

INTRODUCTION

Welcome



Design Control Overview

Click the forward arrow to begin.



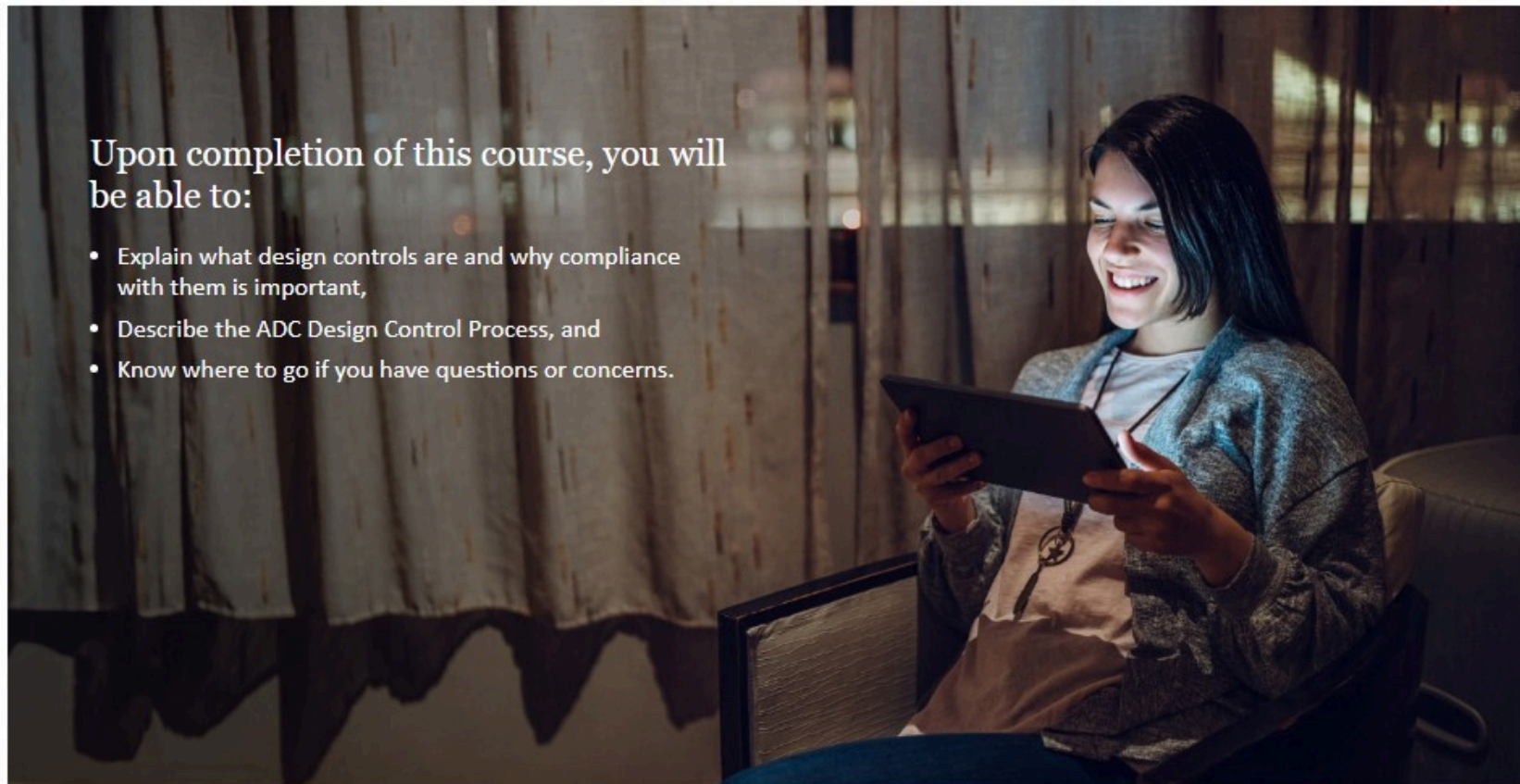
INTRODUCTION

Objectives



Upon completion of this course, you will be able to:

- Explain what design controls are and why compliance with them is important,
- Describe the ADC Design Control Process, and
- Know where to go if you have questions or concerns.



Menu



1 | ADC Design Controls

Here you will learn why we have established the ADC Design Control process.

4 MINUTES ⌚

Click the panel to get started.

2 | The ADC Design Control Process

Here you will learn about the five phases of the ADC Design Control process.

8 MINUTES ⌚



3 | Knowledge Check

Assess your understanding of the key concepts and principles of this course.

3 MINUTES ⌚



Importance of ADC Design Controls



The success of Abbott Diabetes Care (ADC) relies on the development of new products, and the modification of our existing products.

These products are designed to meet the needs of both the business and our end-users.



Importance of ADC Design Controls



In order to meet these needs we have established the ADC Design Control process.

The ADC Design Control process receives inputs from the Business Processes on the users' needs and the intended uses of the product. It then

- Formalizes these inputs into user, system, and design requirements; and
- Executes the product development lifecycle to produce a product that meets these needs and intended uses.



Importance of ADC Design Controls



The ADC Design Control process is designed to comply with the regulations and standards applicable to device product development.

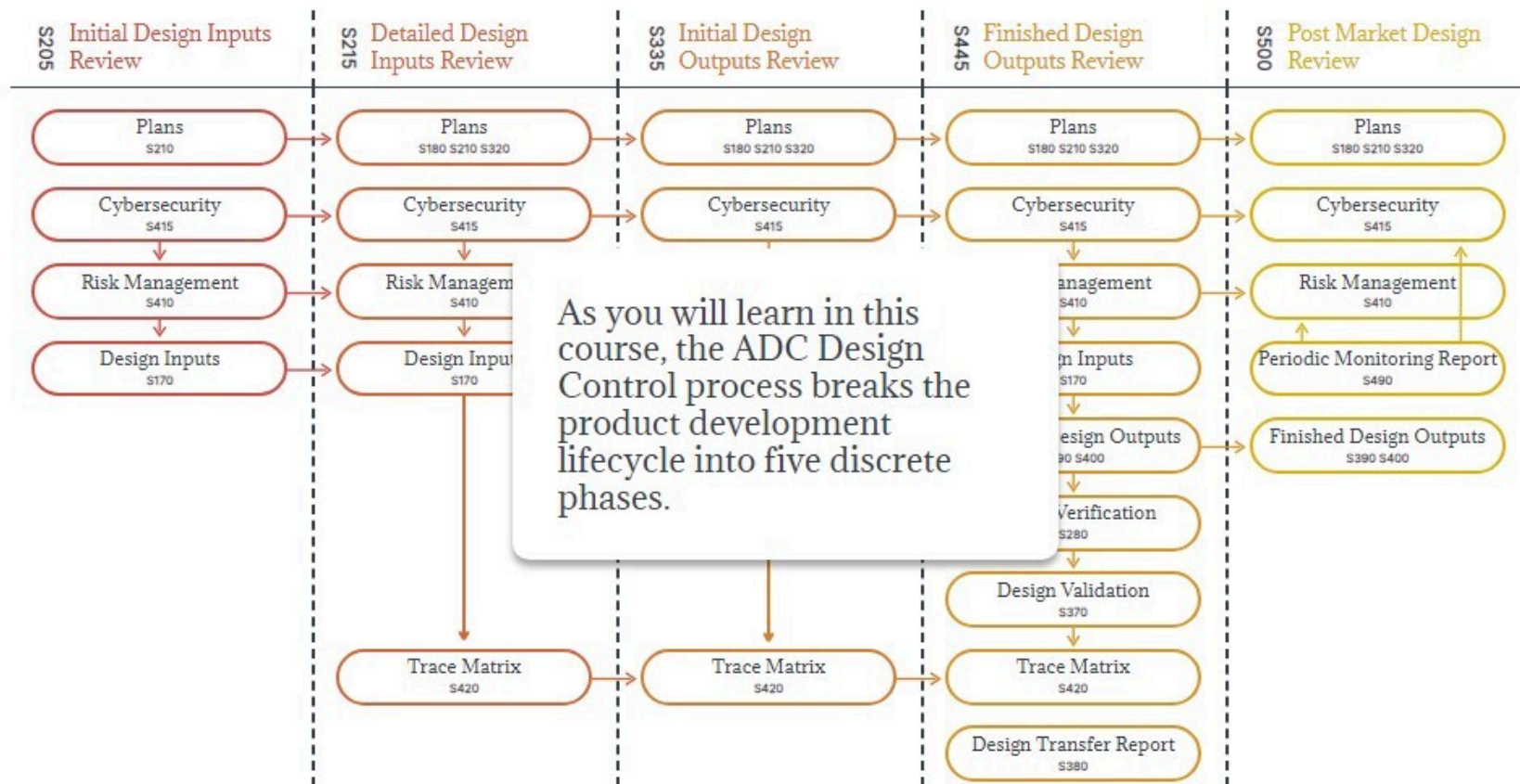
It ensures that

- All design activities are planned before execution,
- Design requirements (design inputs) are defined and translated into specifications that are used to build the product (design outputs), and
- Risk is managed throughout the entire process.



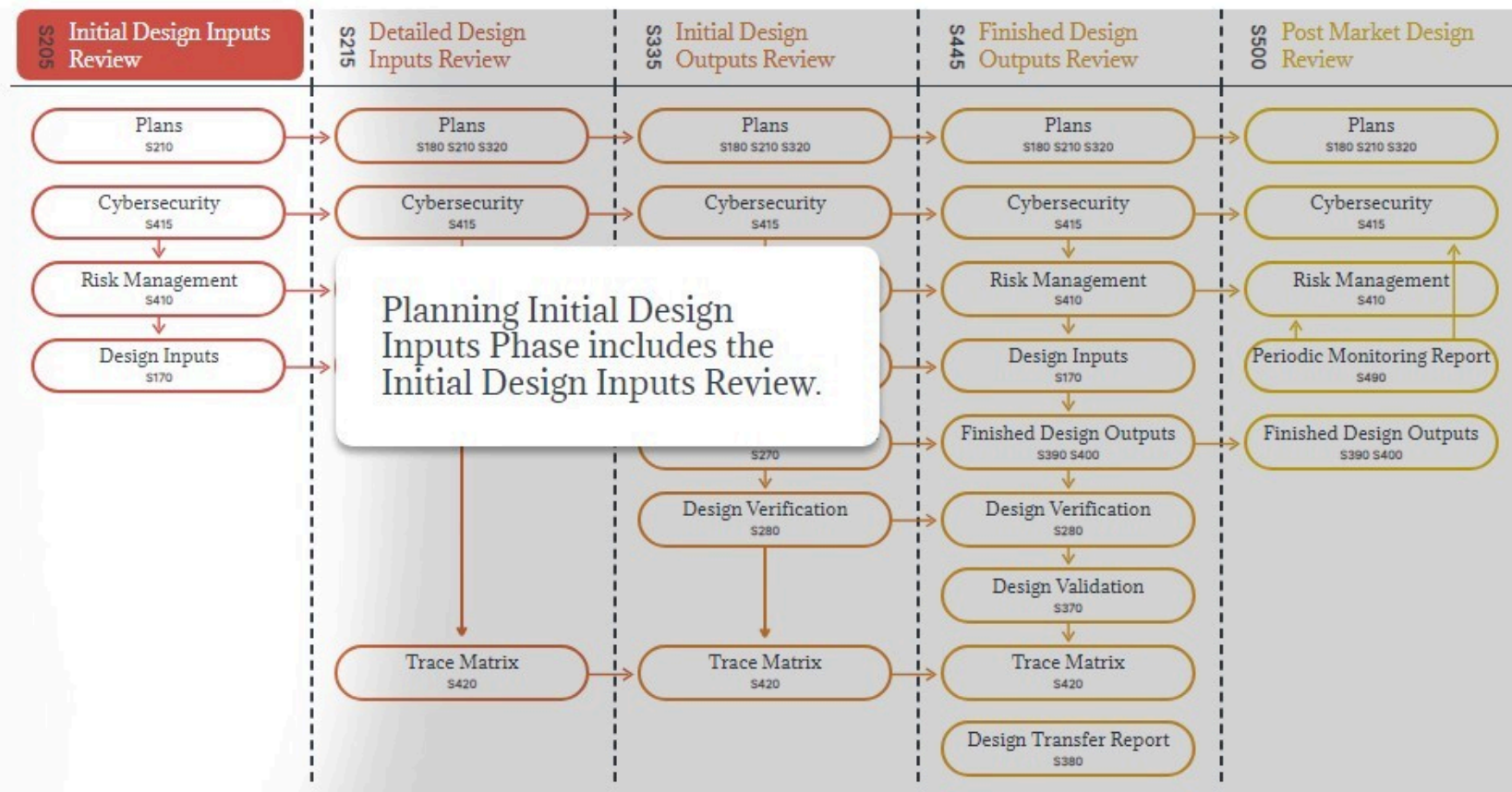
ADC DESIGN CONTROLS

Roles and Responsibilities



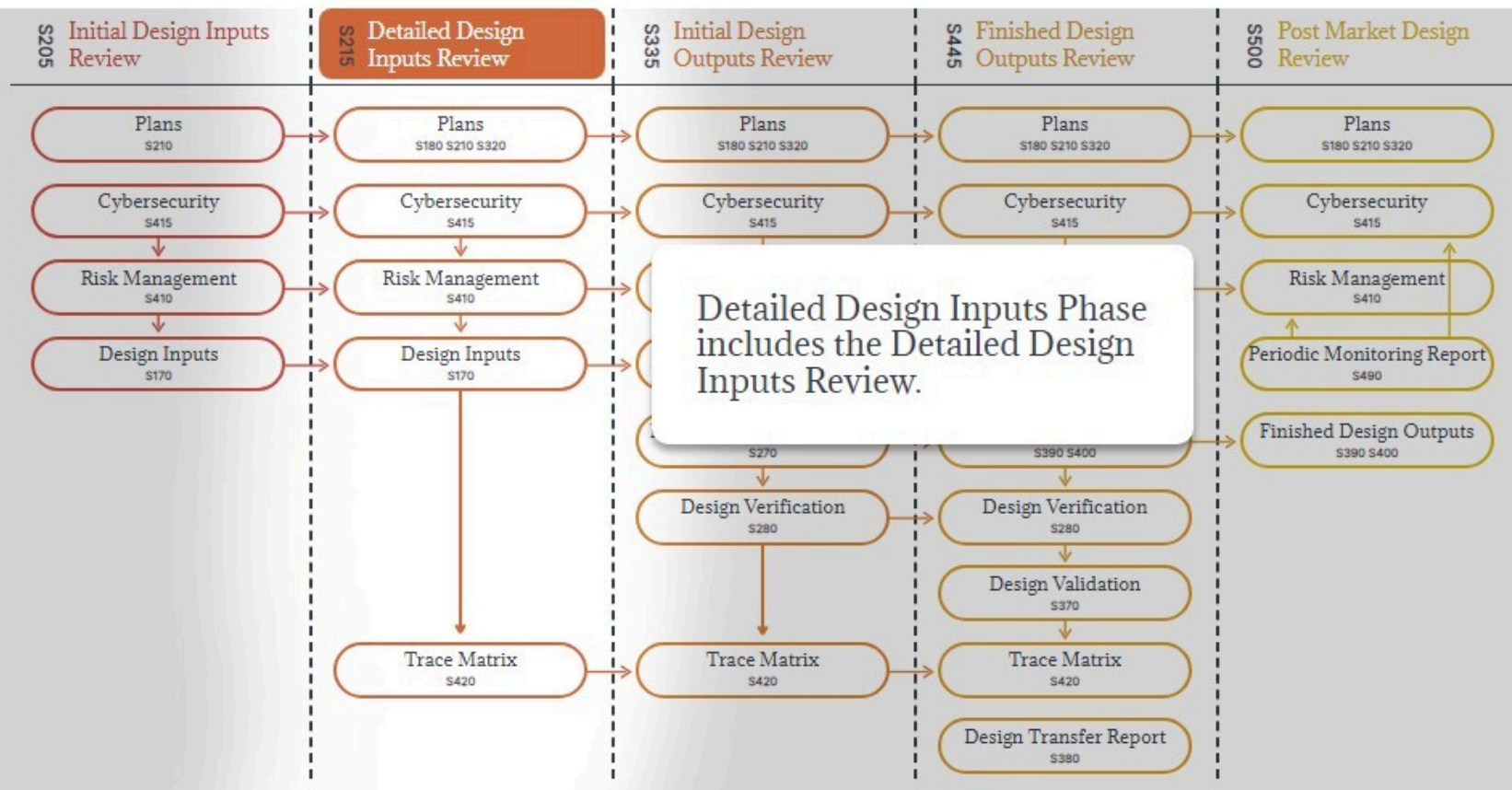
ADC DESIGN CONTROLS

Roles and Responsibilities



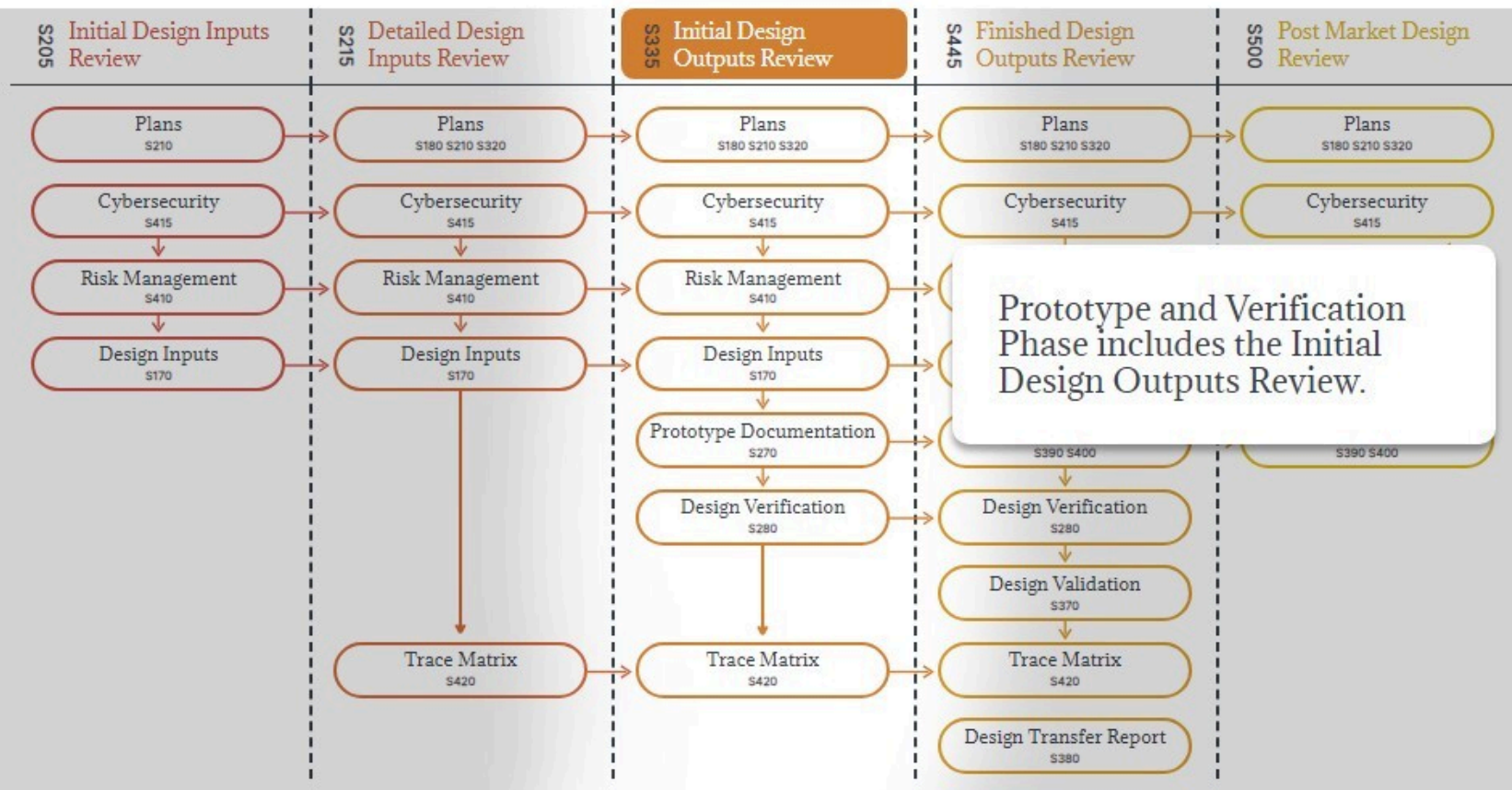
ADC DESIGN CONTROLS

Roles and Responsibilities



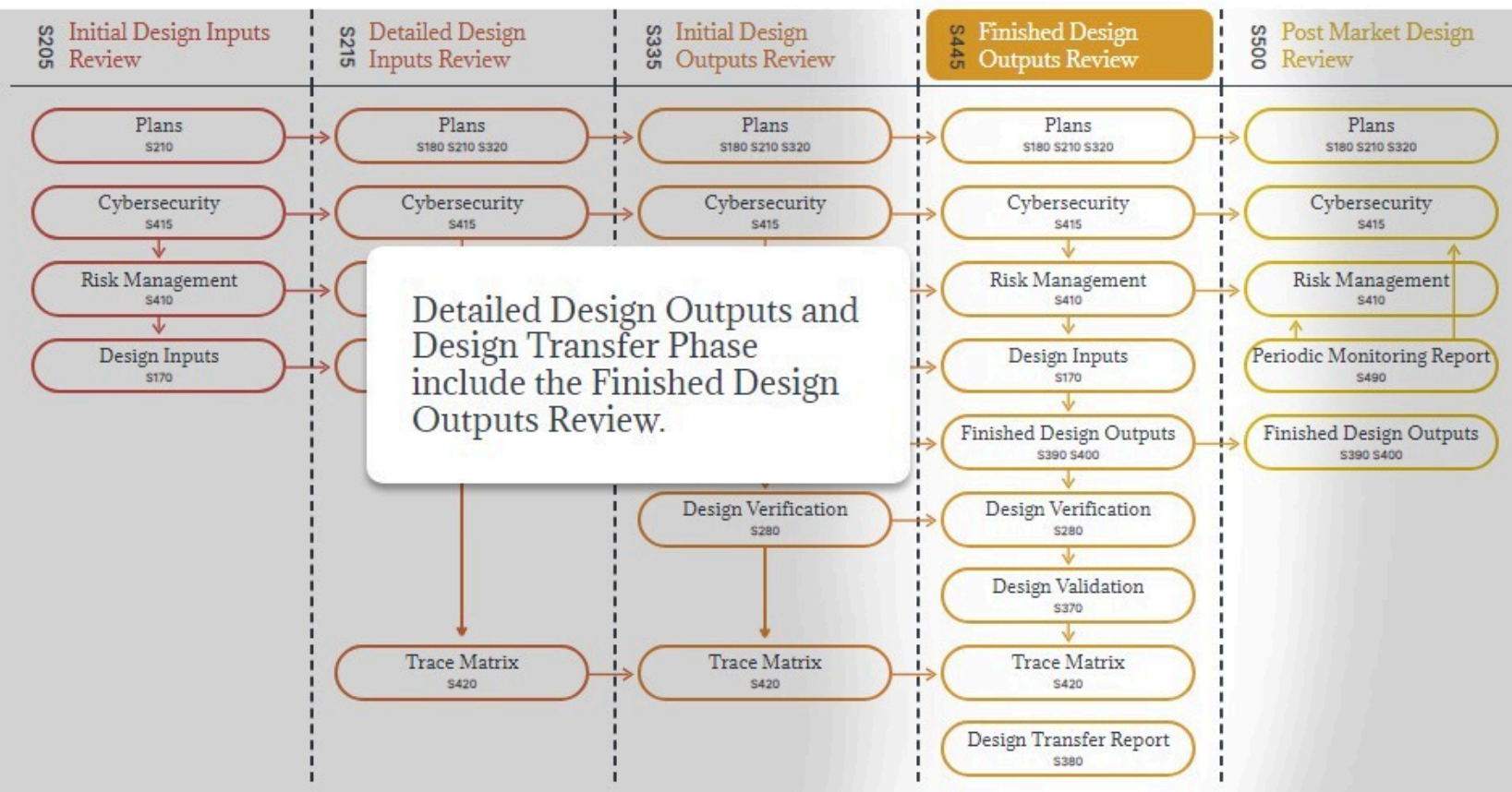
ADC DESIGN CONTROLS

Roles and Responsibilities



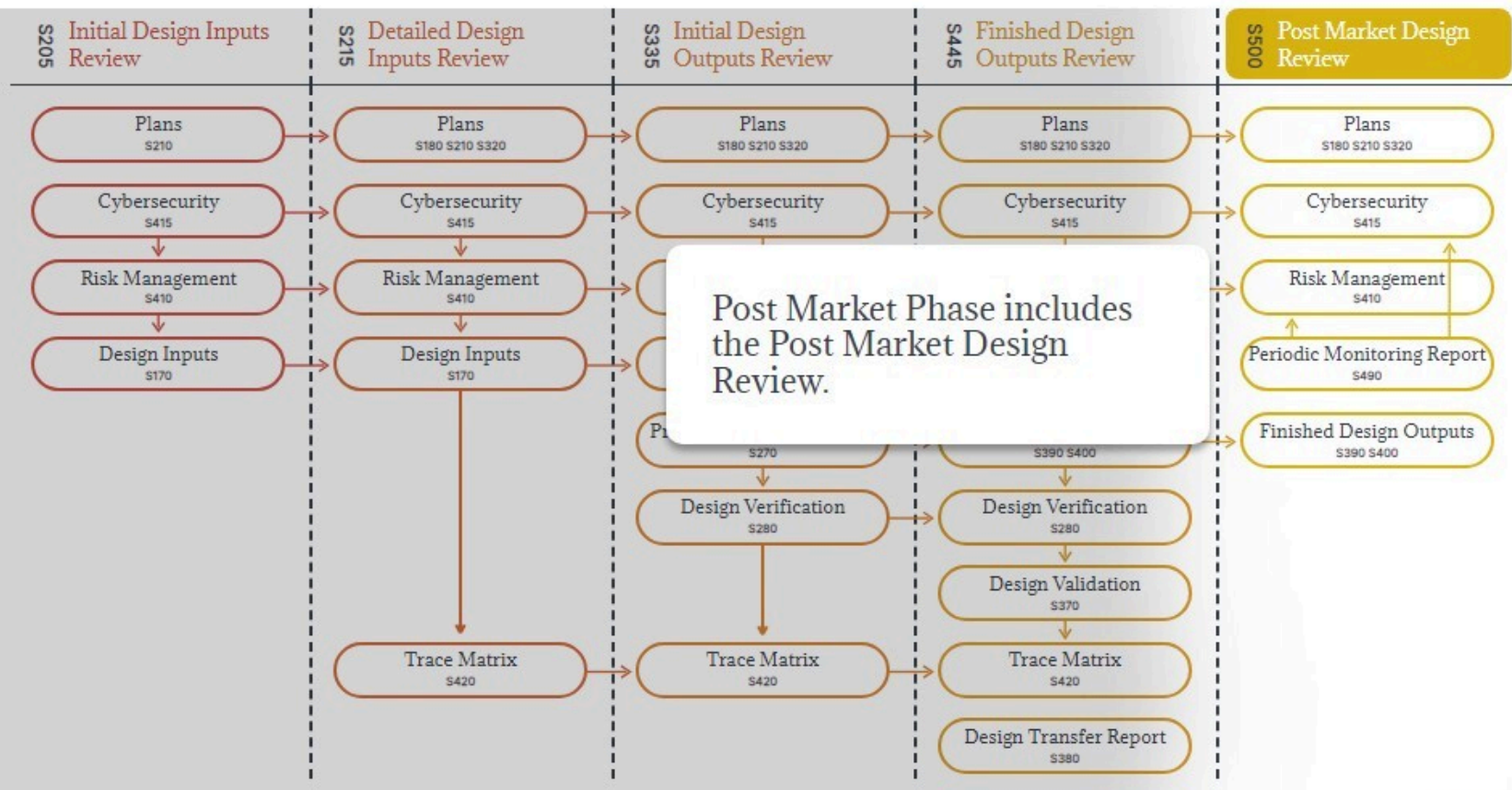
ADC DESIGN CONTROLS

Roles and Responsibilities



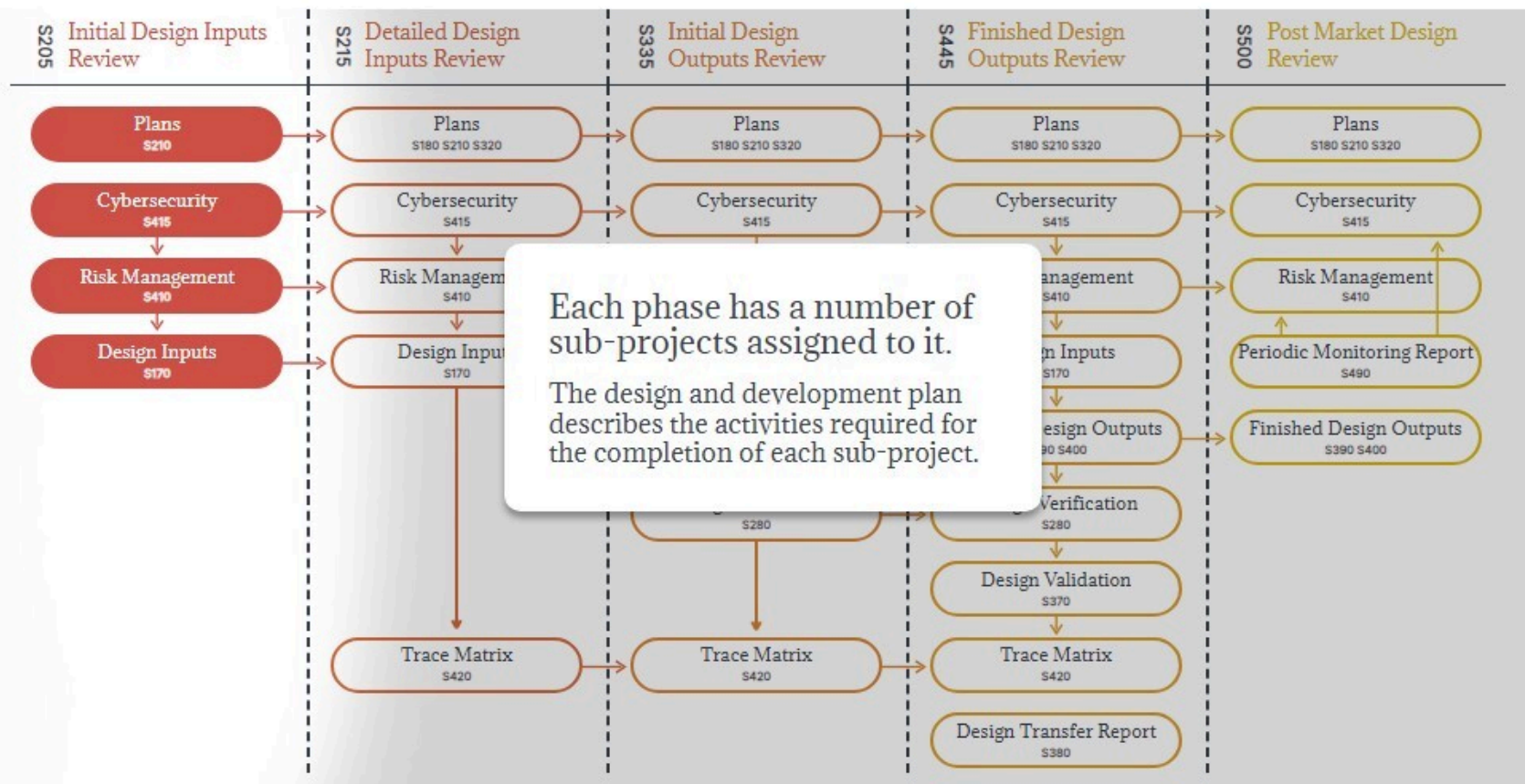
ADC DESIGN CONTROLS

Roles and Responsibilities



ADC DESIGN CONTROLS

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ADC DESIGN CONTROLS

Roles and Responsibilities



Responsibility for specific activities is assigned by the design and development plan. Individuals from various functions are involved in its implementation.

CLICK EACH OF THE PANELS TO LEARN MORE.



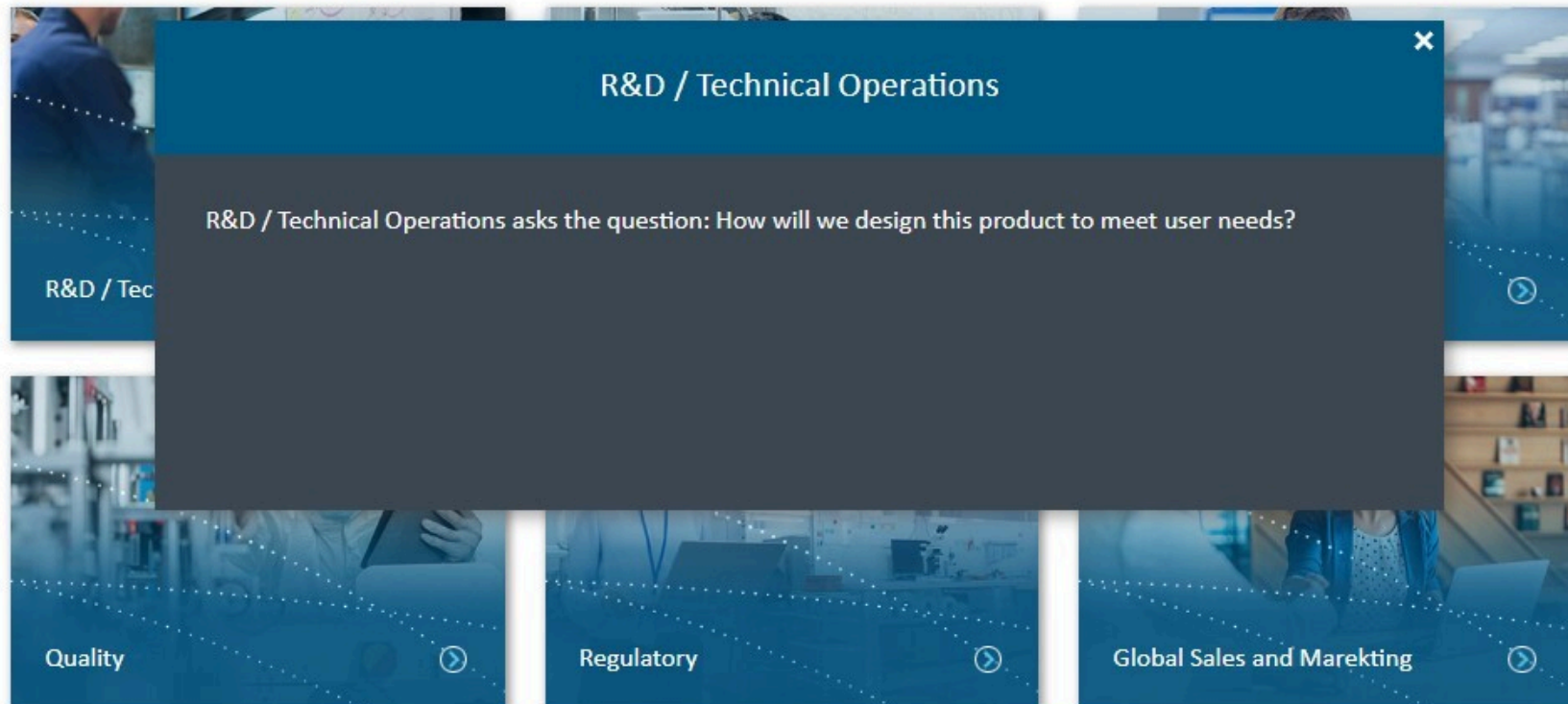
ADC DESIGN CONTROLS

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Roles and Responsibilities



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CLICK EACH OF THE PANELS TO LEARN MORE.

Project Leadership

Project Leadership asks: What are the user needs for this product? What does the business need to market this product?

R&D / Tech

Quality

Regulatory

Global Sales and Marketing

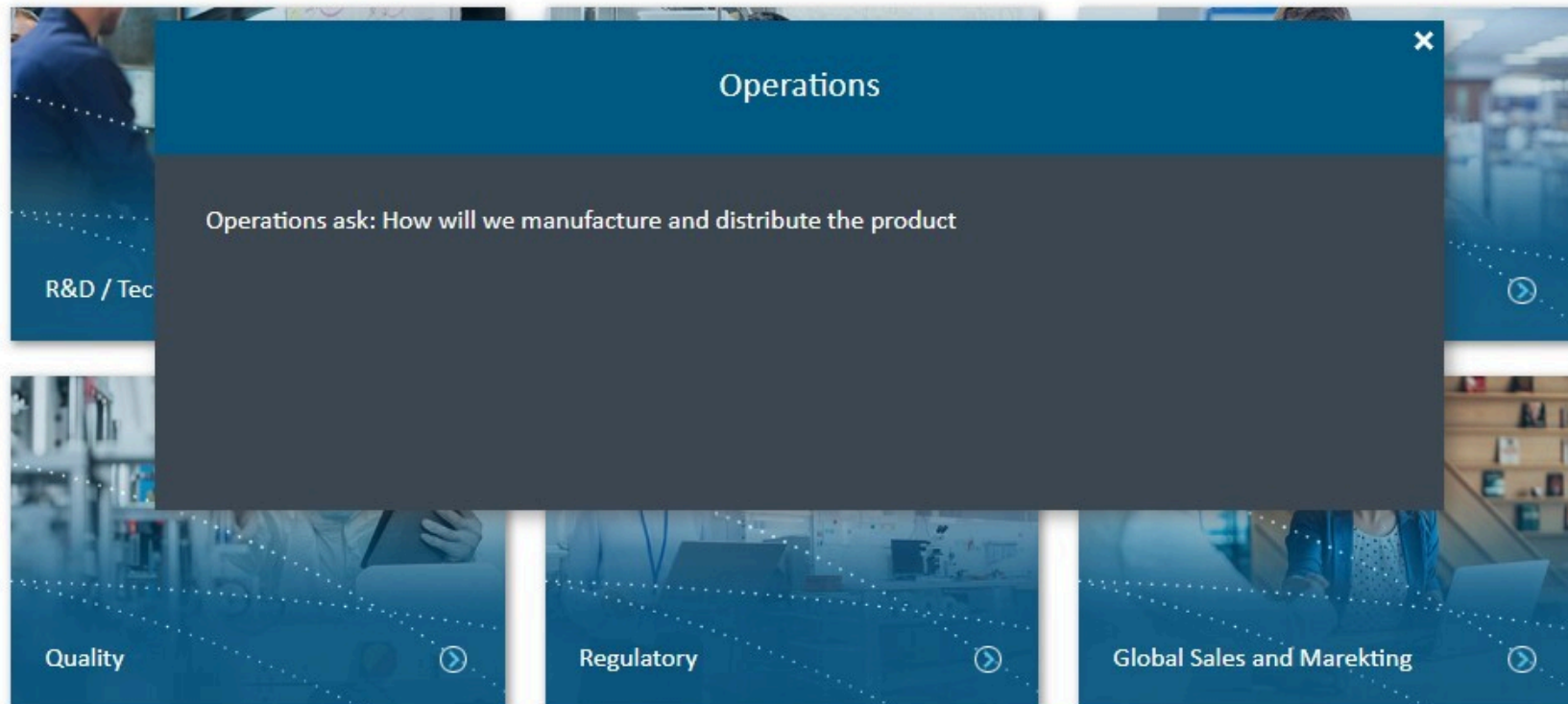


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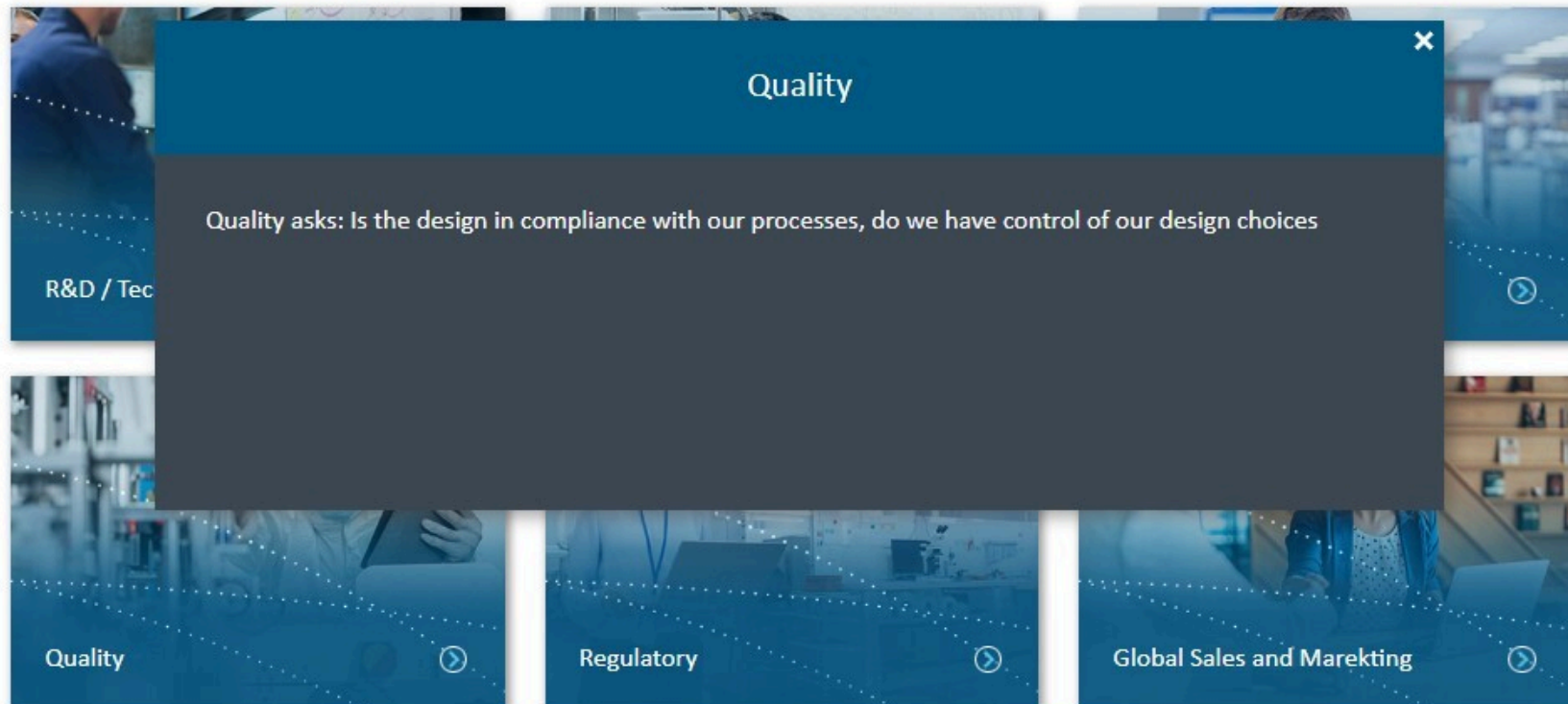
ADC DESIGN CONTROLS

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Roles and Responsibilities



Responsibility for specific activities is assigned by the design and development plan. Individuals from various functions are involved in its implementation.

CLICK EACH OF THE PANELS TO LEARN MORE.

Regulatory

Regulatory asks: Does the scope of change require a submission or review by a regulatory body, what information is required for that submissions? Does the product labelling meet all regulatory requirements?

R&D / Tech

Quality

Regulatory

Global Sales and Marketing

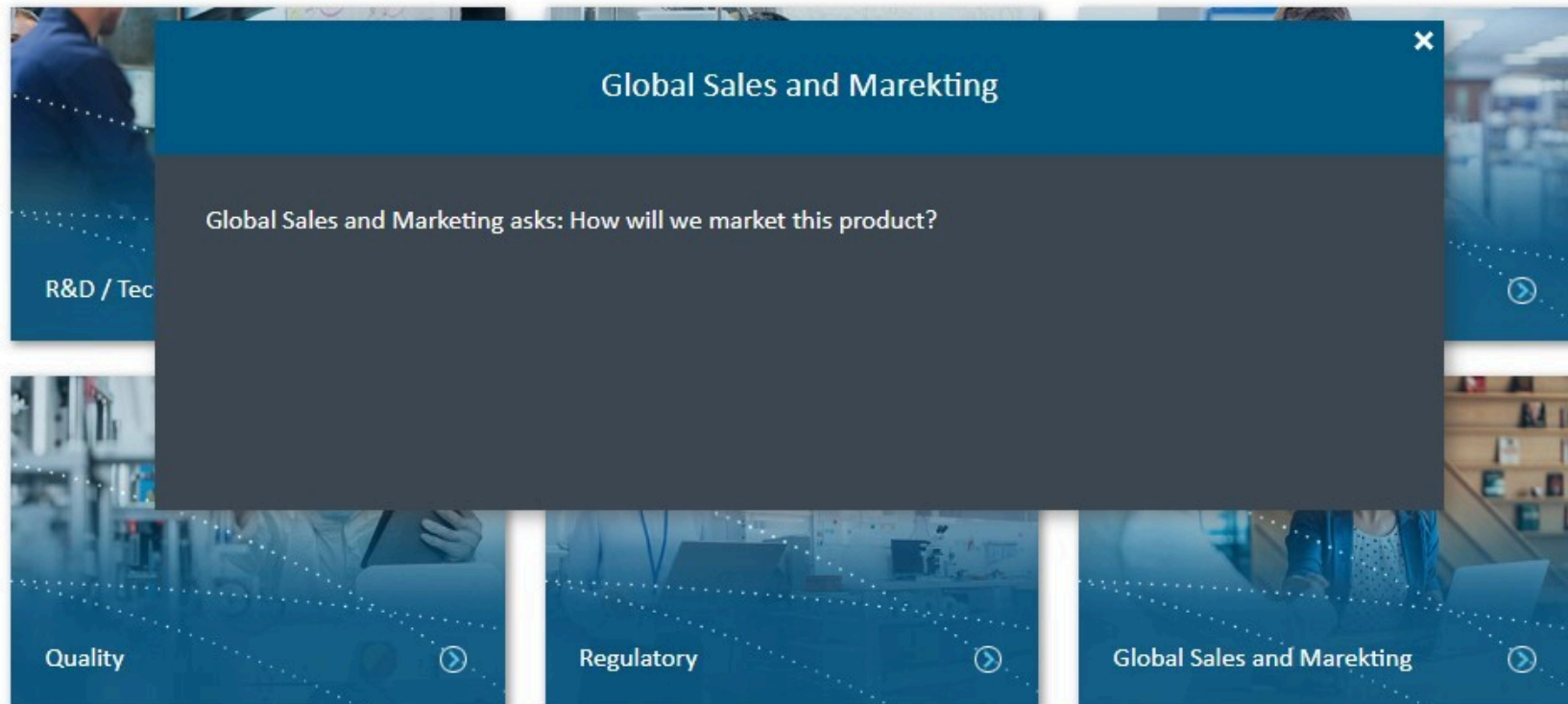


Roles and Responsibilities



Responsibility for specific activities is assigned by the design and development plan. Individuals from various functions are involved in its implementation.

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Roles and Responsibilities



The Development Program Manager oversees the entire process.

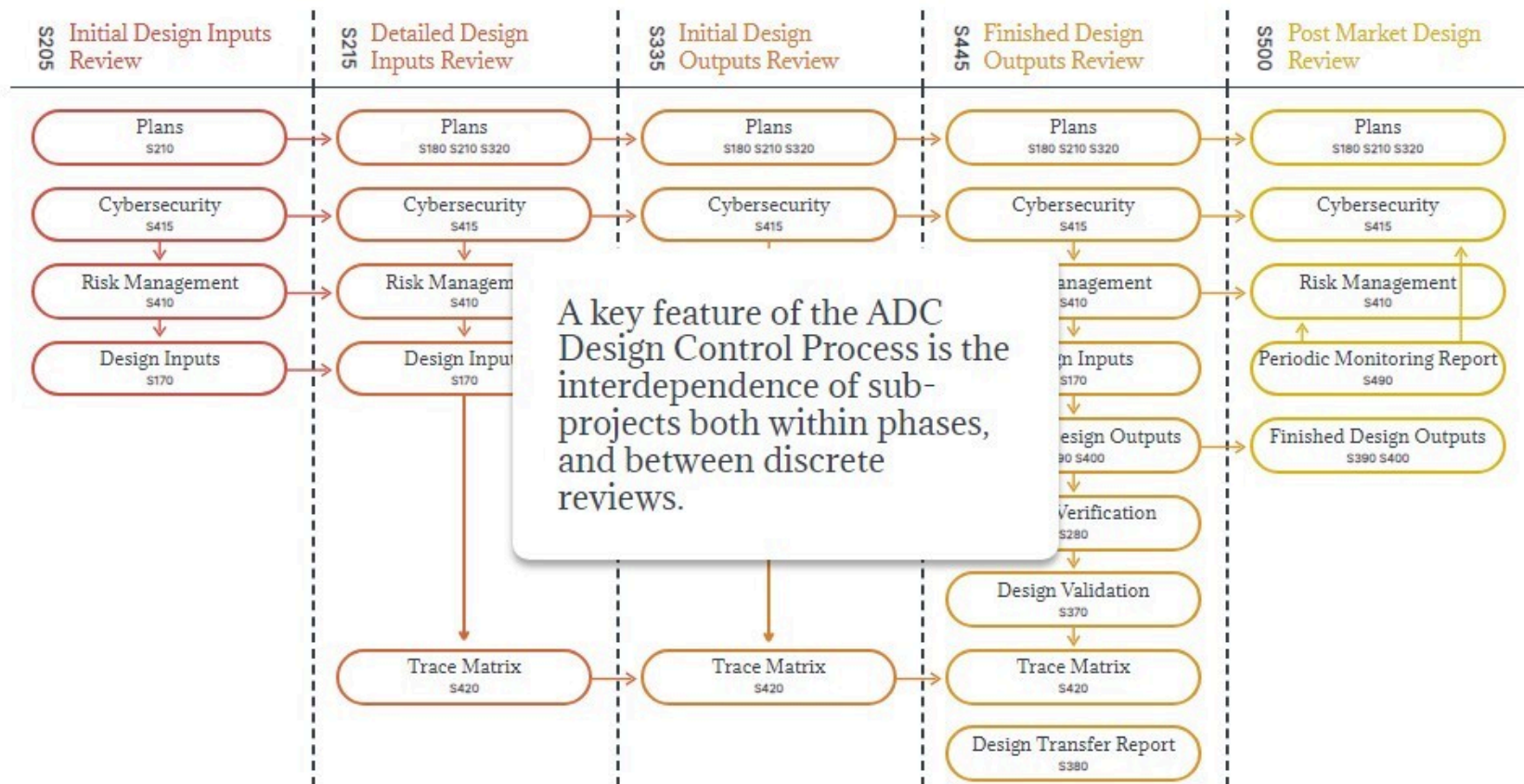
They are responsible for

- Developing, and gaining cross-functional agreement on the design and development plan;
- Assuring that all activities are executed according to the plan; and
- Ensuring, along with the Quality Assurance, that the Design History File provides an accurate record of the design and development process execution.



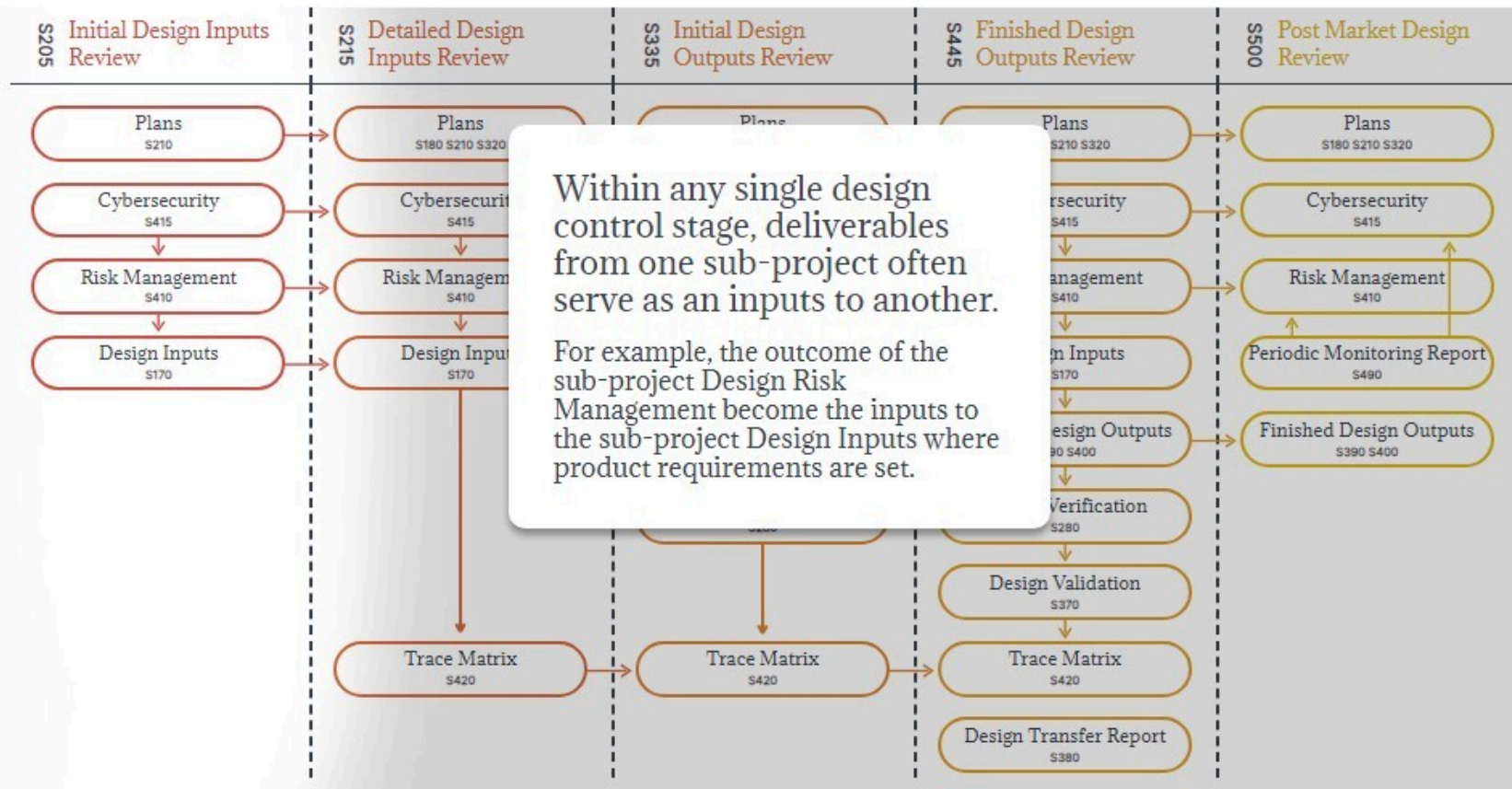
ADC DESIGN CONTROLS

Relationship between Sub-Projects



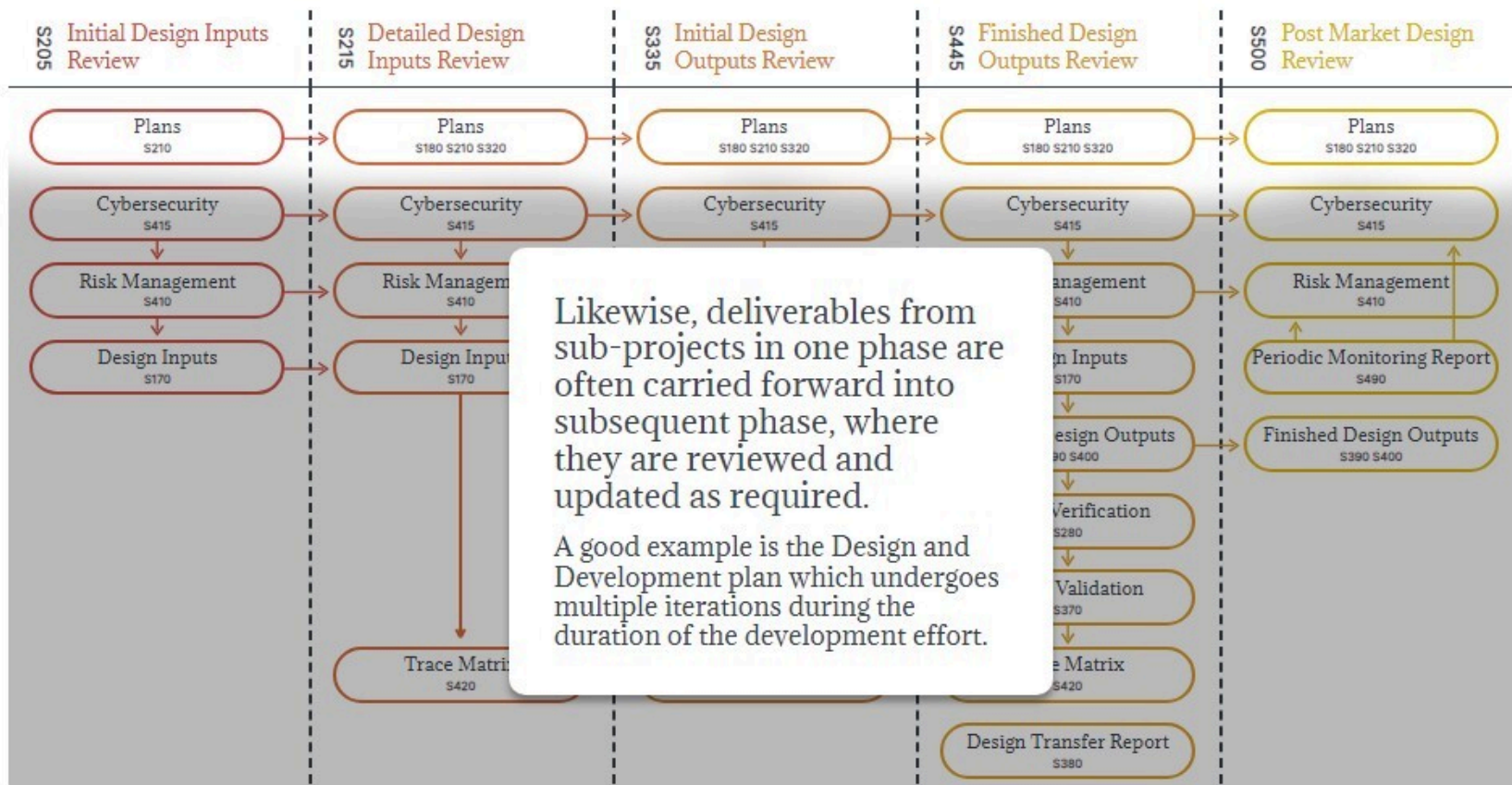
ADC DESIGN CONTROLS

Relationship between Sub-Projects



ADC DESIGN CONTROLS

Relationship between Sub-Projects



Managing 'Living' Deliverables



Finally, design and development is a living process.

At any given point in time, the data, documents, records and other deliverables created, used, or shared are changing and evolving. For this reason, it is important to keep all data up-to-date, not only at each key milestone (design review), but throughout the entire process.





Review



Review

Take a moment to review some of the key concepts in this section.

Click the arrow to begin your review.



Review



Structure of ADC Design Control Process

The ADC Design Control process breaks product development into five discrete phases; each phase containing a number of sub-projects.



Review



Review



Responsibilities

Individuals from various functions are involved in the implementation of the ADC Design Control process. The Development Program Manager oversees the entire process.



Review



Relationships Between Sub-projects

Deliverables from one sub-project often serve as an inputs to another sub-project.



Review



Deliverables Carried Forward

Many of the key deliverables approved in earlier review phases are carried forward, reviewed and updated in subsequent phases.



Review



Continuous Updates

All data must be kept up-to-date throughout the entire ADC Design Control Process and not only at key milestones (design reviews).



To check your progress, click
the Menu button



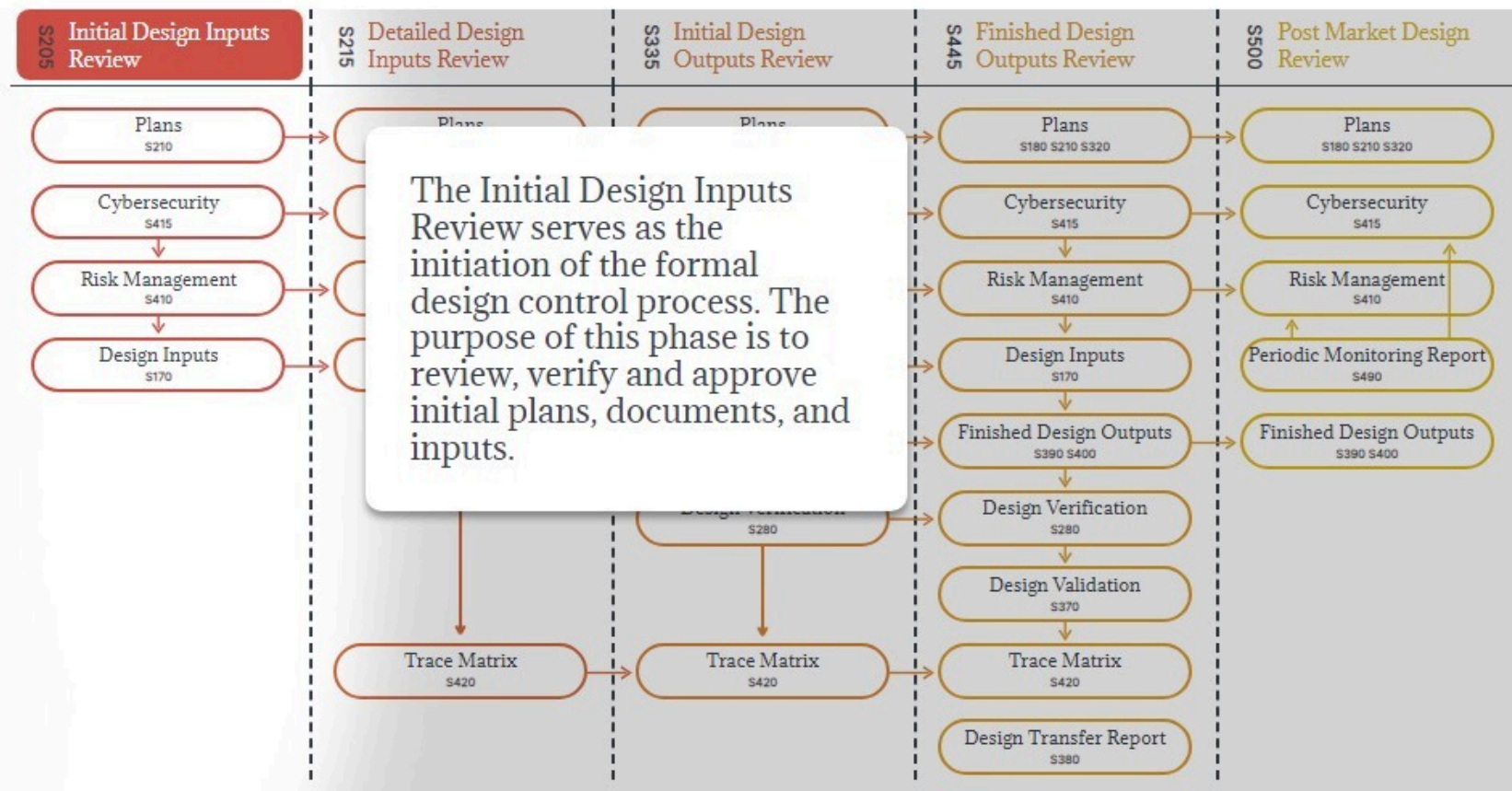
You have completed section 1 of 3

CLICK THE FORWARD ARROW TO CONTINUE LEARNING



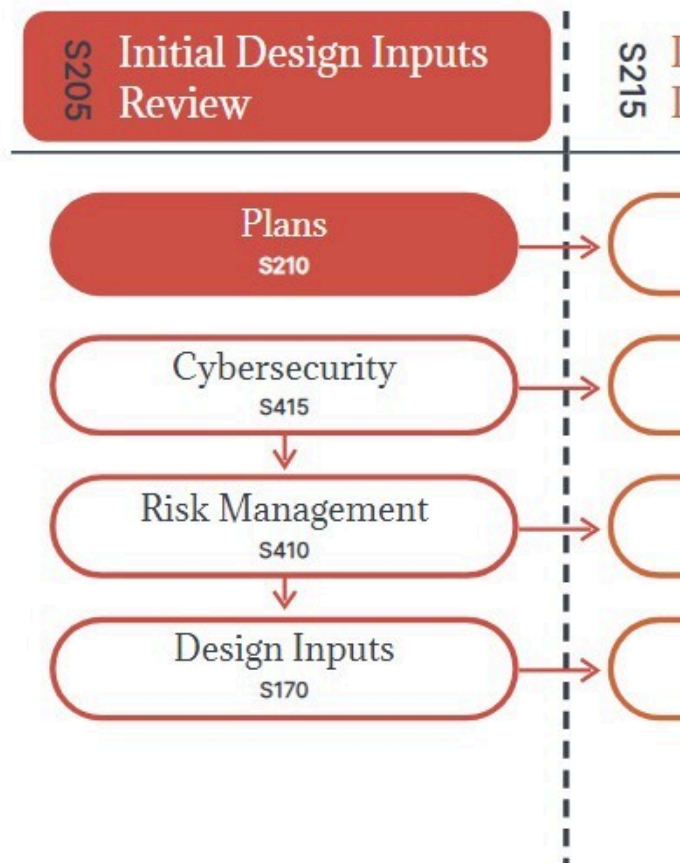
THE ADC DESIGN CONTROL PROCESS

Initial Design Inputs Review



THE ADC DESIGN CONTROL PROCESS

Initial Design Inputs Review



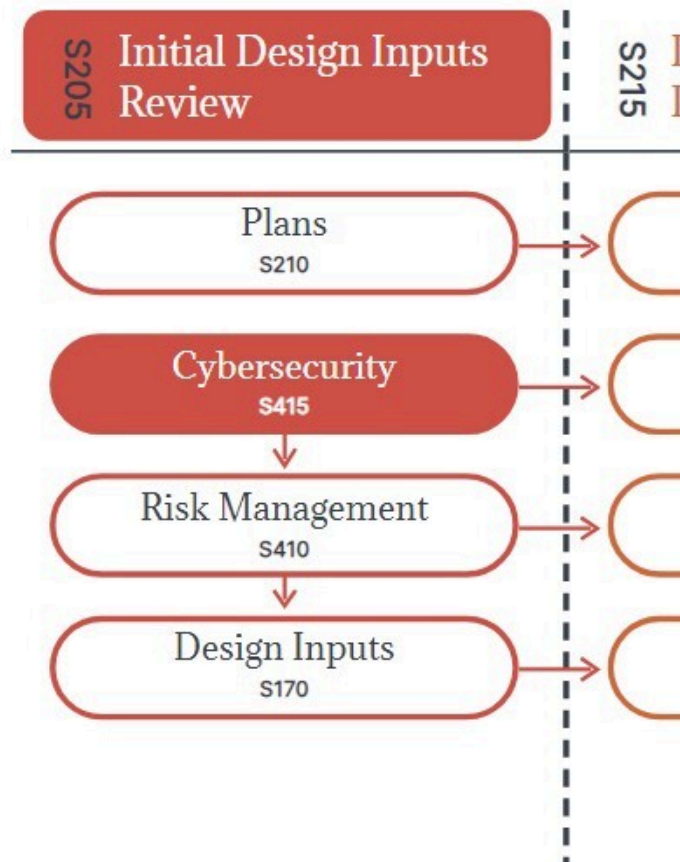
An initial design and development (D&D) plan is created. The D&D plan contains the plan, schedule, and resource requirements for each phase and component of the design and development process.

The D&D plan may also identify ways the project may modify or customize the design controls process.



THE ADC DESIGN CONTROL PROCESS

Initial Design Inputs Review

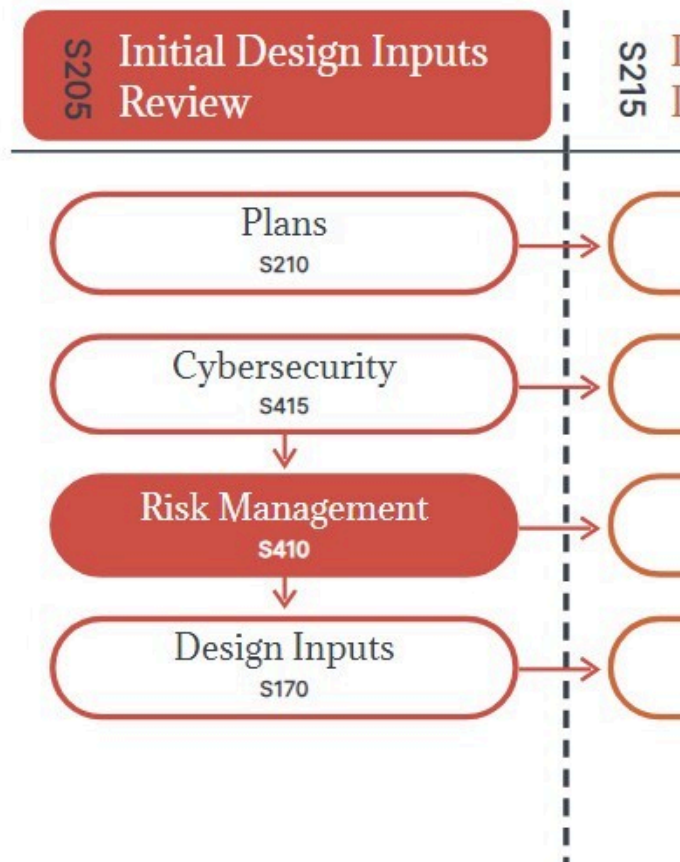


An initial list of Cybersecurity risk management activities (such as risk assessments, controls, and estimations) are identified.



THE ADC DESIGN CONTROL PROCESS

Initial Design Inputs Review

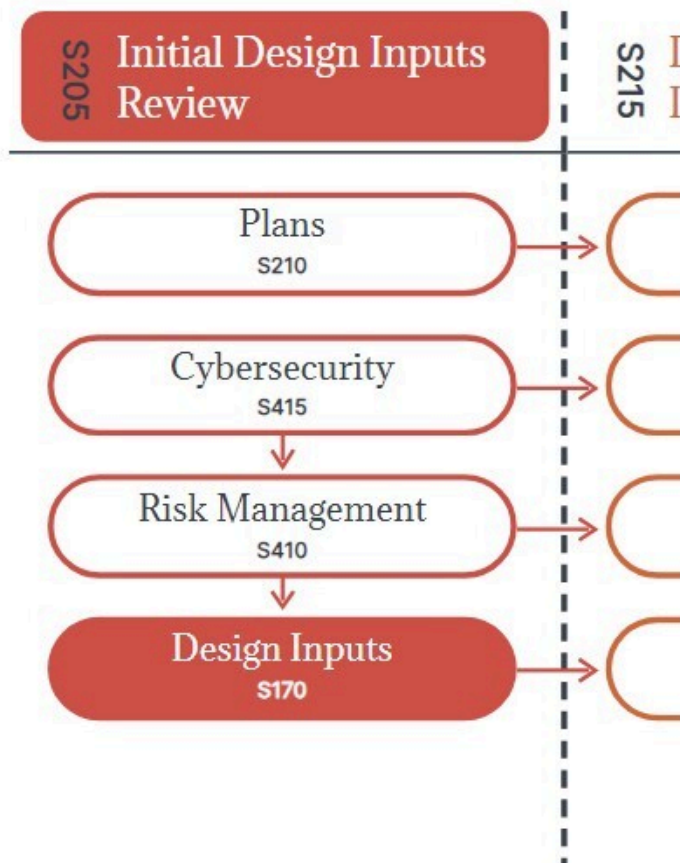


An initial list of risk management activities (such as functional, performance, safety and reliability testing) are identified and documented.



THE ADC DESIGN CONTROL PROCESS

Initial Design Inputs Review



An initial, but comprehensive, list of design inputs are recorded. Design inputs are the requirements of the product. This includes:

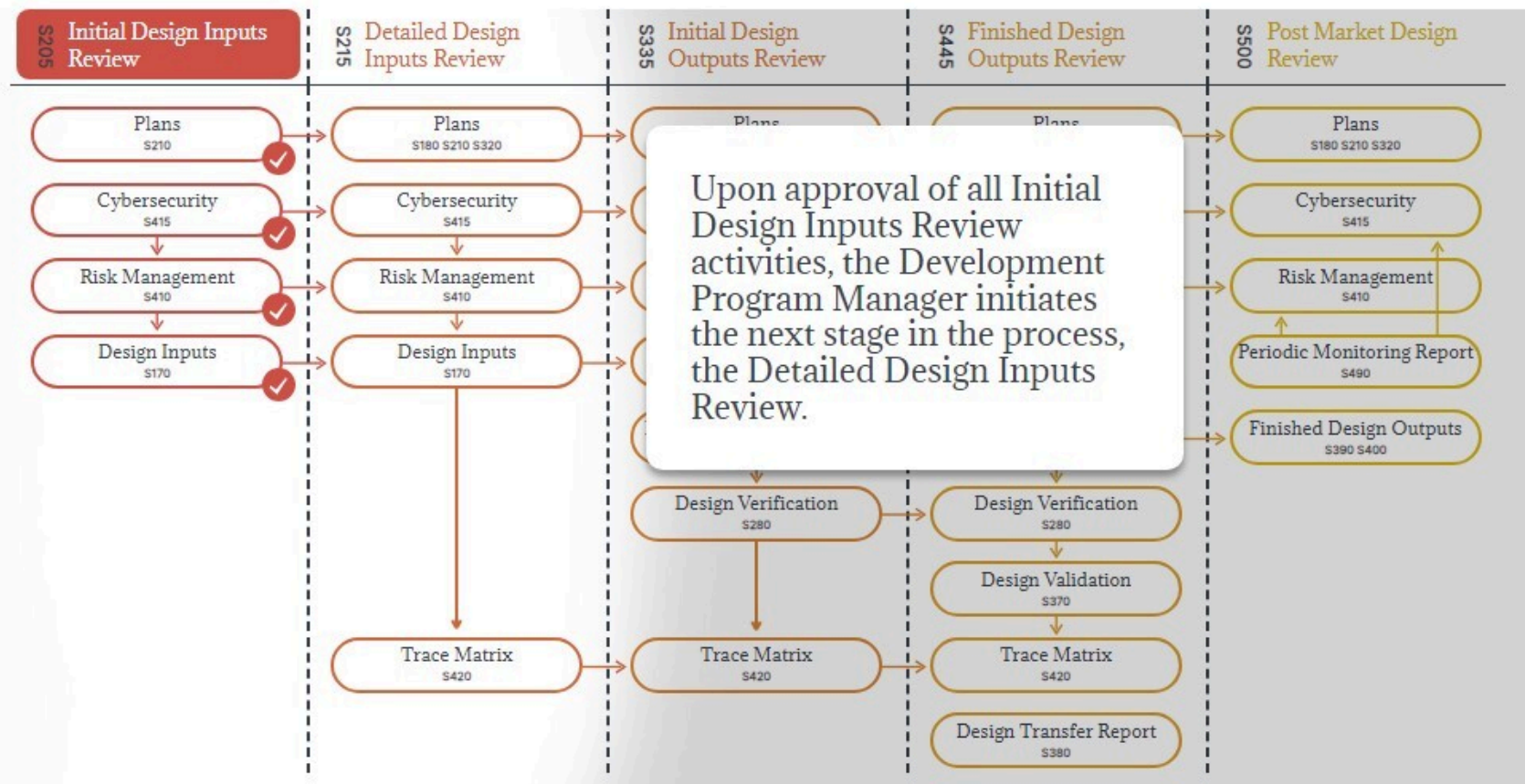
- User requirements,
- Technical requirements, such as those relating to performance, functionality, and reliability; and
- Regulatory requirements, such as those relating to packaging, labelling, and design standards.

It is important to note that all design inputs must be defined such that objective evidence that the requirement is satisfied can be established through verification and validation testing. For the initial design inputs review, design inputs are typically developed at the system level.



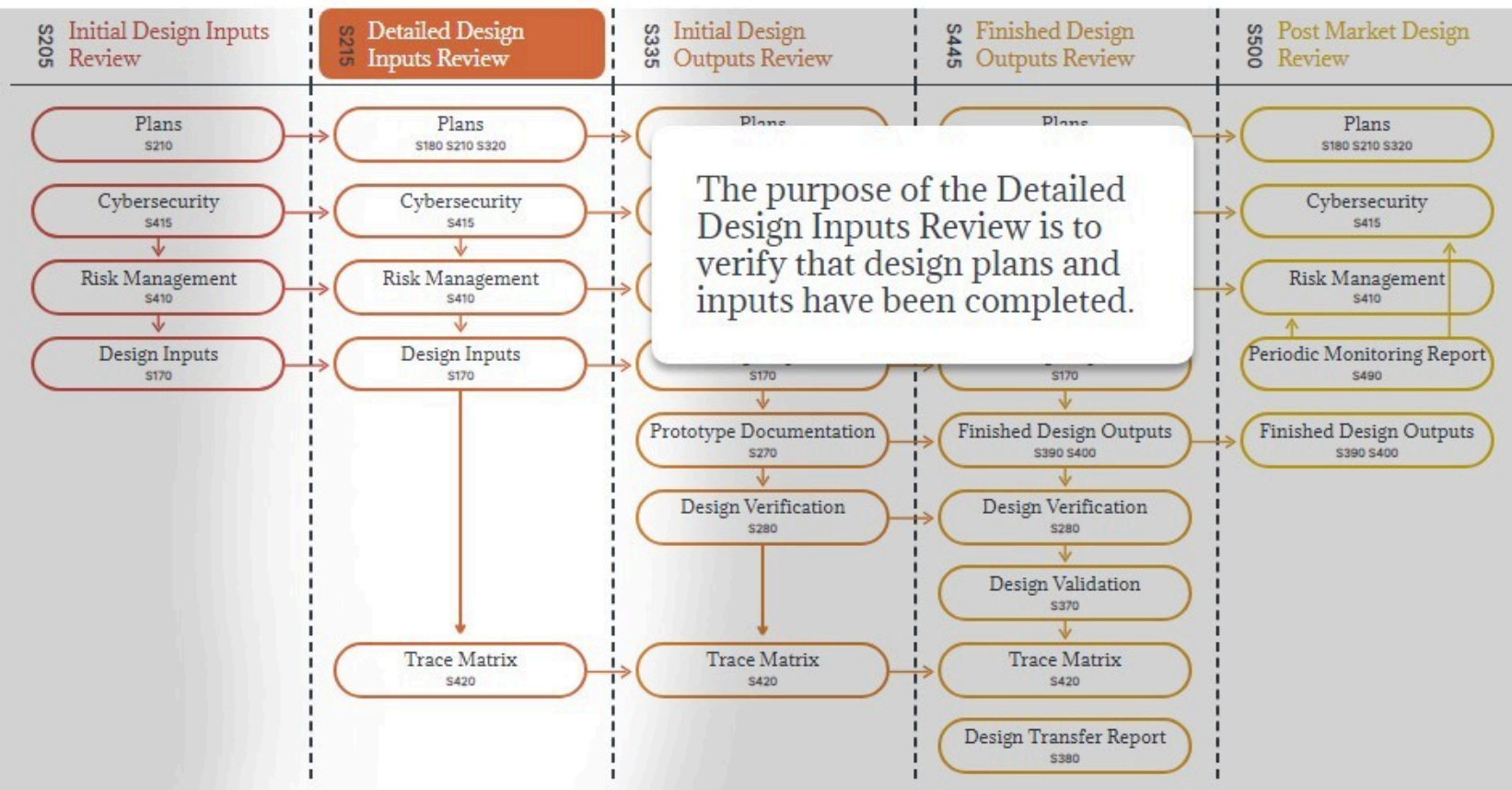
THE ADC DESIGN CONTROL PROCESS

Initial Design Inputs Review



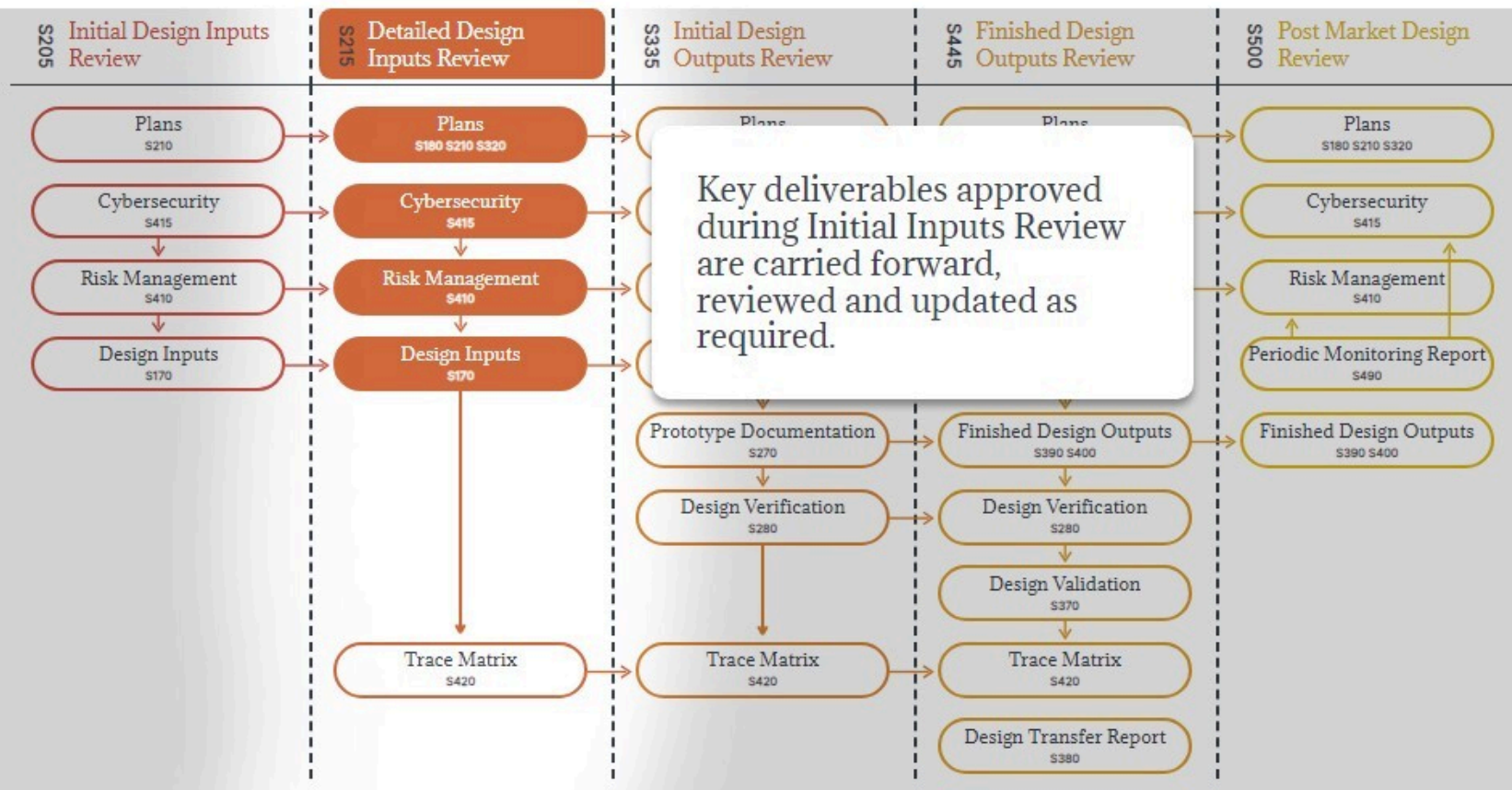
THE ADC DESIGN CONTROL PROCESS

Detailed Design Inputs Review

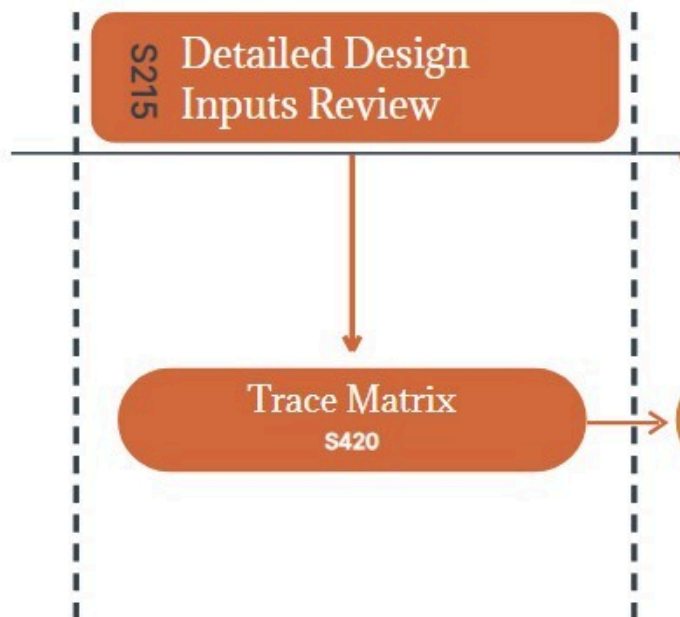


THE ADC DESIGN CONTROL PROCESS

Detailed Design Inputs Review



Detailed Design Inputs Review



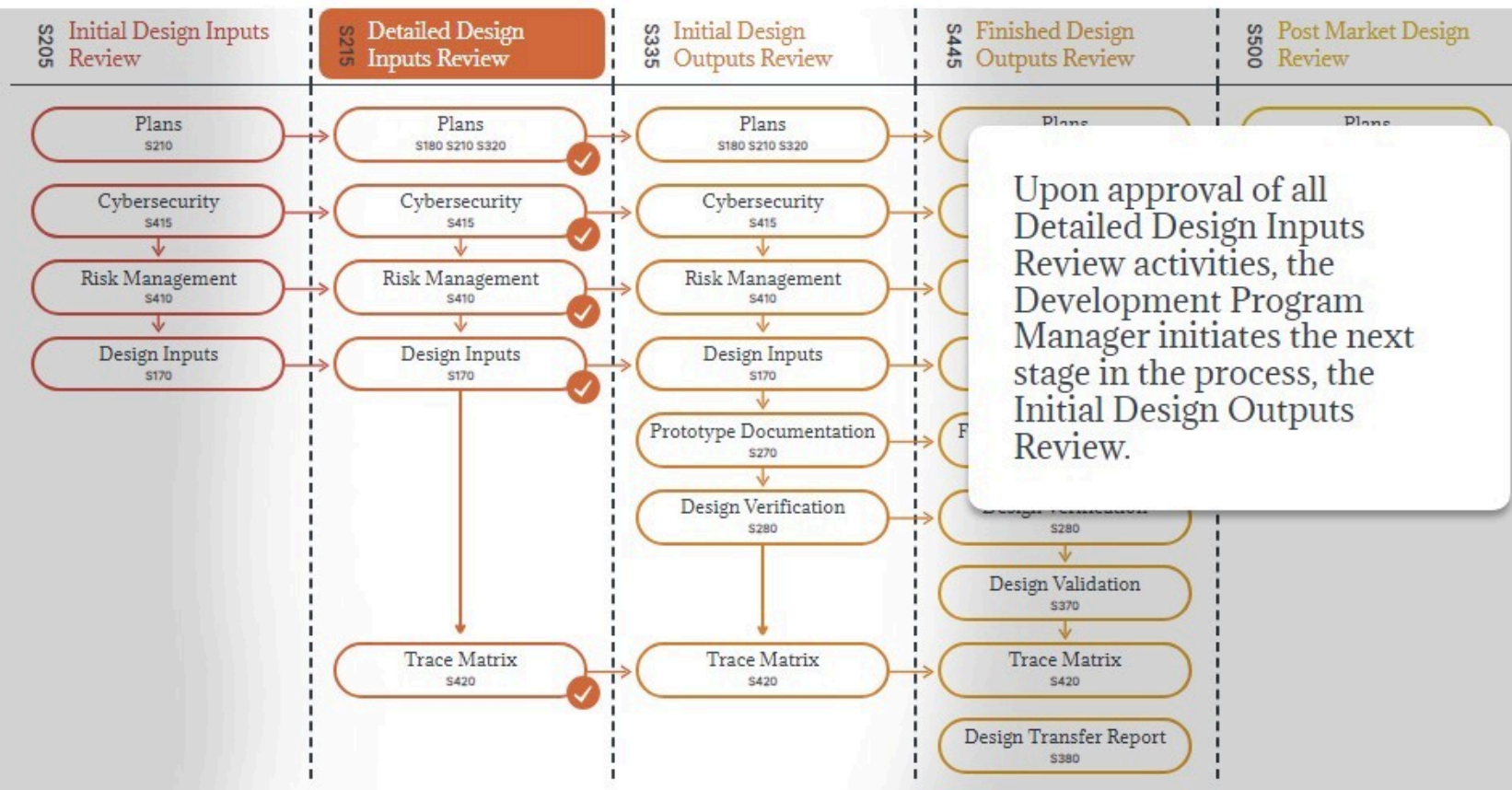
The Trace Matrix is introduced at this stage. It is used to document the relationship between the design requirements and the design verification and validation activities in order to demonstrate the design requirements have been met. For the detailed design inputs review, design inputs are developed at all subsystem levels.

At the detailed design inputs review, the trace matrix captures traceability between top level user needs, and system and subsystem requirements. The trace matrix is reviewed for conflicting and ambiguous requirements.



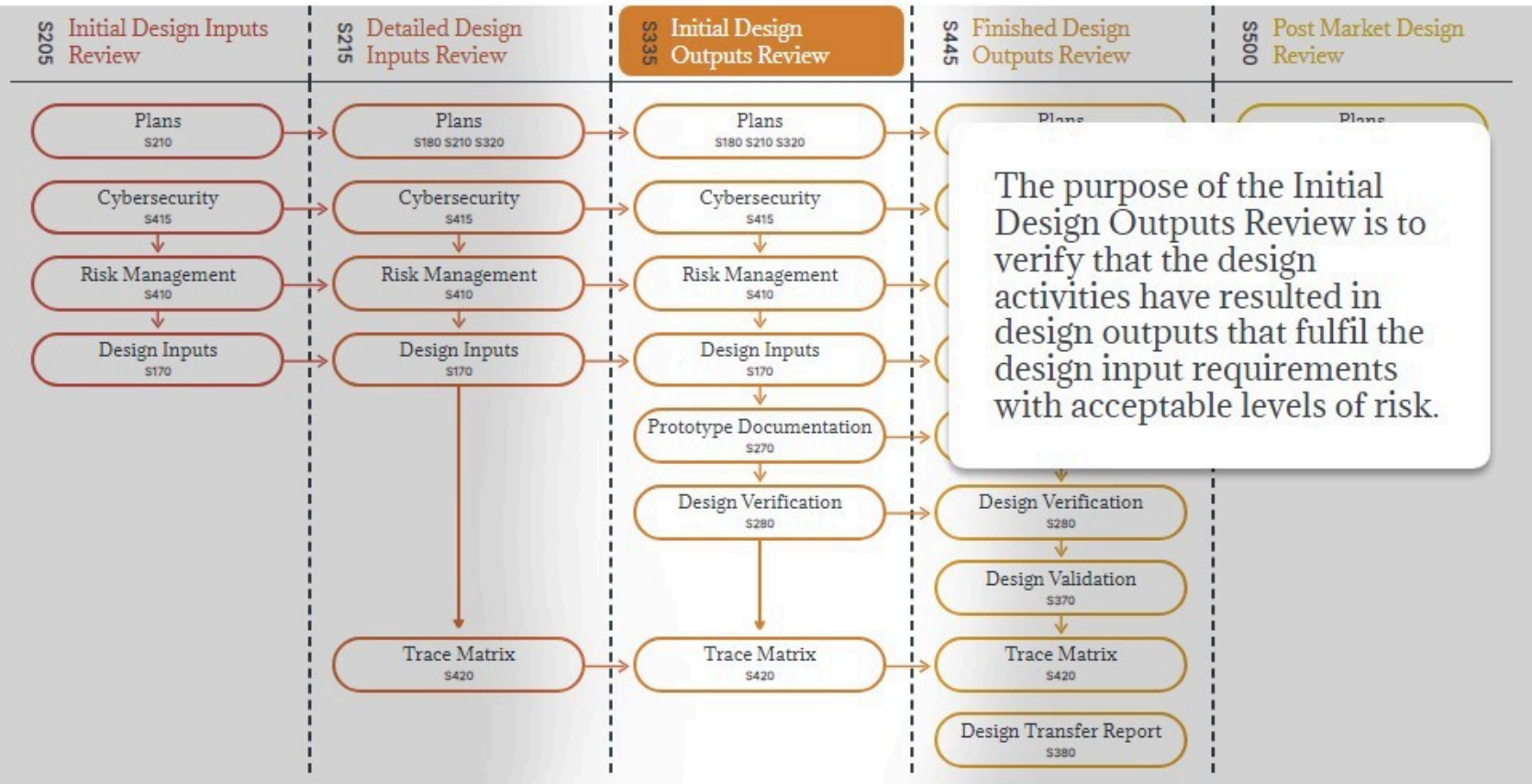
THE ADC DESIGN CONTROL PROCESS

Detailed Design Inputs Review



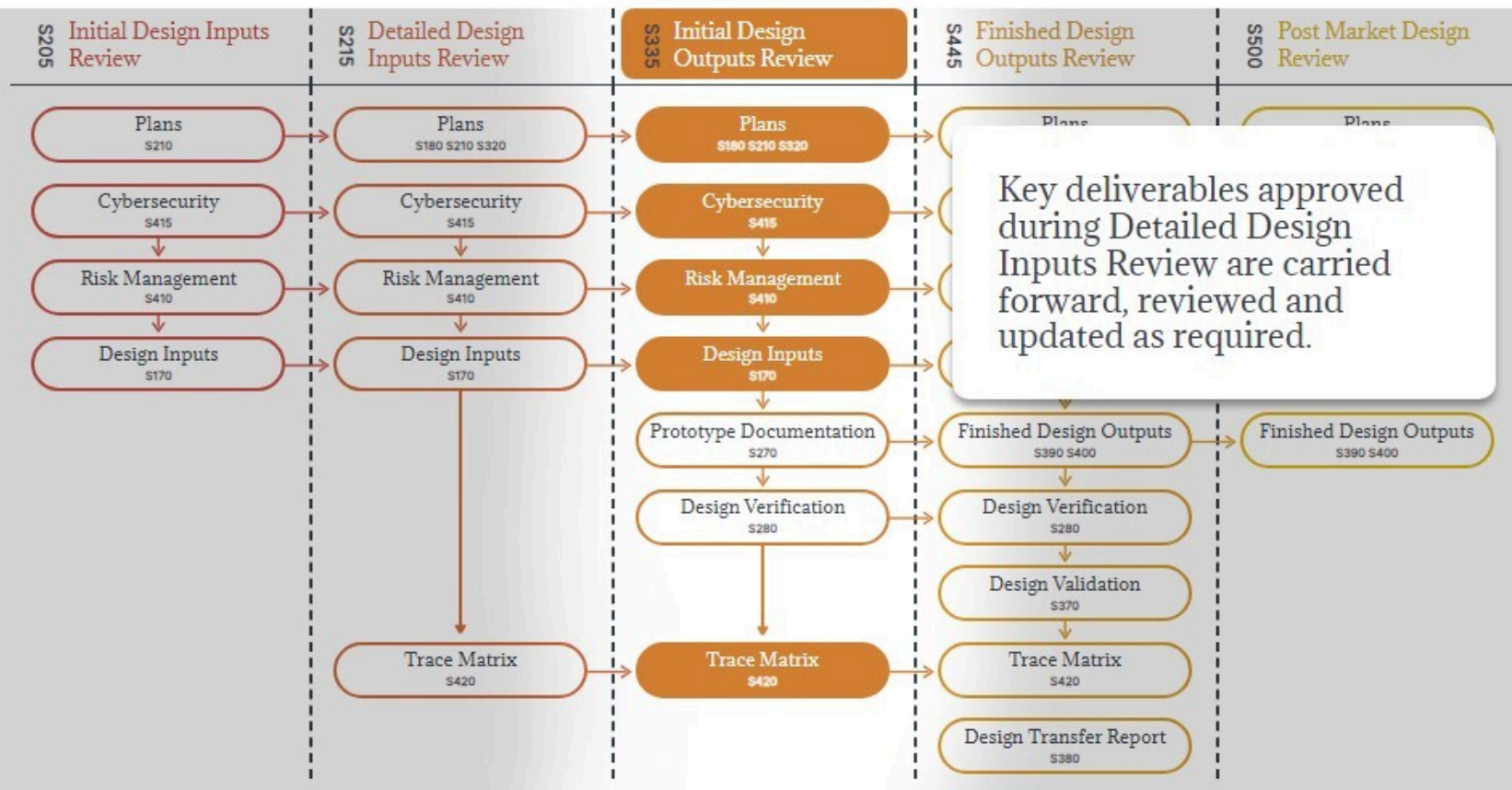
THE ADC DESIGN CONTROL PROCESS

Initial Design Outputs Review



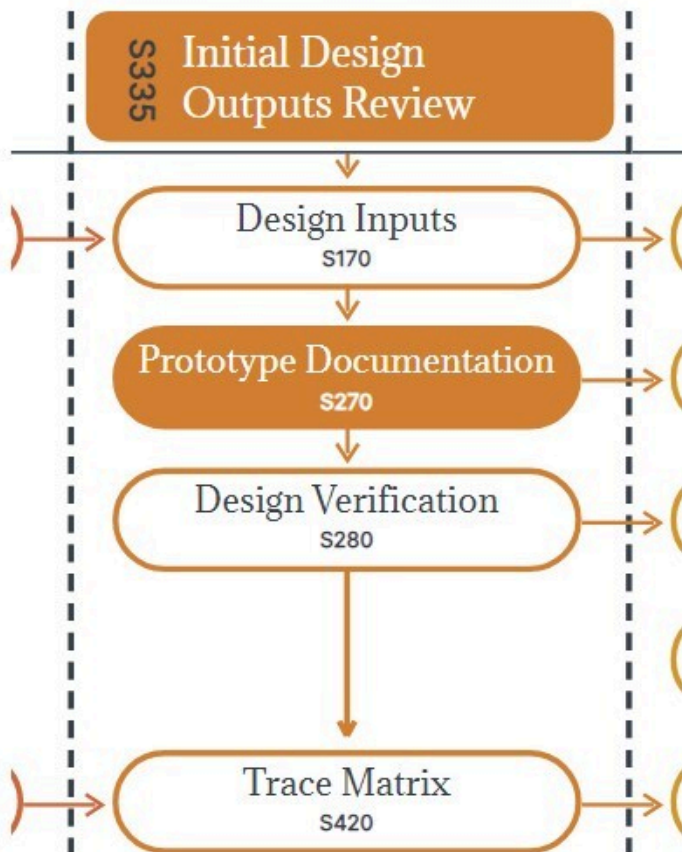
THE ADC DESIGN CONTROL PROCESS

Initial Design Outputs Review



THE ADC DESIGN CONTROL PROCESS

Initial Design Outputs Review

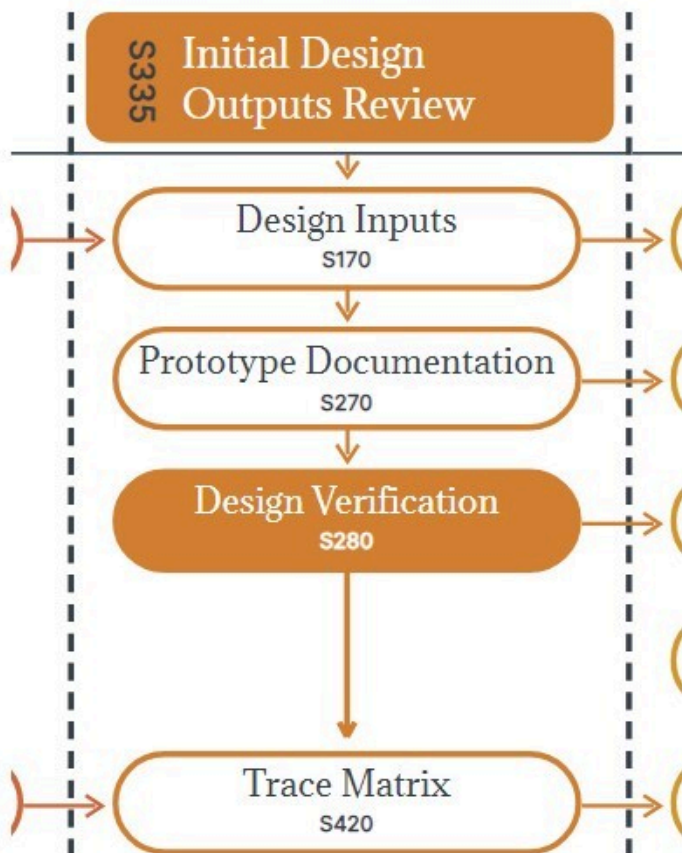


Prototype documentation based on initial outputs is created. This documentation establishes the Design History Record (DHR) of the prototype used in verification and validation testing.



THE ADC DESIGN CONTROL PROCESS

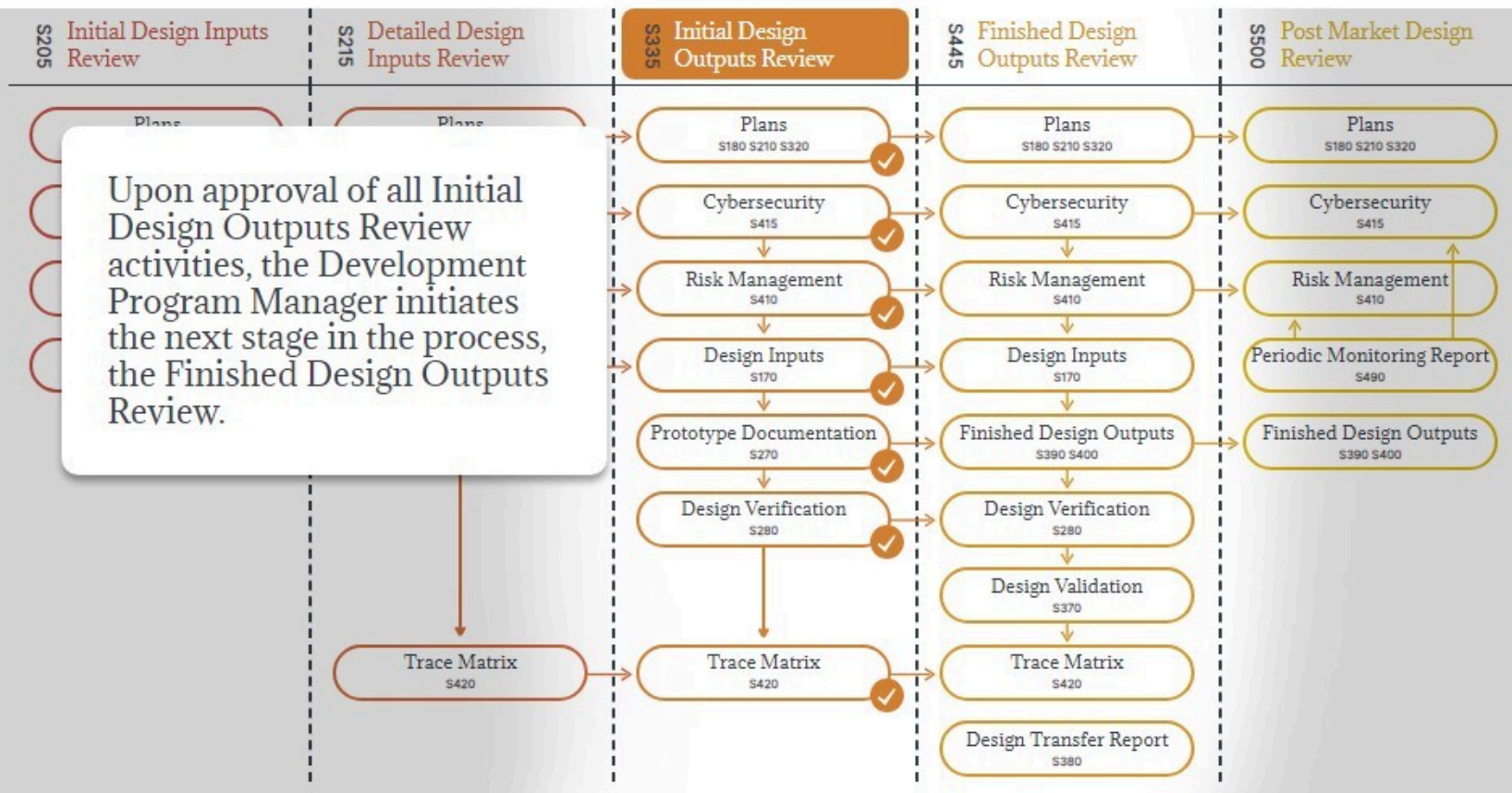
Initial Design Outputs Review



Design verification confirms that the initial design outputs fulfil the specified design input requirements. The results are documented in the Trace Matrix and the DHF.

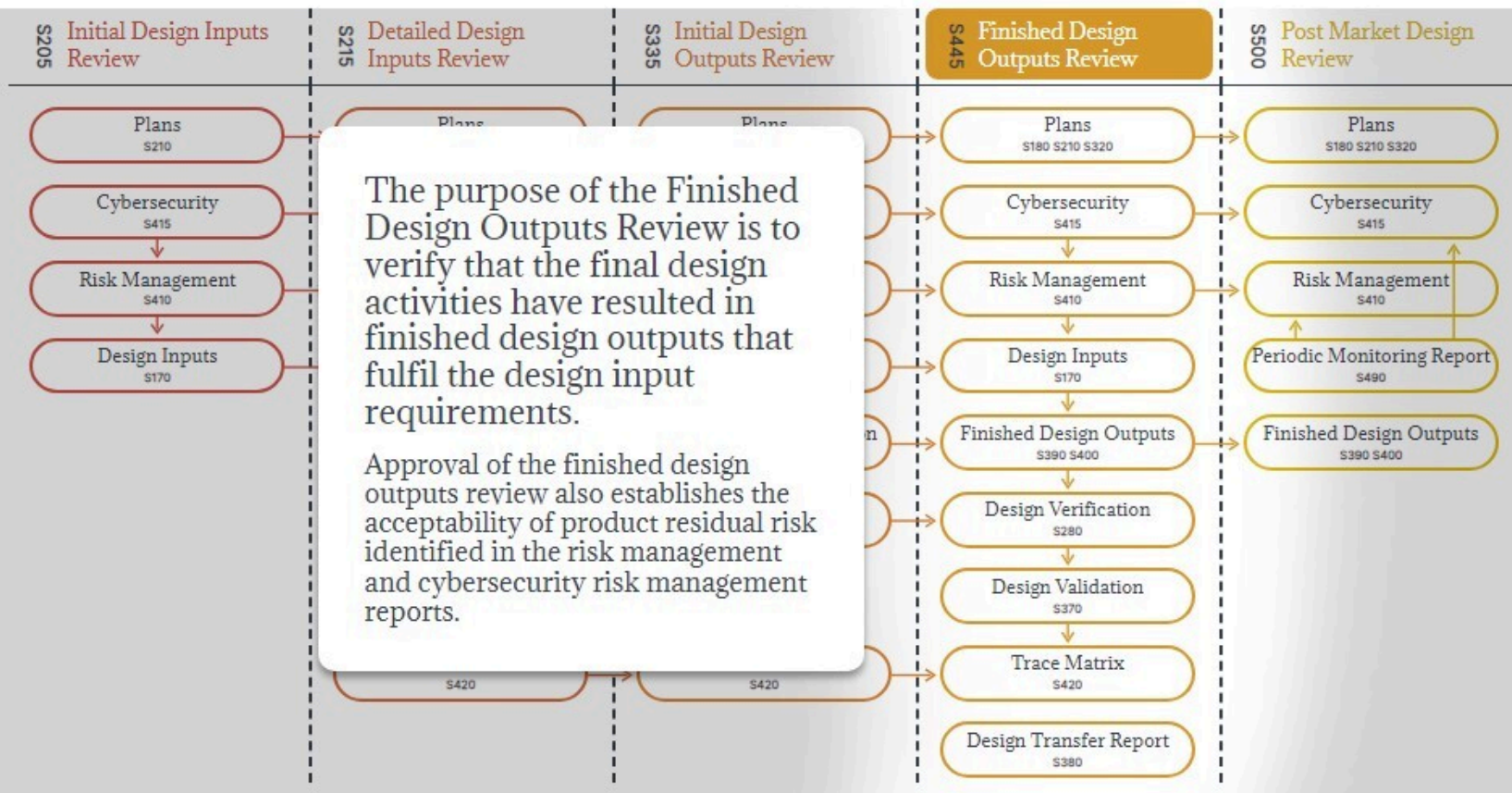
THE ADC DESIGN CONTROL PROCESS

Initial Design Outputs Review



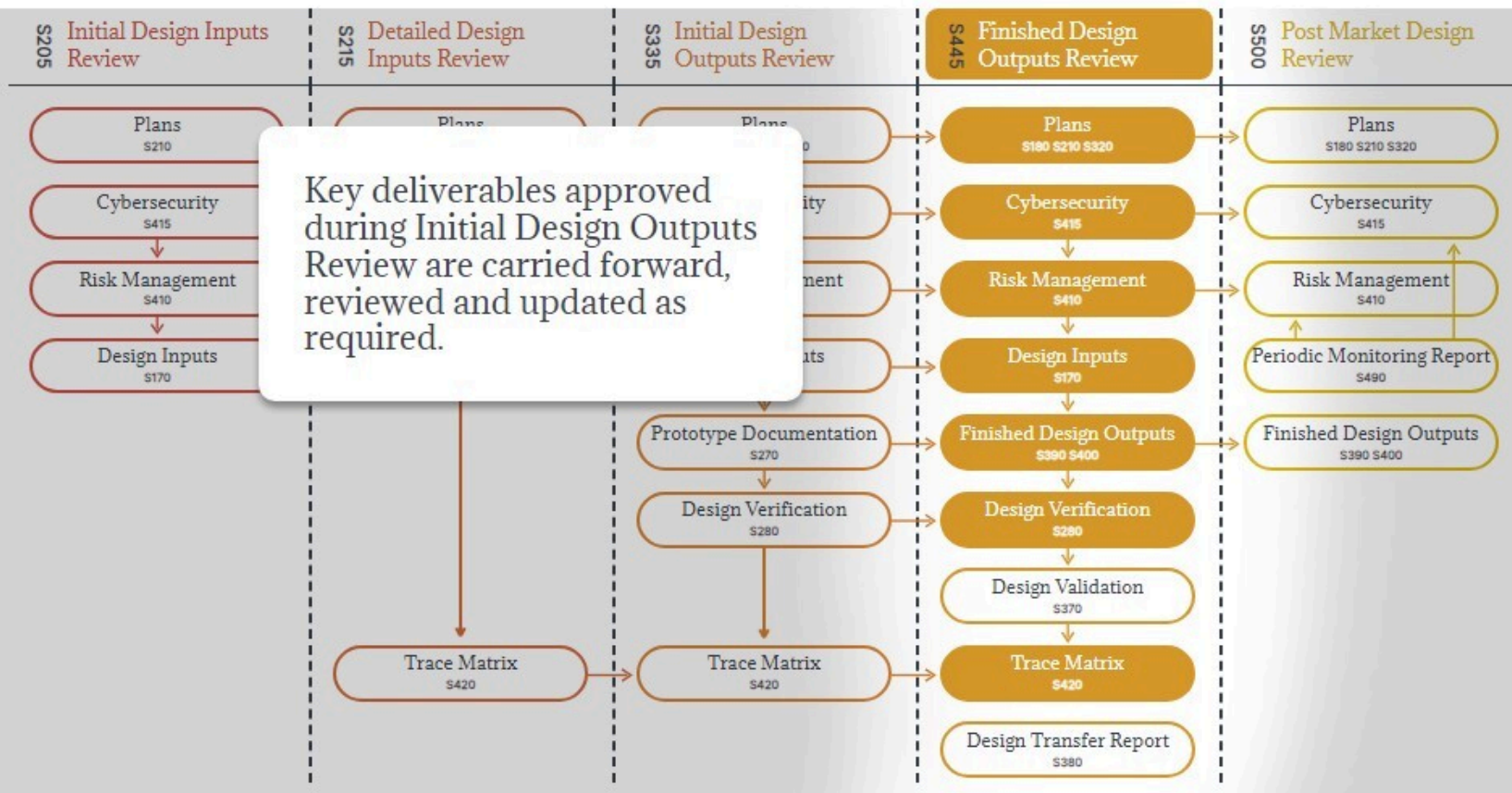
THE ADC DESIGN CONTROL PROCESS

Finished Design Outputs Review



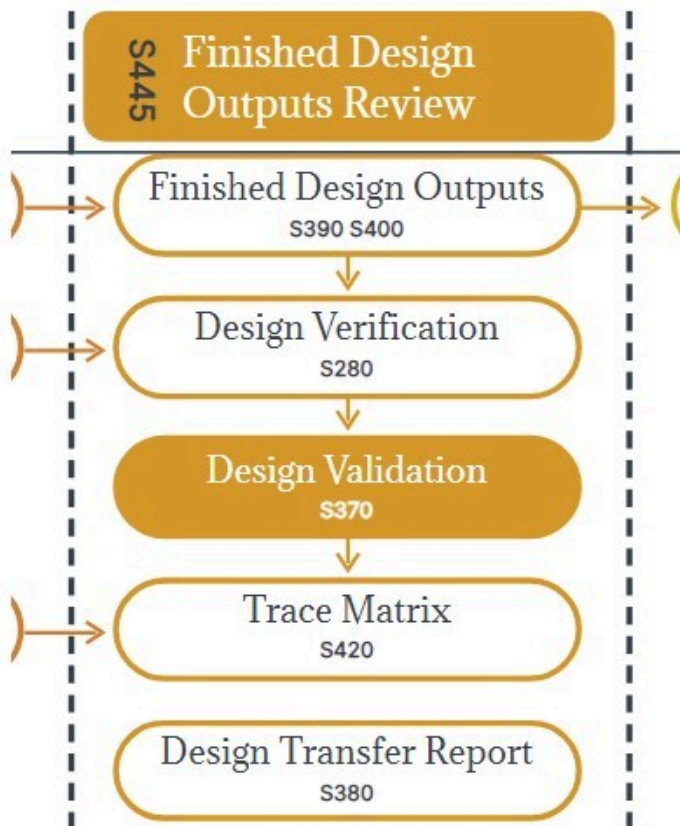
THE ADC DESIGN CONTROL PROCESS

Finished Design Outputs Review



THE ADC DESIGN CONTROL PROCESS

Finished Design Outputs Review

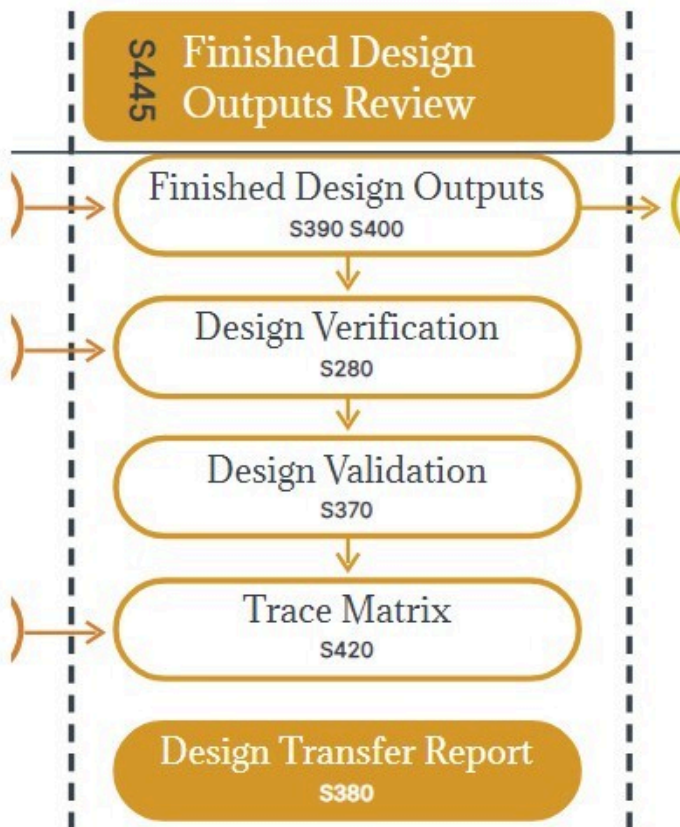


Design validation ensures the product design meets the user needs and intended uses by testing initial production units or their equivalents under actual (or simulated-use) conditions. Validation testing may include human factors or clinical testing. The results of the design validation are documented in the Trace Matrix and the DHR.



THE ADC DESIGN CONTROL PROCESS

Finished Design Outputs Review

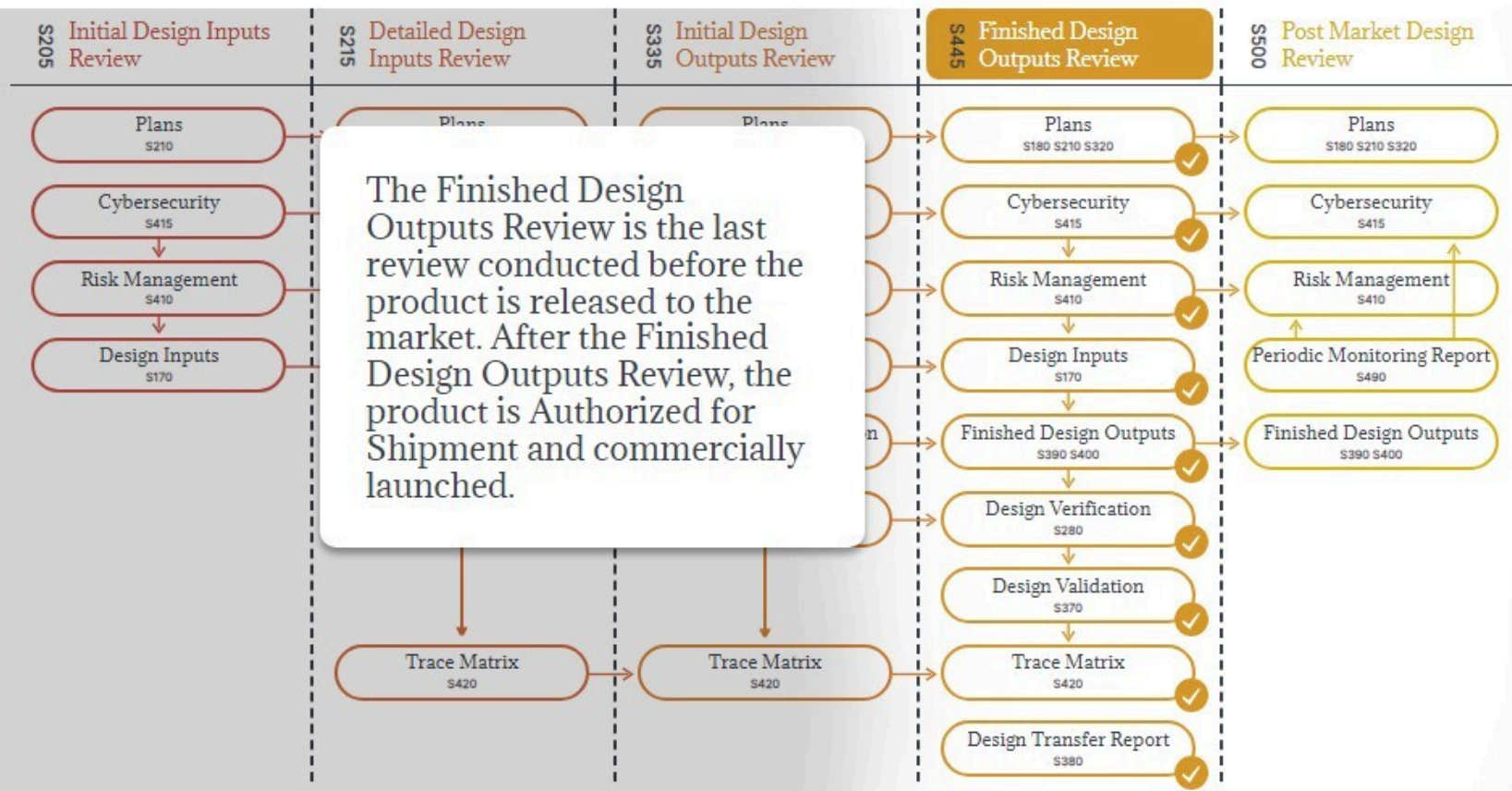


Design transfer ensures that design and development outputs are verified as suitable for manufacturing before becoming final product specifications.



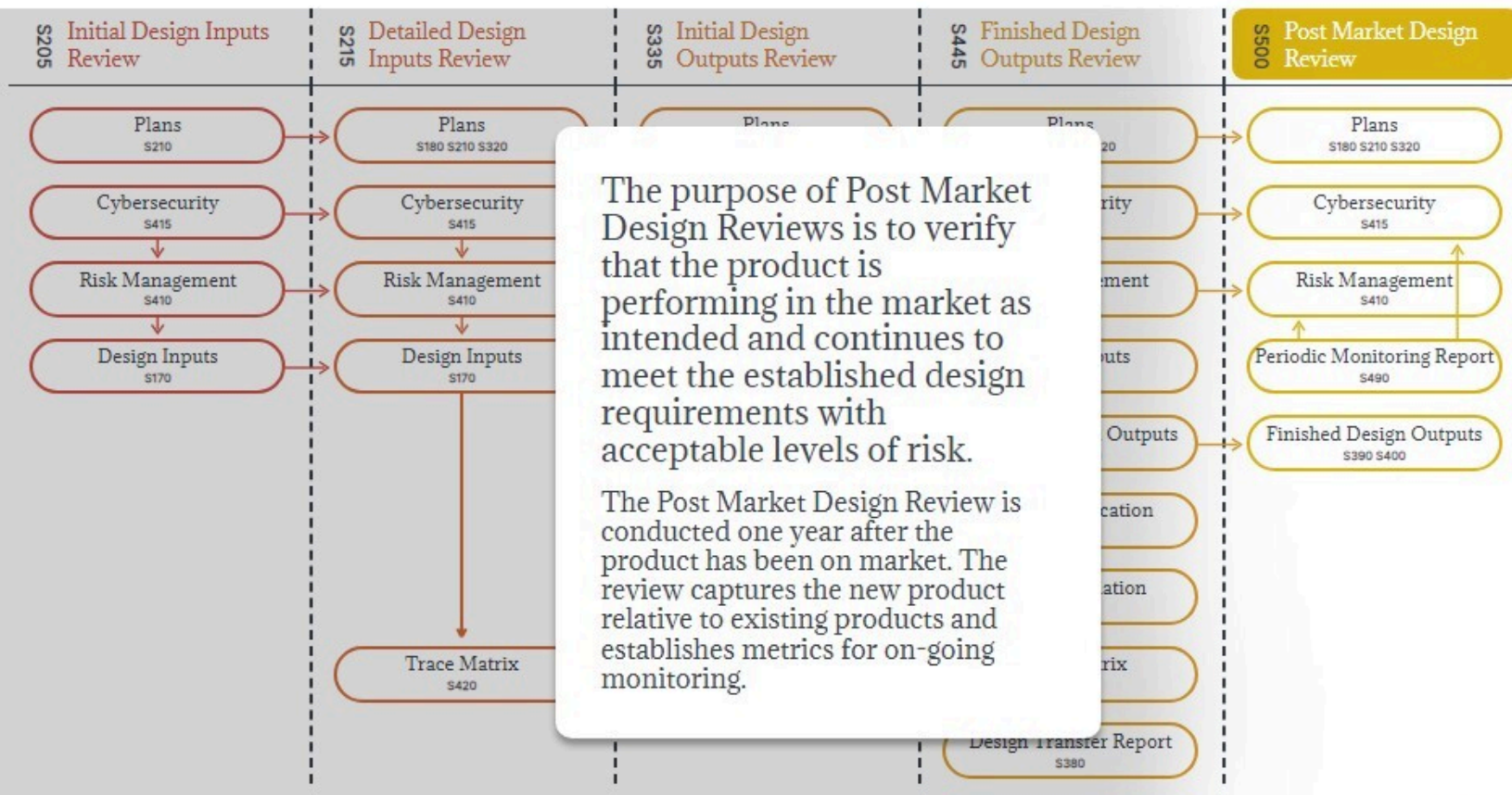
THE ADC DESIGN CONTROL PROCESS

Finished Design Outputs Review



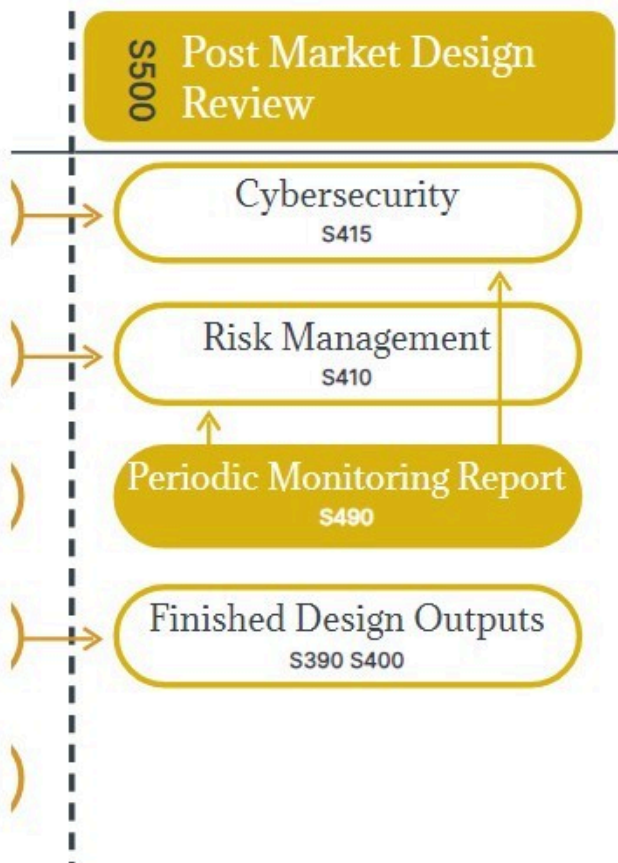
THE ADC DESIGN CONTROL PROCESS

Post Market Design Review



THE ADC DESIGN CONTROL PROCESS

Post Market Design Review



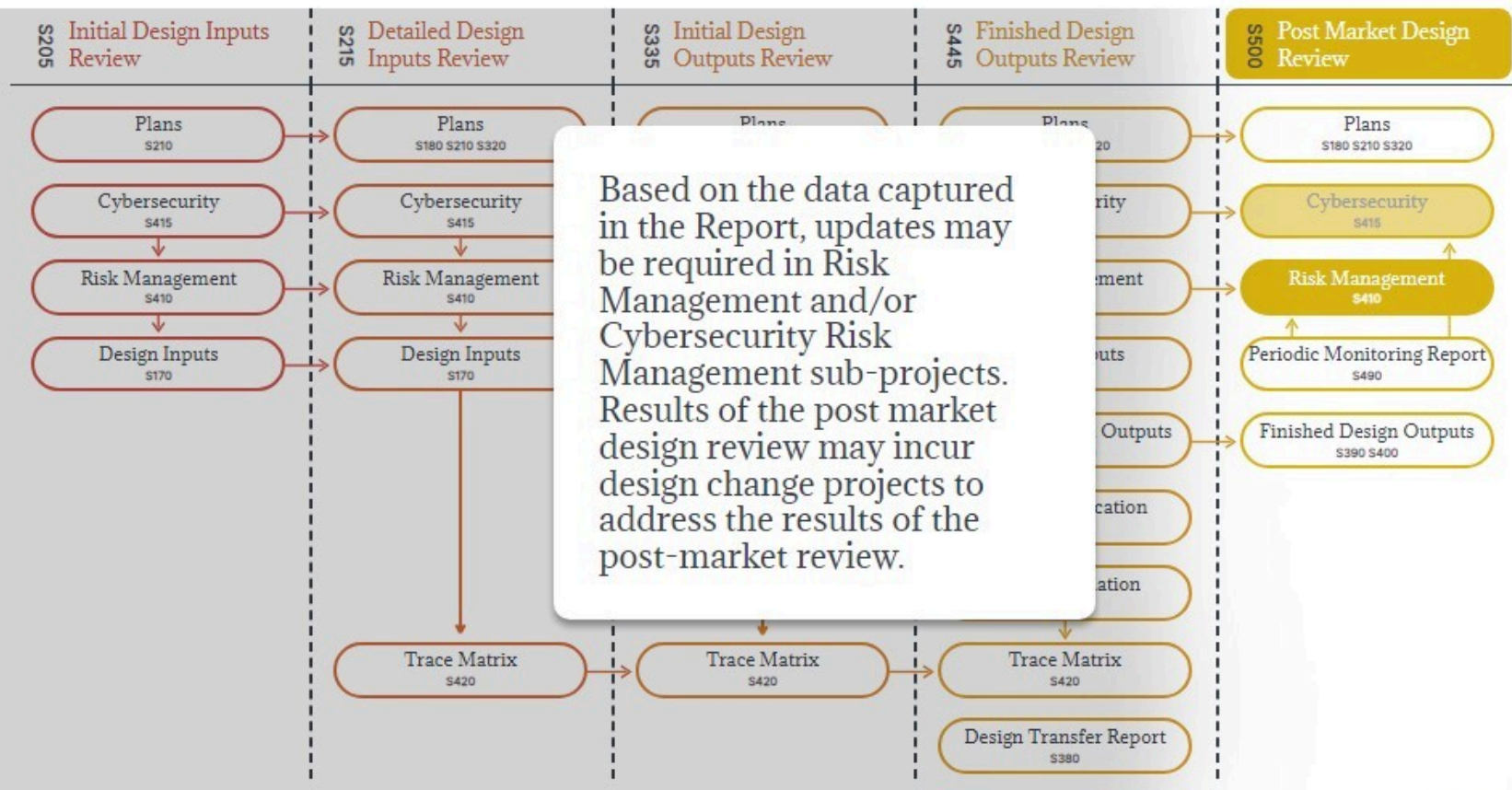
A Periodic Monitoring Report is created as part of the post market review process. The Report provides a summary of the product's post launch performance history, including:

- Acceptance trends,
- Tests results,
- Complaint data,
- Clinical performance data, and
- Risk Evaluations.



THE ADC DESIGN CONTROL PROCESS

Post Market Design Review





THE ADC DESIGN CONTROL PROCESS

Review



Review

Take a moment to review some of the key concepts in this section.

Click the arrow to begin your review.



Review



Initial Design Inputs Review

The purpose of the Initial Design Inputs Review is to review, verify and approve initial plans, documents, and inputs.



Review



Detailed Design Inputs Review

The purpose of the Detailed Design Inputs Review is to verify that design plans and inputs have been completed.



Review



Initial Design Outputs Review

The purpose of the Initial Design Outputs Review is to verify that the design outputs fulfil the design input requirements with acceptable levels of risk.



Review



Finished Design Outputs Review

The purpose of the Finished Design Outputs Review is to verify that the final design activities have resulted in finished design outputs that fulfil the design input requirements.



4



Review



Post Market Design Review

The purpose of Post Market Design Reviews is to verify that the product is performing in the market as intended.





THE A

Re

To check your progress, click
the Menu button



You have completed section 2 of 3

CLICK THE FORWARD ARROW TO CONTINUE LEARNING



KNOWLEDGE CHECK

Introduction



The Knowledge Check that follows consists of 5 questions. You must score 80% or higher to successfully complete this course.

WHEN YOU ARE READY, CLICK THE KNOWLEDGE CHECK BUTTON.

KNOWLEDGE CHECK



KNOWLEDGE CHECK

Assessment



1

The ADC Design Control process ensures which of the following:

Check all that apply.

- 1 | All design activities are planned before execution,
- 2 | Design requirements (design inputs) are defined and translated into specifications to build the product (design outputs)
- 3 | Risk is managed throughout the entire process.

NEXT

1

2

3

4

5





KNOWLEDGE CHECK

Assessment



2

How many phases does the ADC Design Control Process have?

1 | 4 phases.

2 | 5 phases.

3 | 6 phases.

NEXT

1

2

3

4

5



KNOWLEDGE CHECK

Assessment



3

Who is ultimately responsible for overseeing the entire ADC Design Control Process?

1 | Operations

2 | Quality

3 | Development Program Manager

4 | Regulatory

NEXT

1

2

3

4

5



KNOWLEDGE CHECK

Assessment



4

Which of the following statements regarding sub-projects are true?

Check all that apply.

- 1 | The design and development plan describes the activities required for the completion of each sub-project.
- 2 | Deliverables from one sub-project often serve as an inputs to another.
- 3 | Deliverables from sub-projects in one phase are often carried forward into a subsequent phase.

NEXT

1

2

3

4

5



KNOWLEDGE CHECK

Assessment



5

The data, documents and records that are created, used and shared during the product development lifecycle are only required to be updated immediately prior to each key milestone (design review)?

1 | True.

2 | False.

SUBMIT

1

2

3

4

5





Where to Get Help



MANAGER OR SUPERVISOR

If you have questions or concerns about an activity or interaction, the best place to start is with your manager or supervisor.

Course Resources



TRANSCRIPT

Click [here](#) for a full transcript of the course.

SUBMIT

1

2

3

4

5

