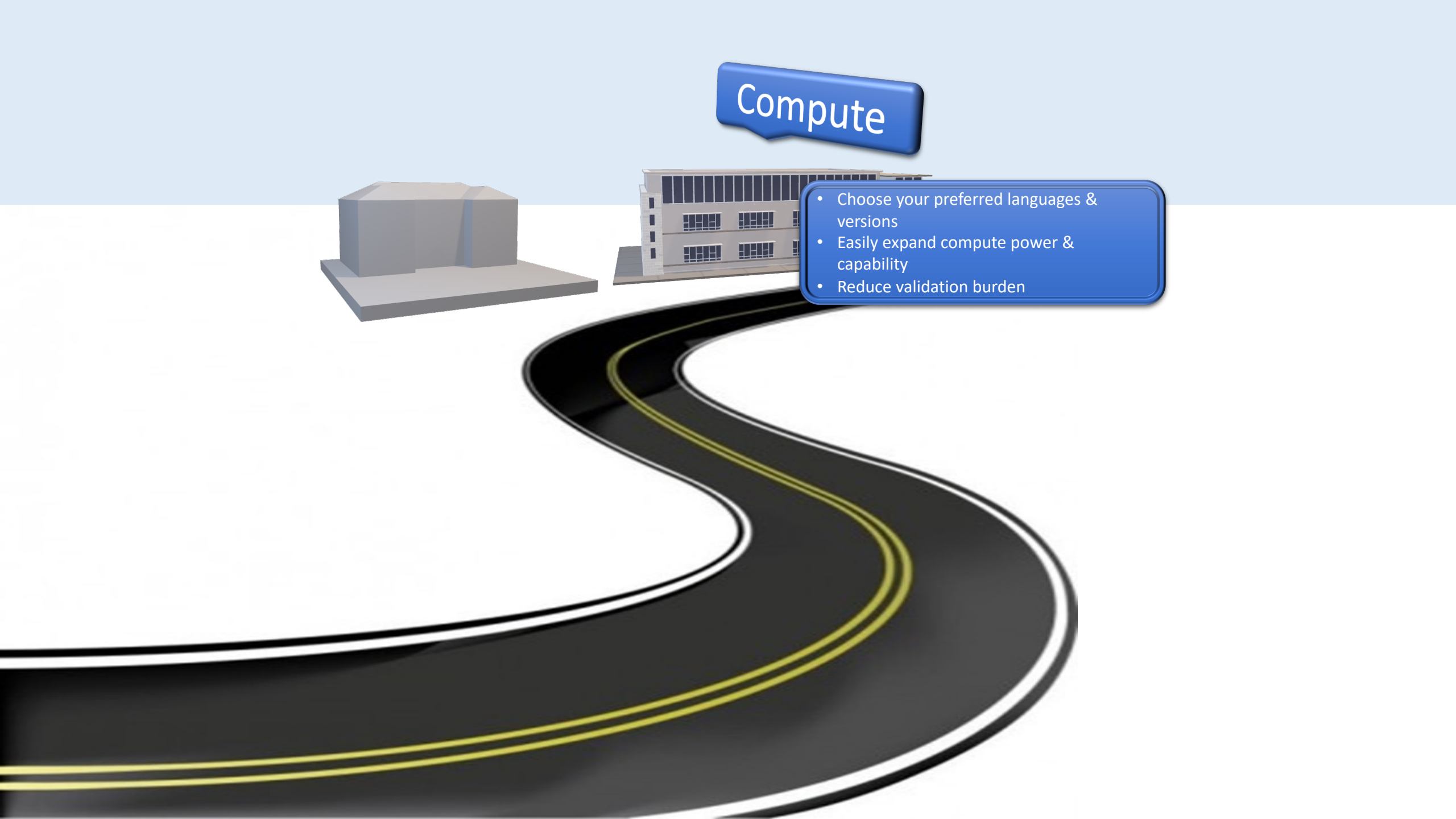




Compute



- Choose your preferred languages & versions
- Easily expand compute power & capability
- Reduce validation burden



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Storage

- Easily & rapidly expand size
- Optimise costs
- Manage on a study-by-study basis

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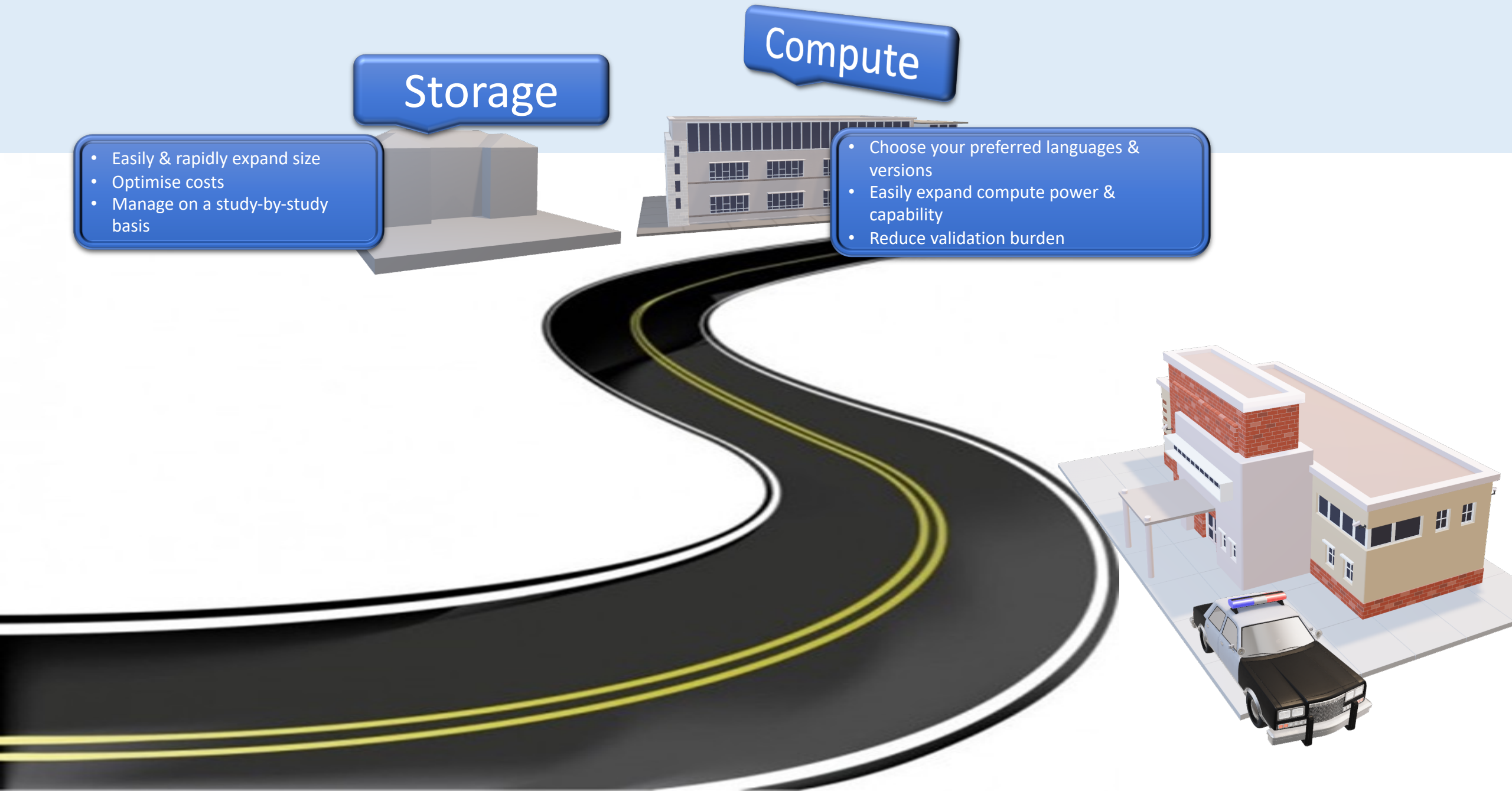


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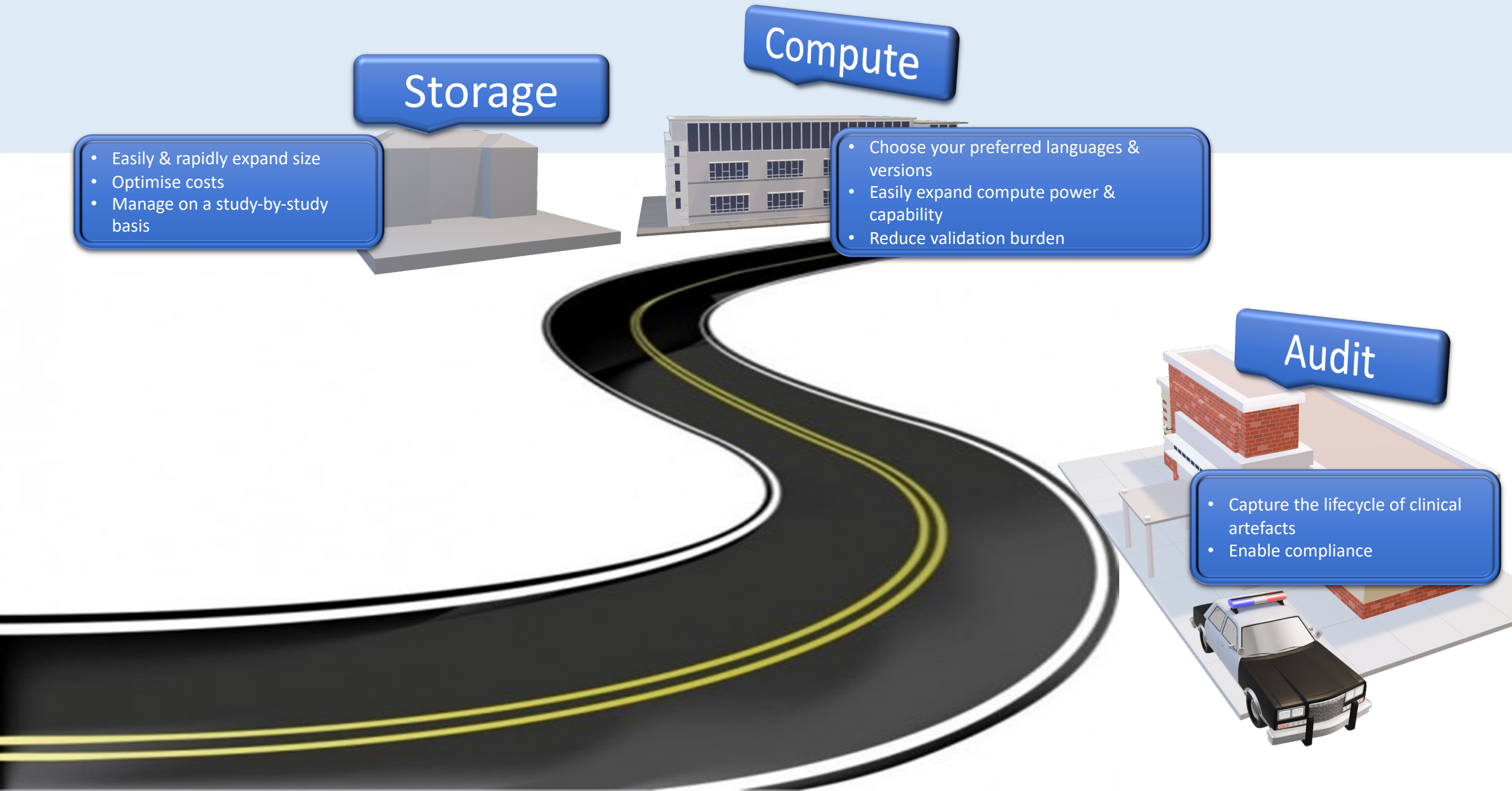
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- Enable compliance



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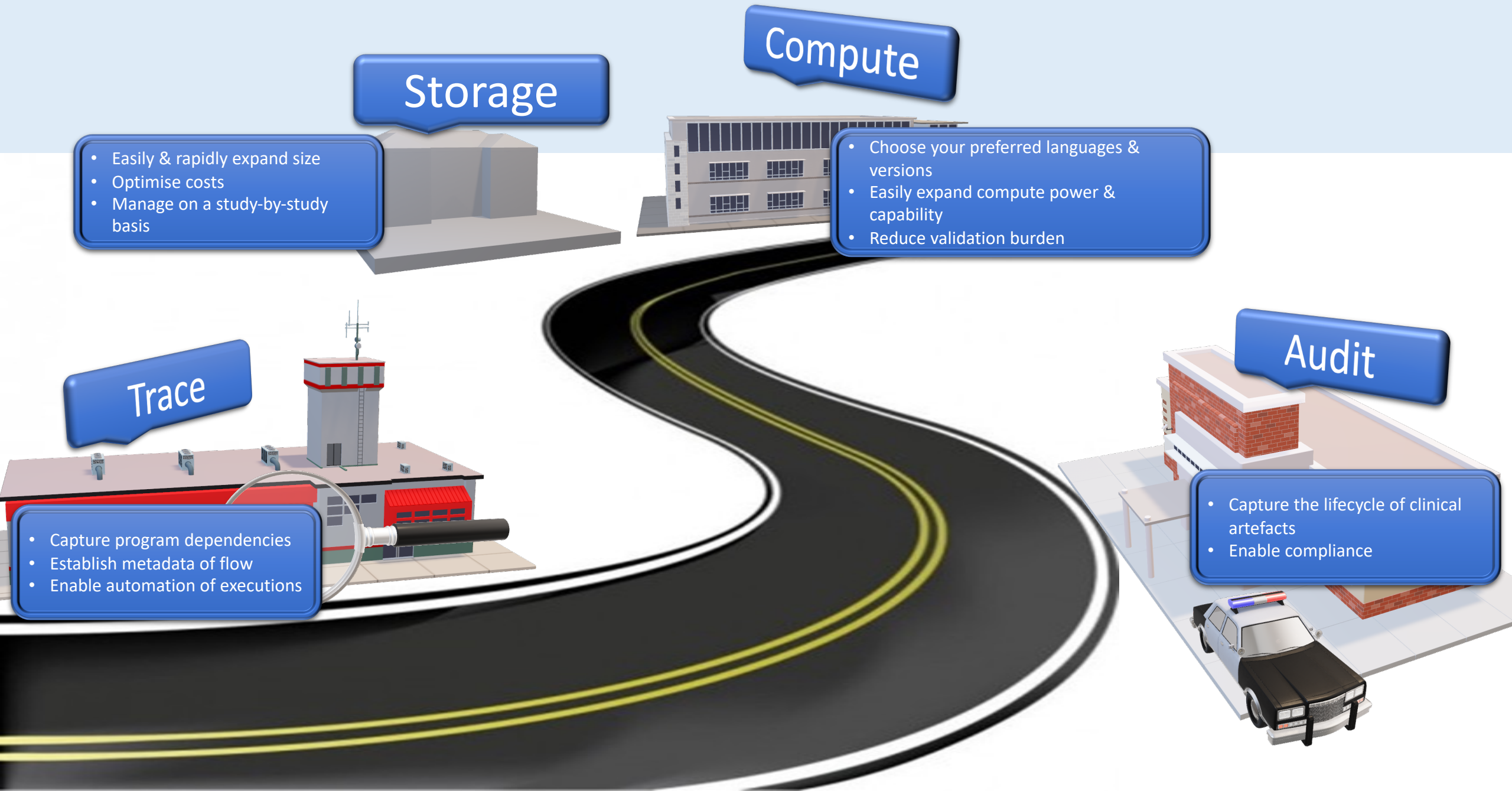
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- Capture program dependencies
- Establish metadata of flow
- Enable automation of executions

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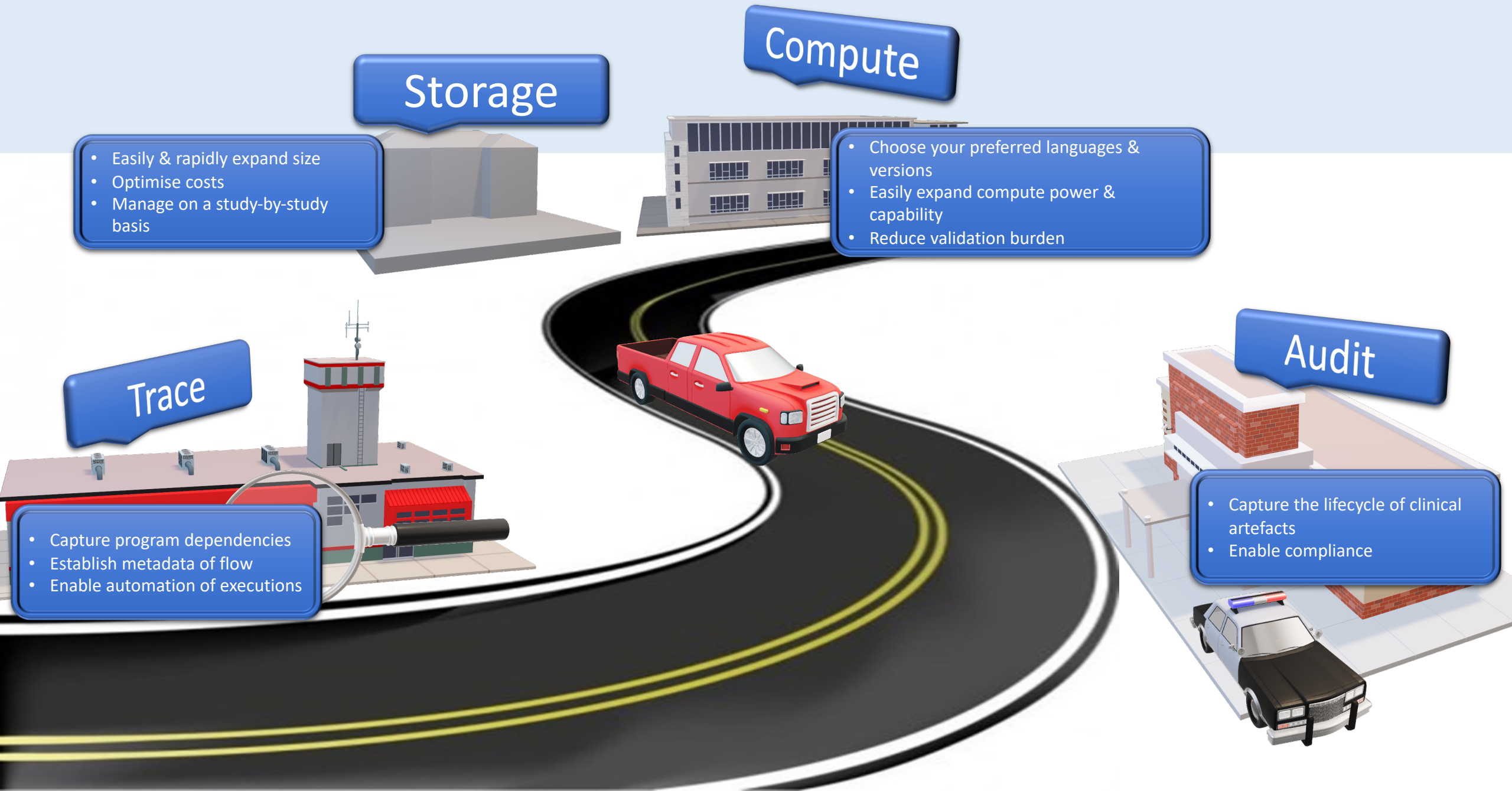
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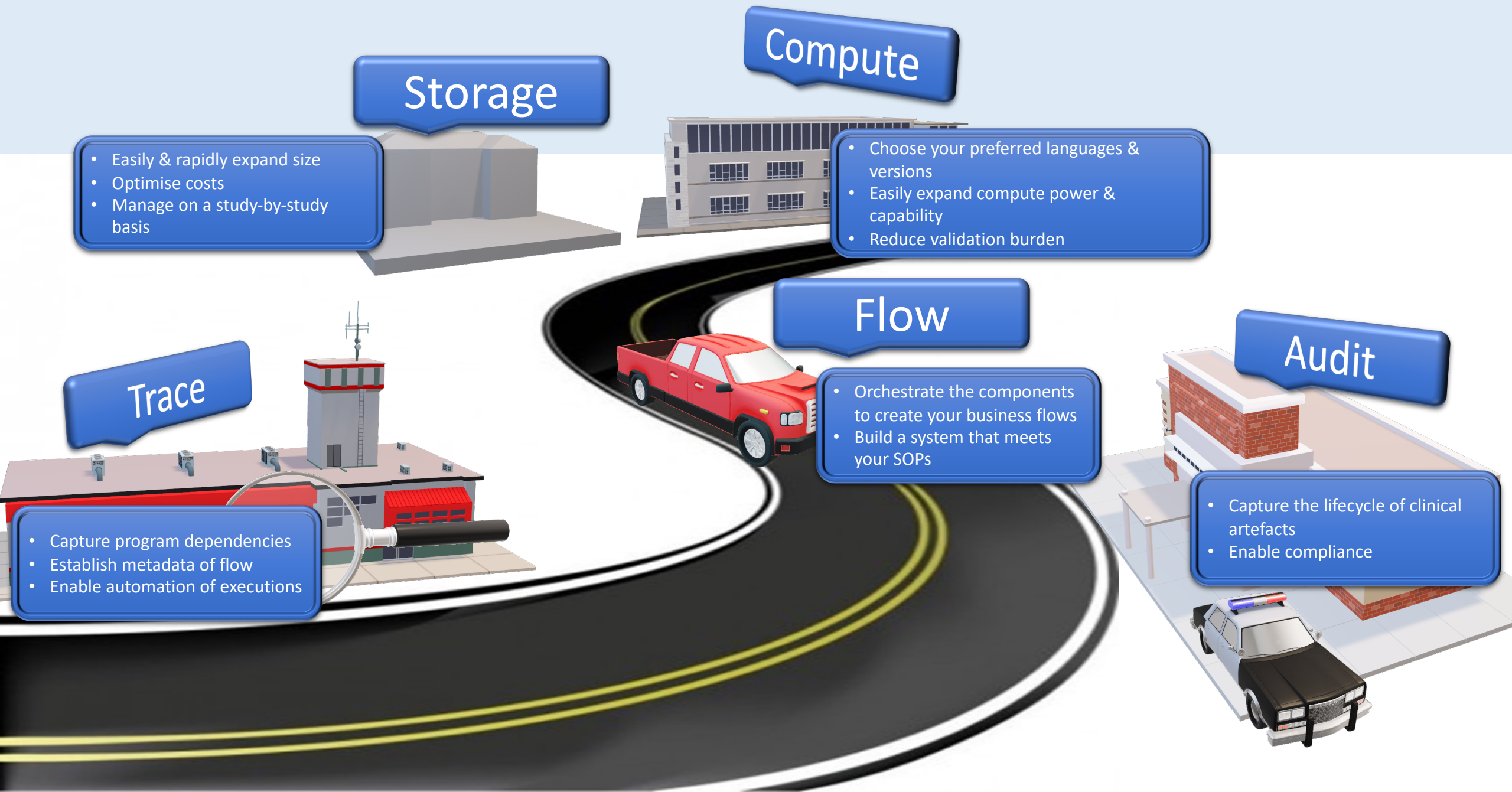
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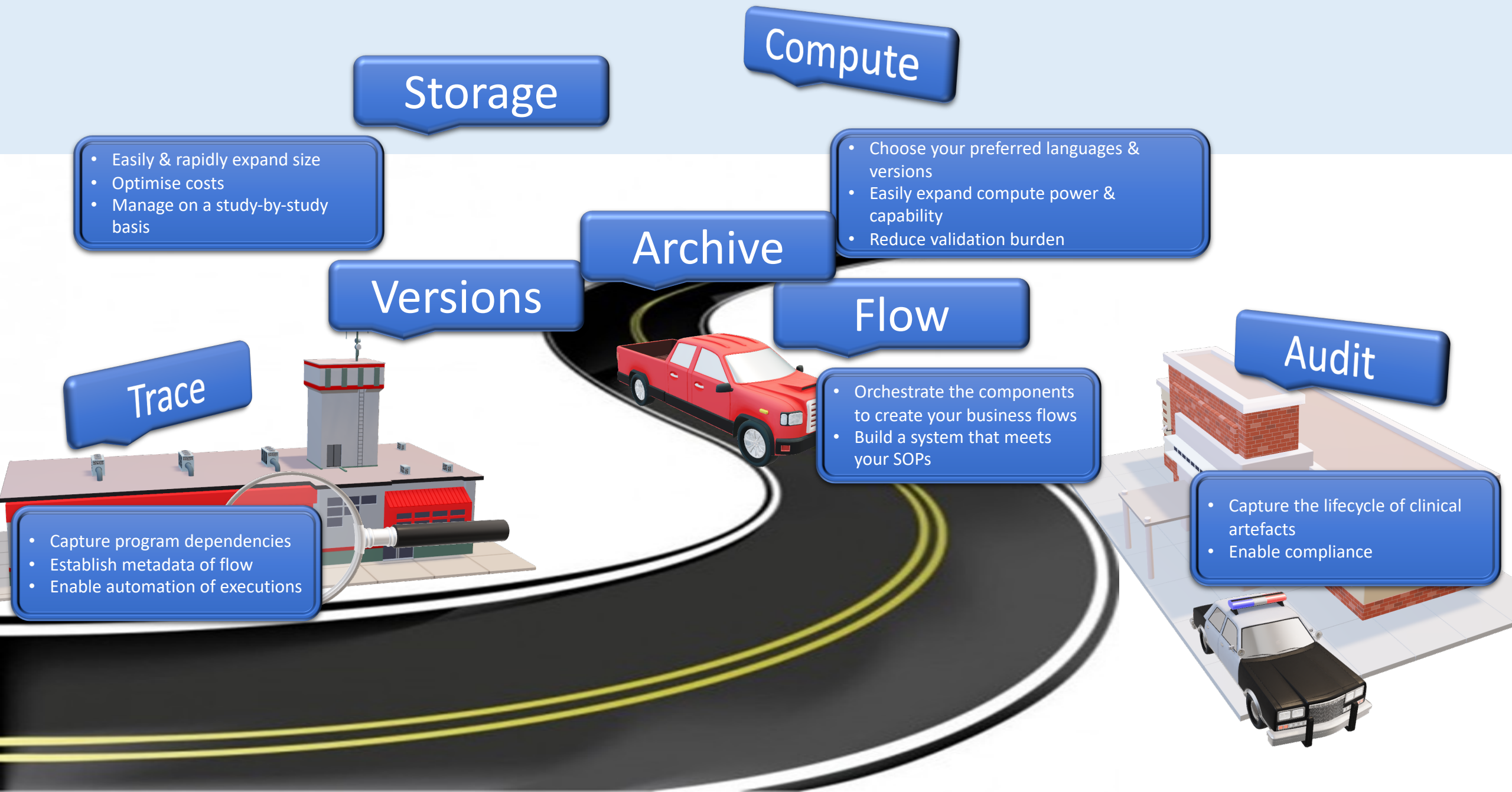
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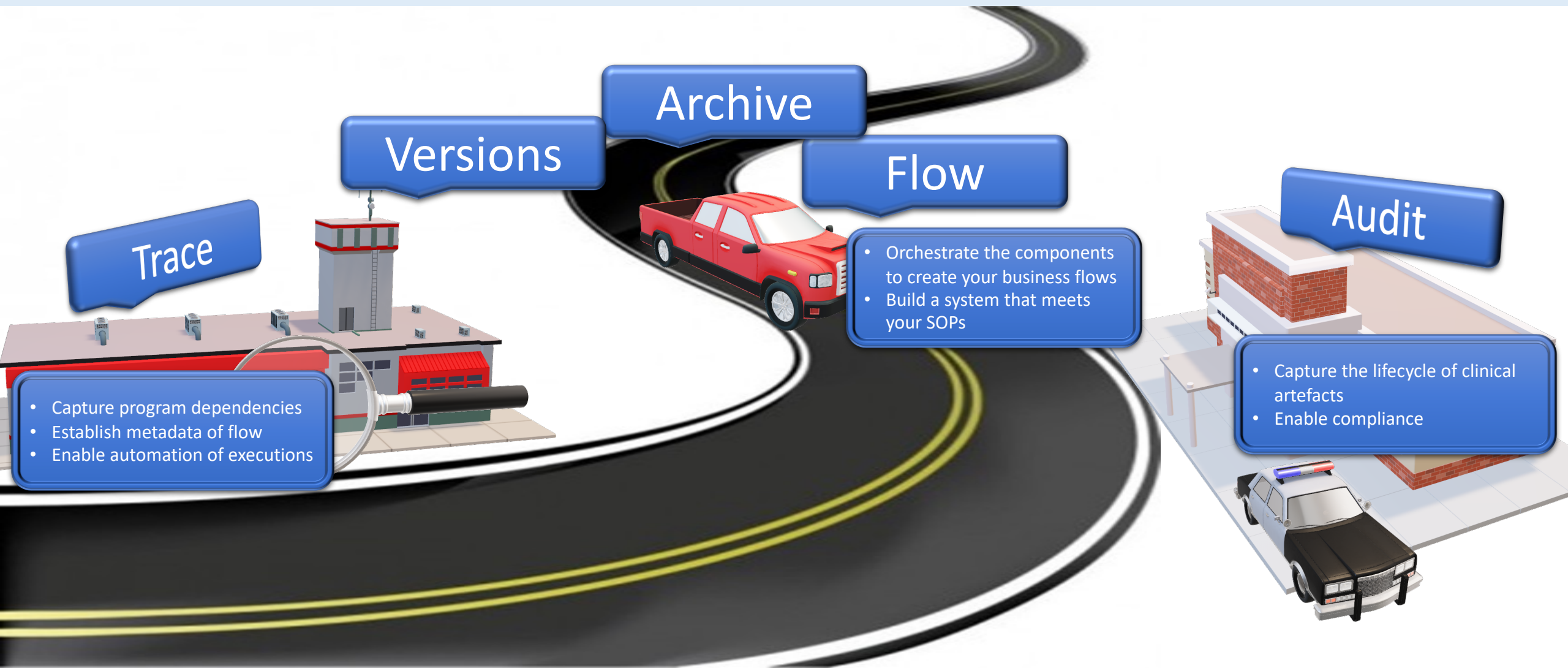
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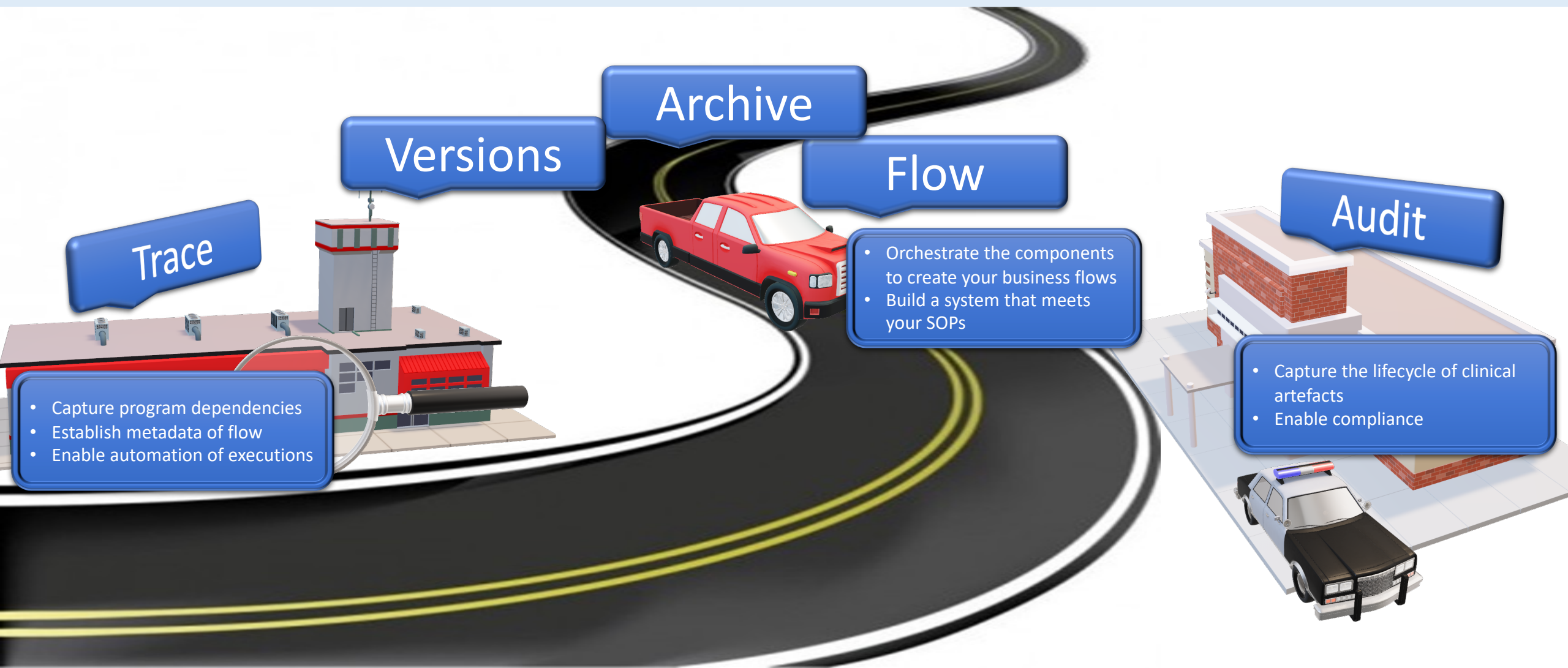
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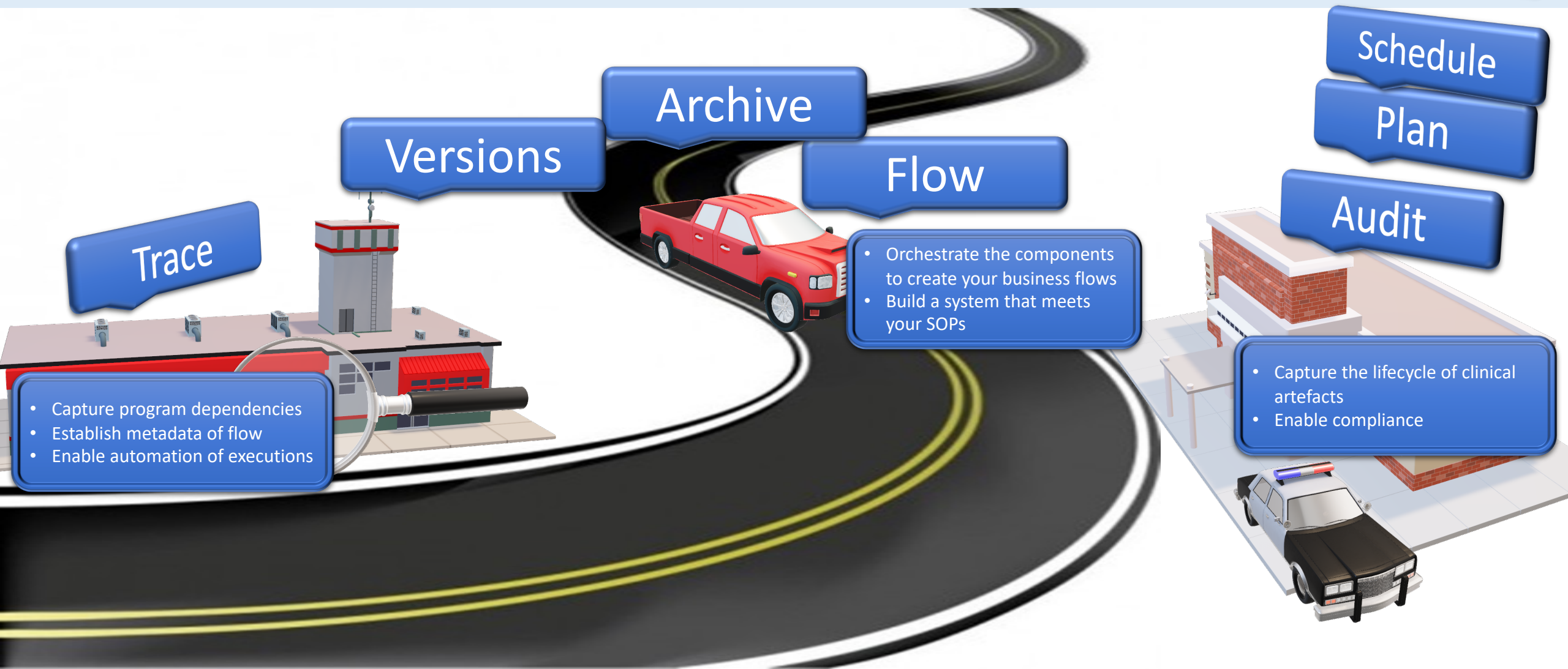
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Insights

Collaborate

Design



Summary

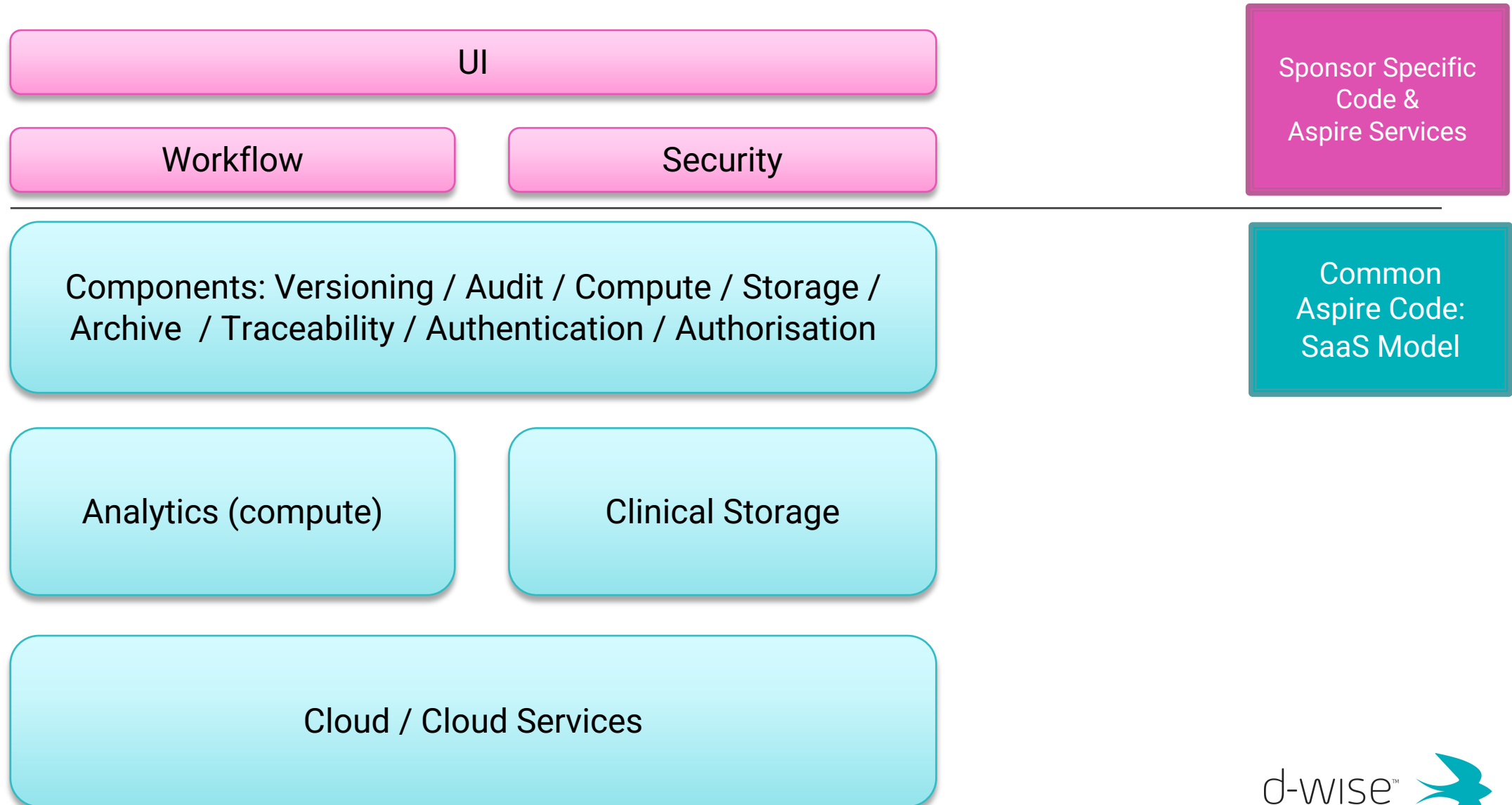
- ✓ Industry wants to transform to a new way
- ✓ Today's technology can support that transformation
- ✓ There is another way
- ✓ Industry can leverage components to build their SimSCE



PHUSE white paper

- Be an application that is intuitive and easy to use application
- Involve modern and scalable forward focused technology. Adopted technology that is reliably used for big data
 - Facilitate multiple programming languages
 - Effectively integrate with a variety of systems and tools to allow seamless access to data
- Successfully manage programming workflow e.g. version control, traceability,
- reproducibility
 - Allow effective outsourcing and collaboration
 - Include automated functionality to replace repetitive and manual-heavy tasks
 - Enable high compute power (high performance computing capability) to enable statistical methods that require complex simulations to be run in minutes
- improved productivity via standardization and automation
- accelerated time to submissions and deliver faster
- improved real-time access to data facilitating fast and high-quality decision making
- costs benefits
- reduced learning curve due to common working model
- attracting new talent
- reduced risks of downtime and unavailability
- truly meeting end-users needs with an improved user experience and satisfaction
- increased efficiencies being able to use different technologies, computes and programming languages adopting an easy to follow workflow
- scalability
- earlier and greater insights for data collection and enabling better decision making
- reduced risks of downtime and unavailability
- complying with rules and regulations
- future proof
- opportunity to consider direct access with health authorities
- support efficient transfer between sponsors with in / out licensing compounds

Architecture



Aspire Themes

