MEDIClever
Reimbursement Consultants

About Services Resources

Navigate your reimbursement pathway smarter.

Synchronizing Reimbursement and Regulatory Activities

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Introduction

We help our clients obtain reimbursement in the following geographies:

- Europe

- North America

- Other

And have done so more than 150 times (next are some of our clients)

Amir Inbar
Founder and CEO

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Senior Reimbursement Consultant, USA

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Advisor

In a Nut Shell

MEDIClever Reimbursement Consultants

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Reimbursement Landscape

1. Reimbursement Landscape
   a. Available reimbursement mechanisms
   b. Decision Makers
   c. Reimbursement strategy

The purpose of this step is to understand the current reimbursement environment relevant for your device/drug.

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Reimbursement Landscape

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a. Available reimbursement mechanisms: Are there any specific codes, payment rates and coverage policies that address the device or drug? If not, which new mechanisms need to be developed (e.g., a new code, an expansion of a coverage policy, a new payment rate to an existing code or all of the above)?

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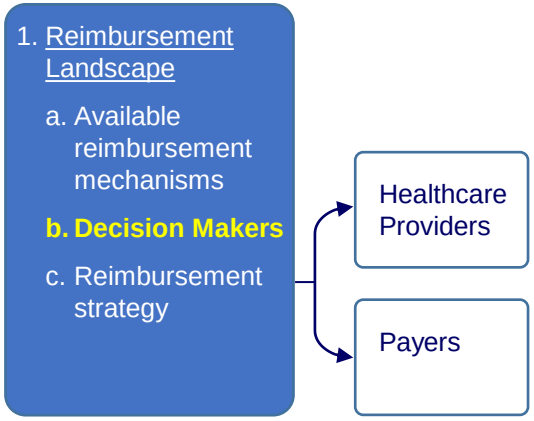
Reimbursement Landscape



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b. Decision makers:

- In case available existing mechanisms were identified in the above 1a, the main decision makers are healthcare providers. No need to approach payers.
- In case new mechanisms need to be developed, the main decision makers are typically payers.

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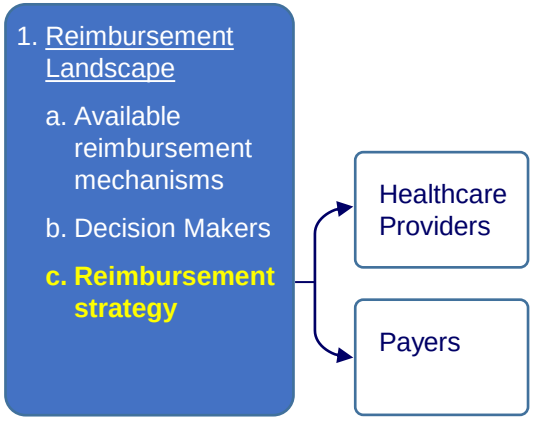
Reimbursement Landscape



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b. **Decision makers**:

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- In case new mechanisms need to be developed, the main decision makers are typically payers.

c. **Reimbursement strategy**: An outline of the typical path for obtaining third-party reimbursement or any other sort of funding, including milestones and timelines, along with an initial reimbursement strategy for the device or drug in each of the selected countries.

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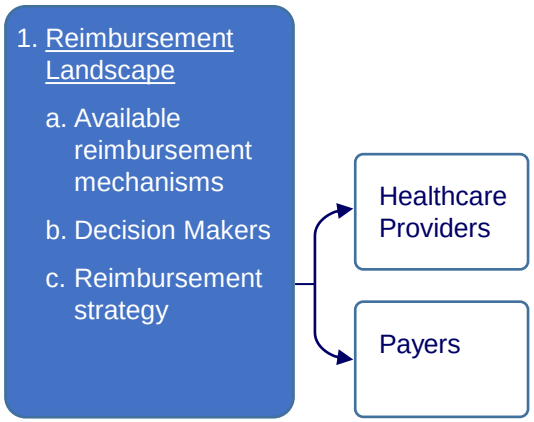
Reimbursement Landscape



One of our clients developed and launched a product in the US market which included a pressure pump. Unfortunately, the pressure settings employed by the pump deviated from the allowable range specified under the existing reimbursed codes. The company was left with one of two options:

1) Develop new reimbursement mechanisms for their product – a long and costly process, or:

2) Redesign the product to fit under existing pressure settings – another costly alternative requiring a new clinical study and regulatory clearance.

Had the company conducted the Reimbursement Landscape in time, setting the appropriate pressure range would be easy and would mean having a reimbursed device in the market today.

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Regulatory Landscape

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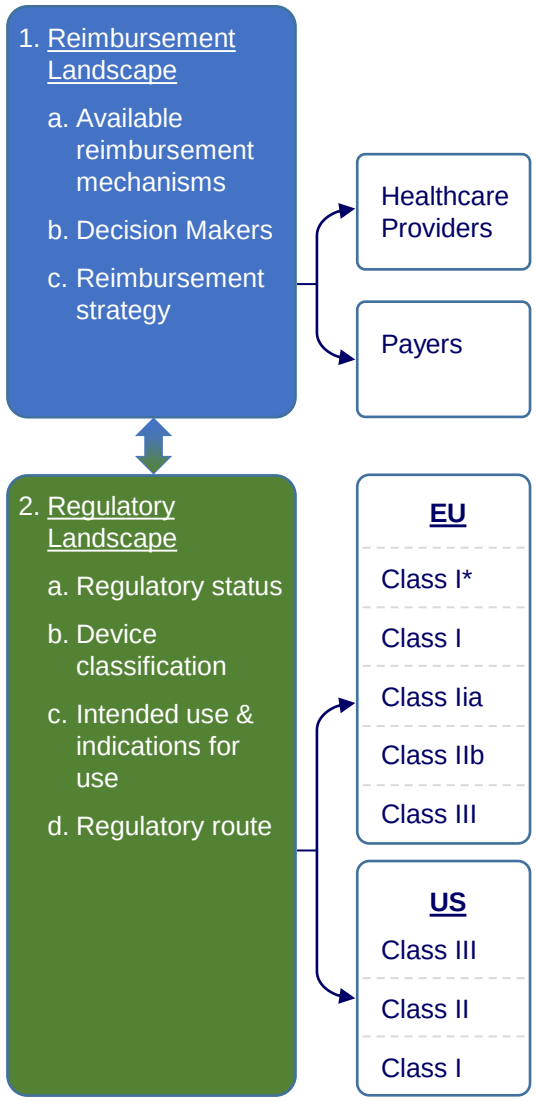

- In parallel, or immediately after the Reimbursement Landscape Report is submitted, our partners provide the Regulatory Landscape Report to determine the product's classification, intended use, indications for use and the anticipated regulatory route.
- Sometimes regulatory status and classification are different between EU and US, and this needs to be taken into account when formulating regulatory, reimbursement and marketing strategies.

** Non-sterile without measuring function*

Regulatory Landscape

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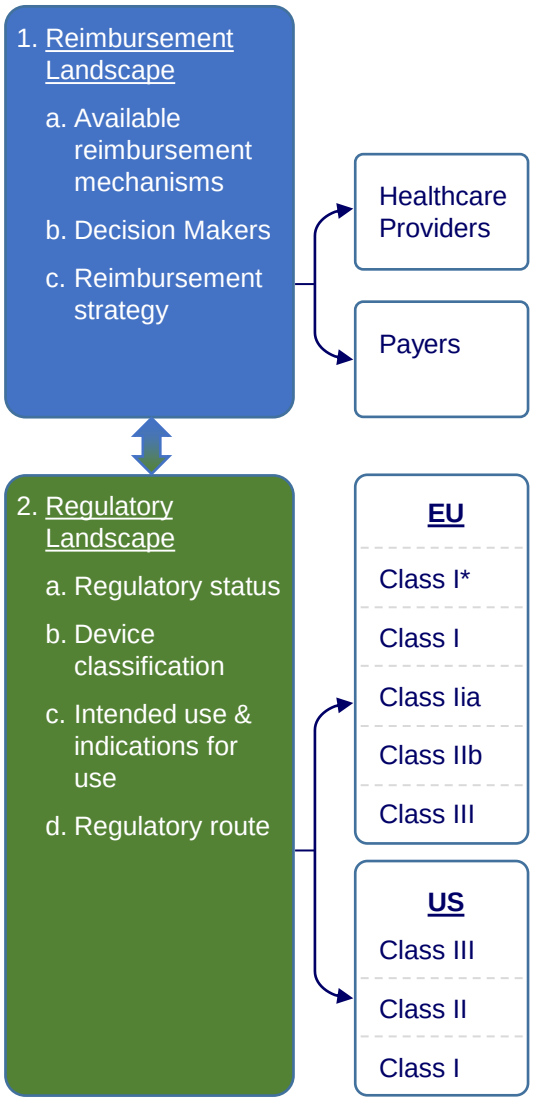
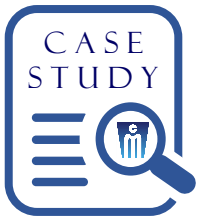




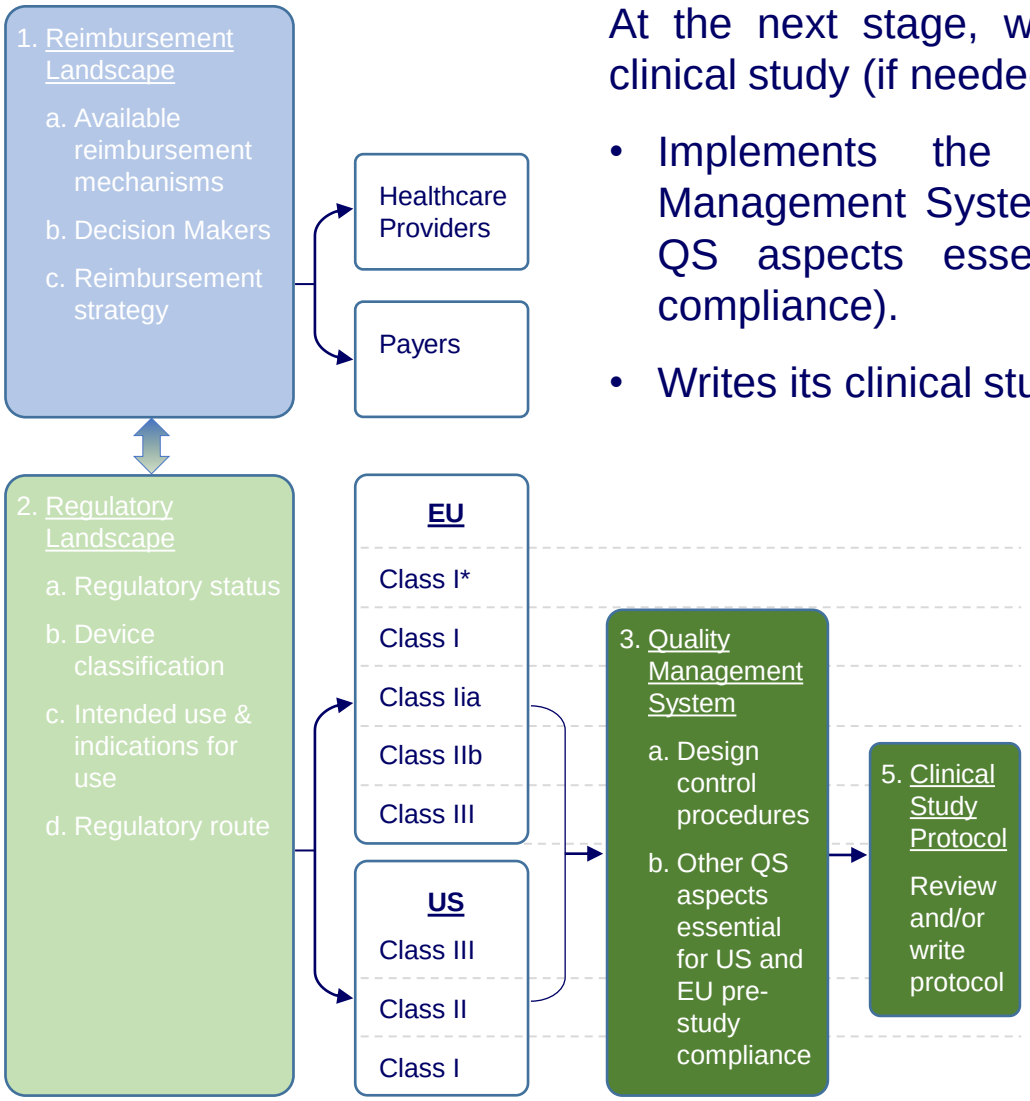
One of our clients asked us to start working on their reimbursement strategy after applying for, and receiving, the regulatory clearance. Unfortunately, the wording that was used in the regulatory application substantially decreased the likelihood of reimbursement. Consequently, the company re-applied for the regulatory clearance, this time, with a modified indication for use.

Needless to say, this delayed the launch of the product resulting in substantial loss to the company.

In this stage we make sure both reimbursement and regulatory strategies are aligned.

** Non-sterile without measuring function*

Preparation for Clinical Study



At the next stage, when the company prepares for its clinical study (if needed, see chart below), it typically:

- Implements the relevant parts of its Quality Management System (e.g., Design Controls and other QS aspects essential for US and EU pre-study compliance).
- Writes its clinical study protocol.

Reimbursement Planning

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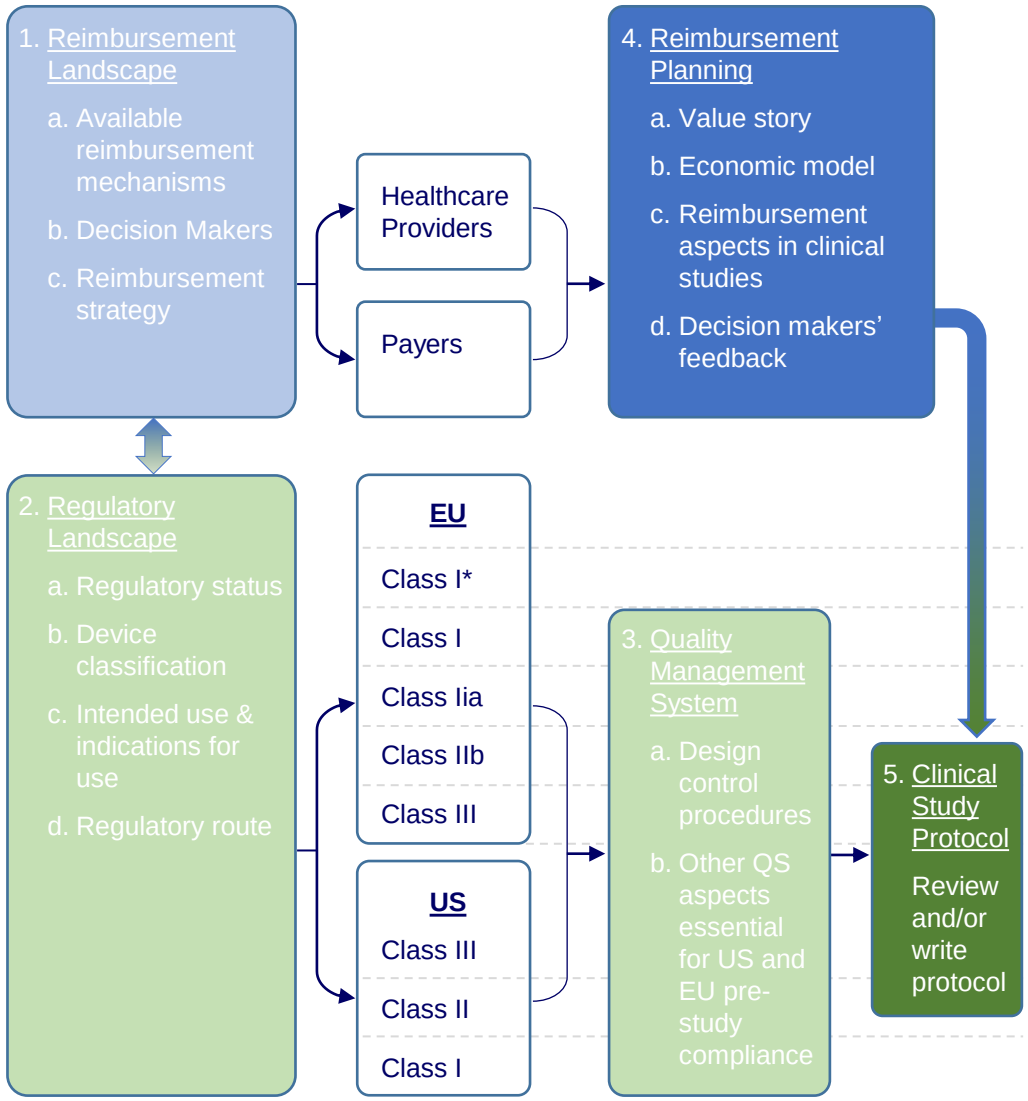

Prior to initiating a clinical study, we plan how to generate the required reimbursement-related 'evidence', from the identified decision makers' (i.e. healthcare providers' / payers') perspective:

a. **Value Story**: Highlights the clinical AND economic benefits of the new product.

b. **Economic Model**: Quantifies the economic benefit, allows for sensitivity analysis and utilized as a pricing tool.

c. **Reimbursement Related Parameters**: Integrated in the study protocol.

d. **Stakeholders' Feedback**: Used to validate decision makers' support based on the presented plan.

Reimbursement Planning

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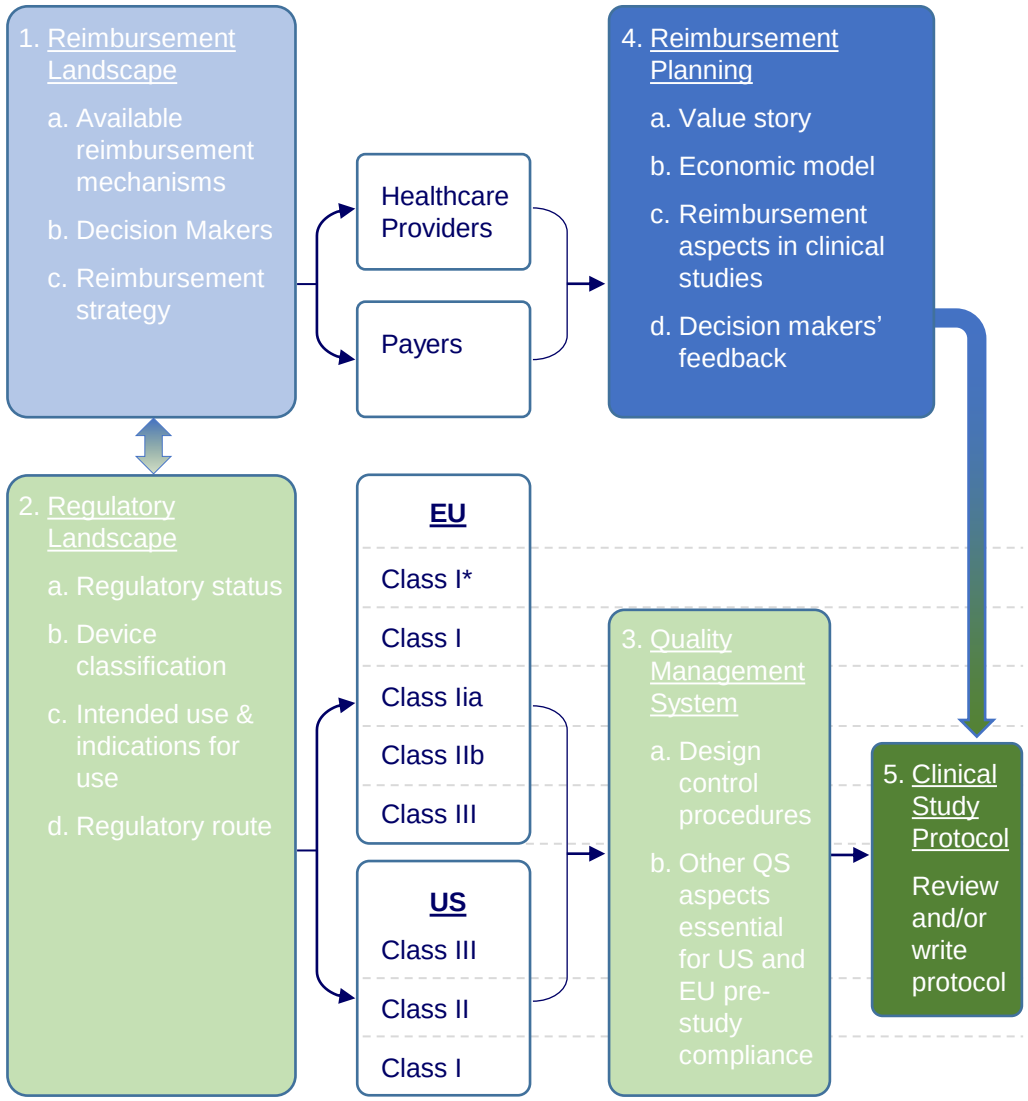


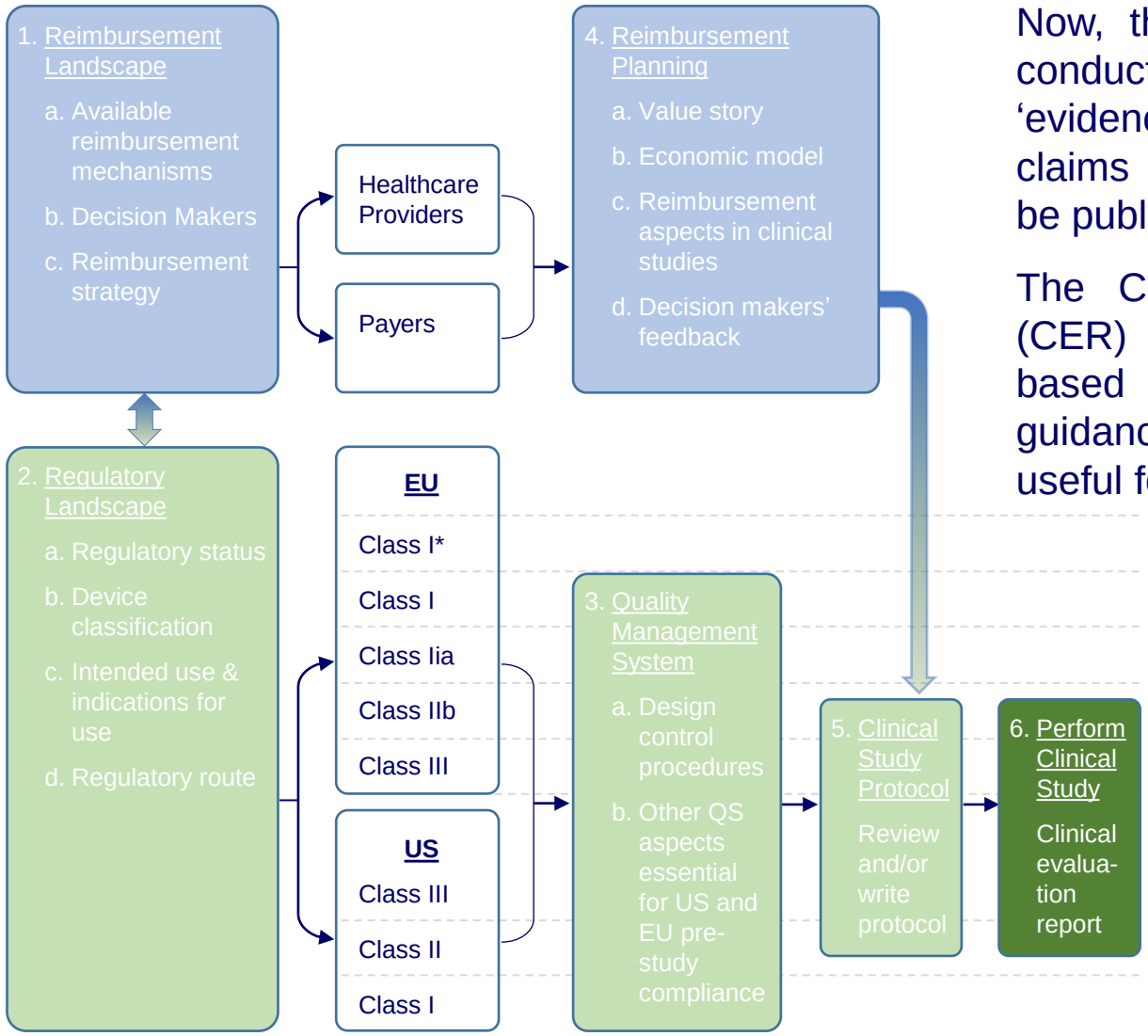
CASE STUDY

One of our clients developed impressive clinical data and asked us to help them obtain reimbursement.

Payers were impressed by the developed clinical 'evidence', but also wanted to understand the associated economic implications. Since these were not observed in the company's clinical trials, the company had to perform a new trial to gather the requested data.

Such economic data could have been easily integrated into the company's previous trials making the investment in a new trial, and the delay in the sale of their product, redundant.

Clinical Study



Now, the clinical study may be conducted and the resulting 'evidence', substantiating the claims in the Value Story, should be published.

The Clinical Evaluation Report (CER) should now be prepared, based on official European guidance. CER may also be useful for US submissions.

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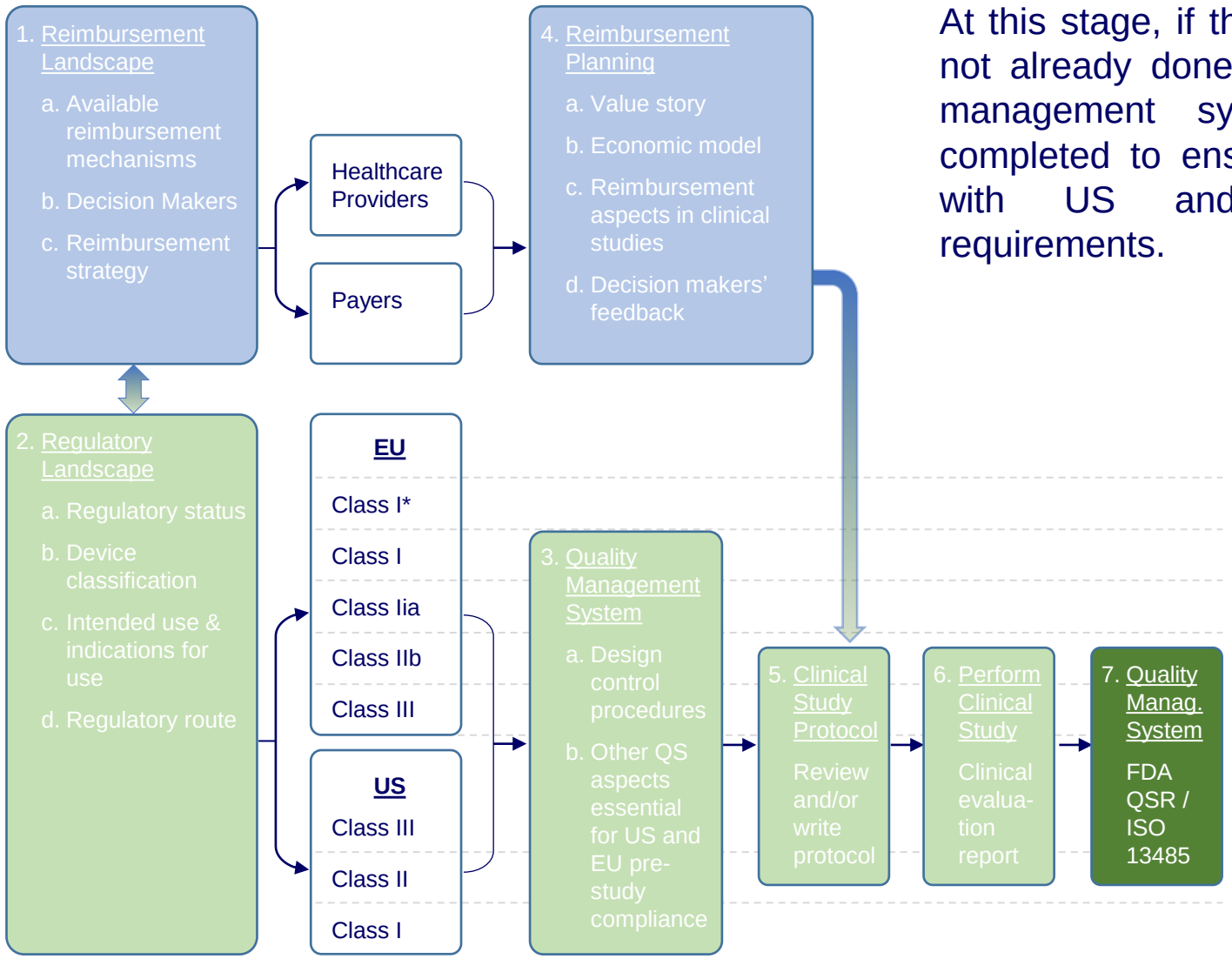
QMS Completion



At this stage, if the company has not already done so, the quality management system can be completed to ensure it complies with US and/or European requirements.

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Regulatory Application

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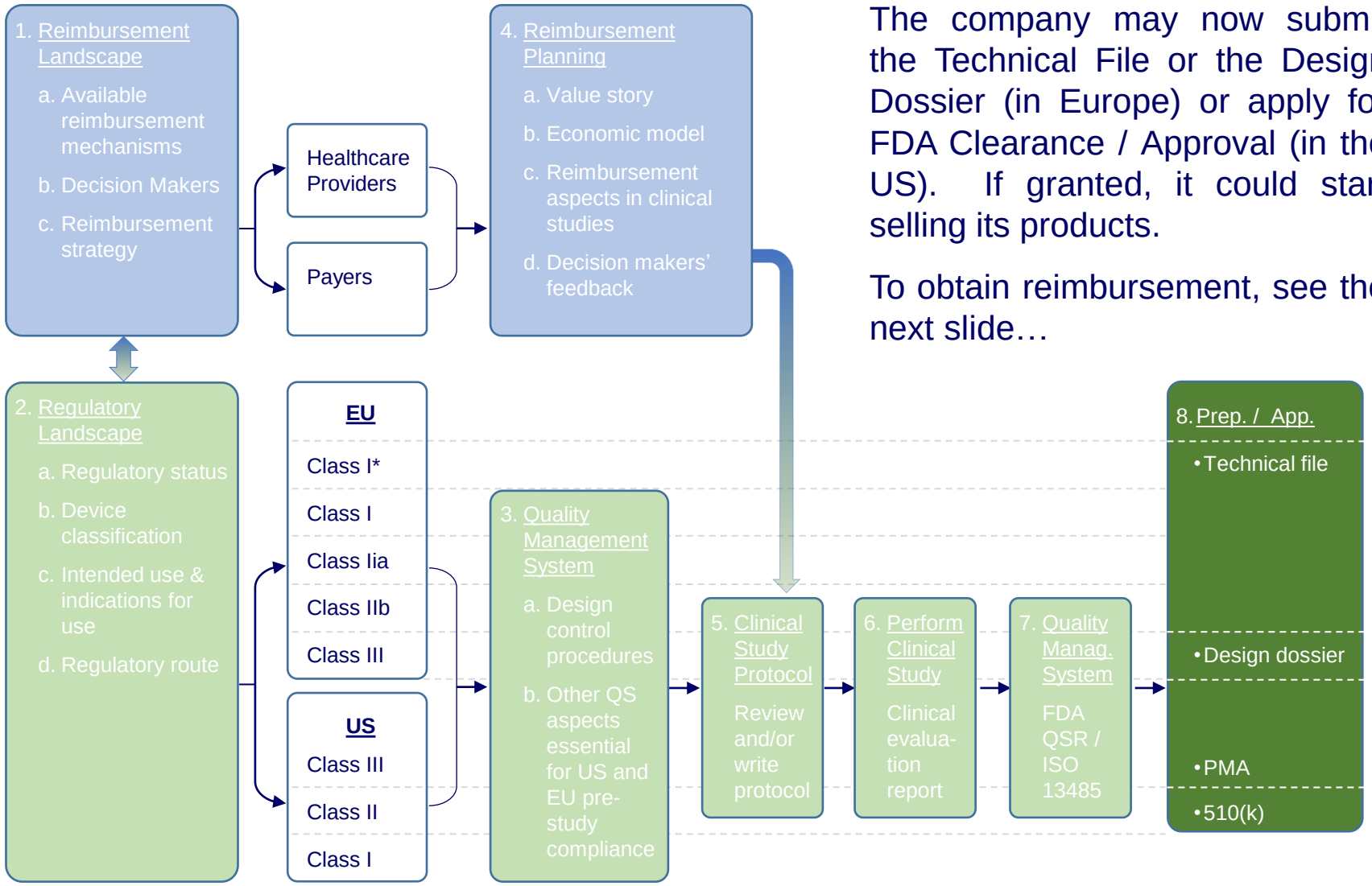
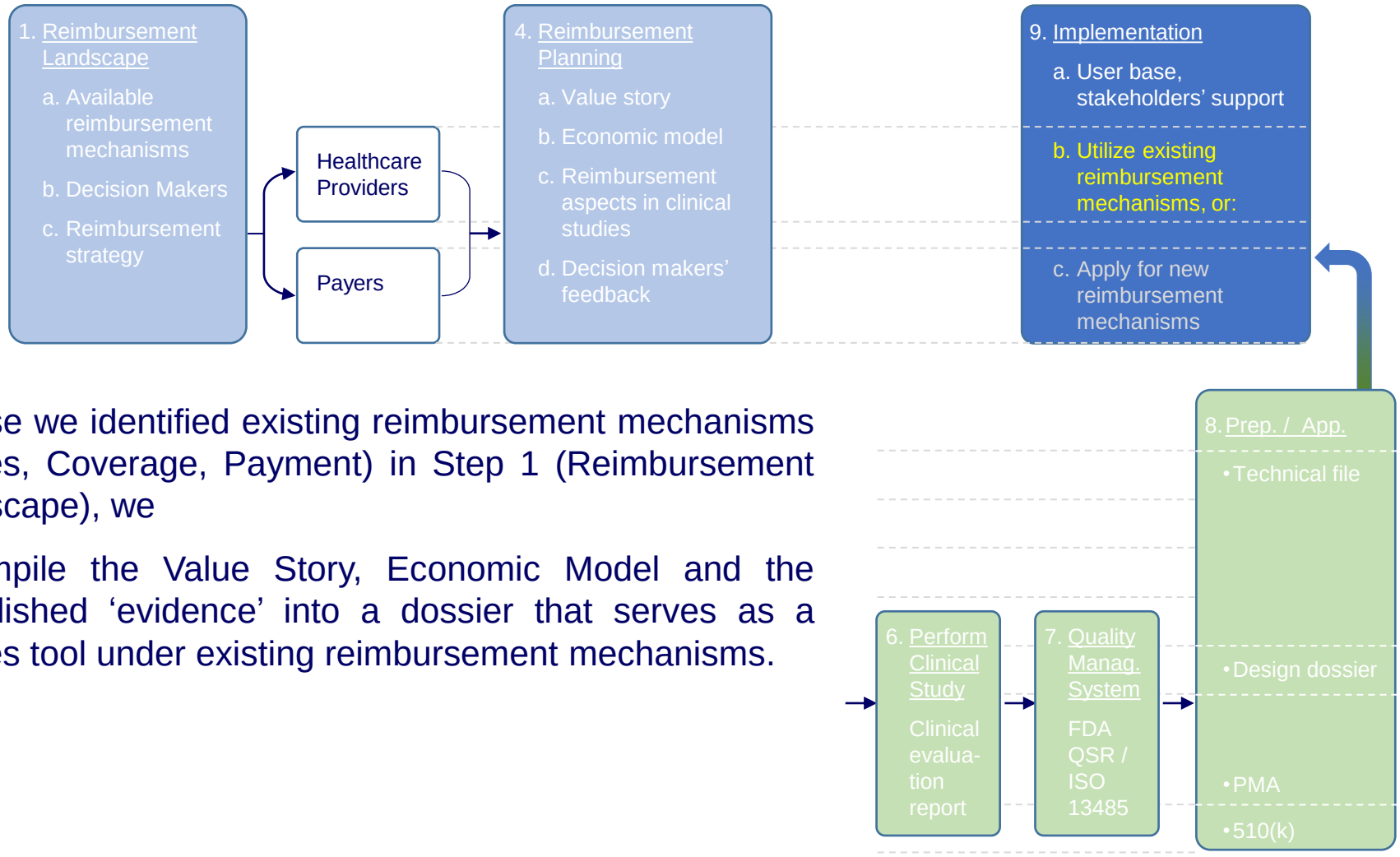


The company may now submit the Technical File or the Design Dossier (in Europe) or apply for FDA Clearance / Approval (in the US). If granted, it could start selling its products.

To obtain reimbursement, see the next slide…

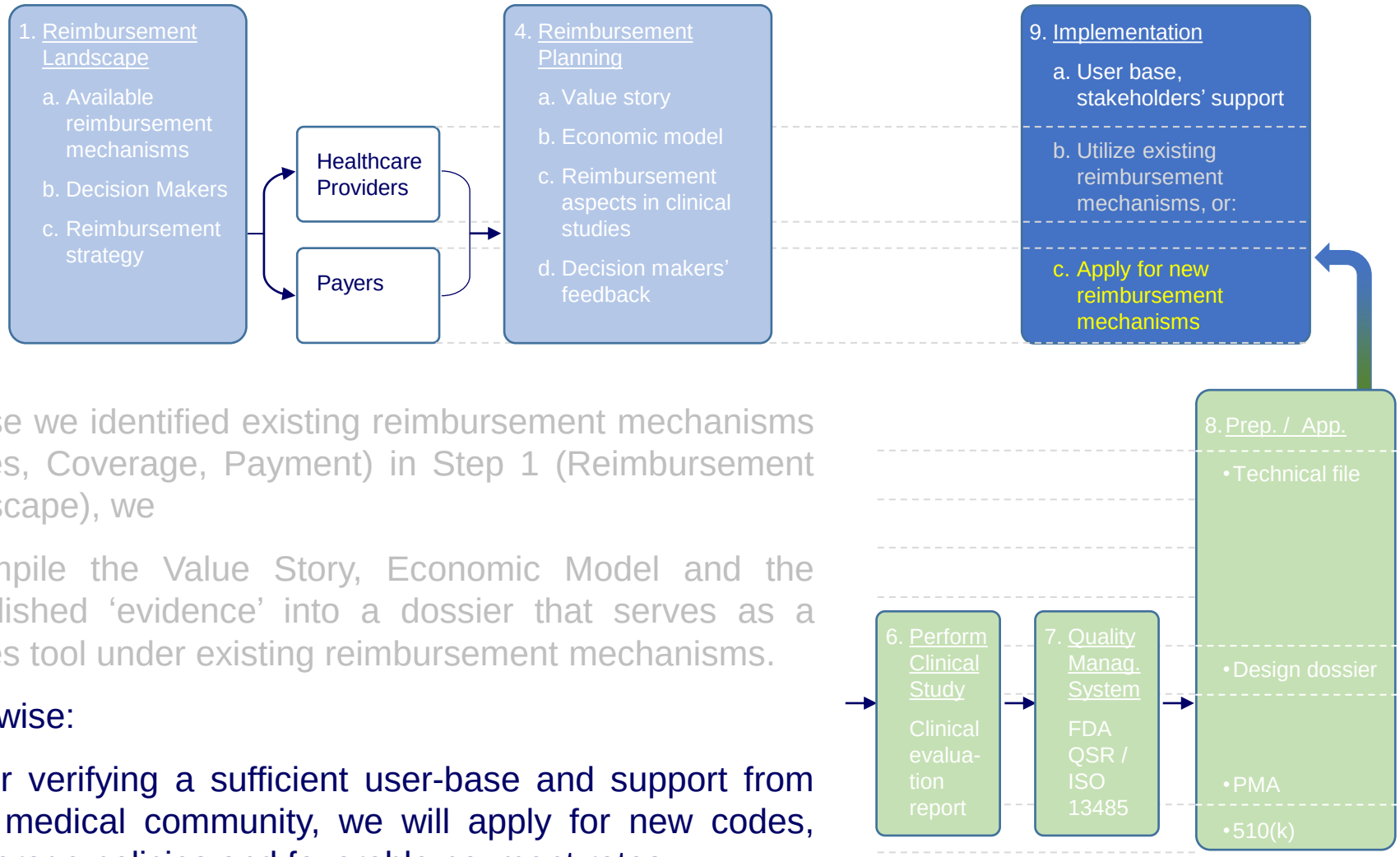
Reimbursement Application



In case we identified existing reimbursement mechanisms (Codes, Coverage, Payment) in Step 1 (Reimbursement Landscape), we

- Compile the Value Story, Economic Model and the published 'evidence' into a dossier that serves as a sales tool under existing reimbursement mechanisms.

Reimbursement Application



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- Compile the Value Story, Economic Model and the published 'evidence' into a dossier that serves as a sales tool under existing reimbursement mechanisms.

Otherwise:

- After verifying a sufficient user-base and support from the medical community, we will apply for new codes, coverage policies and favorable payment rates.

The Process

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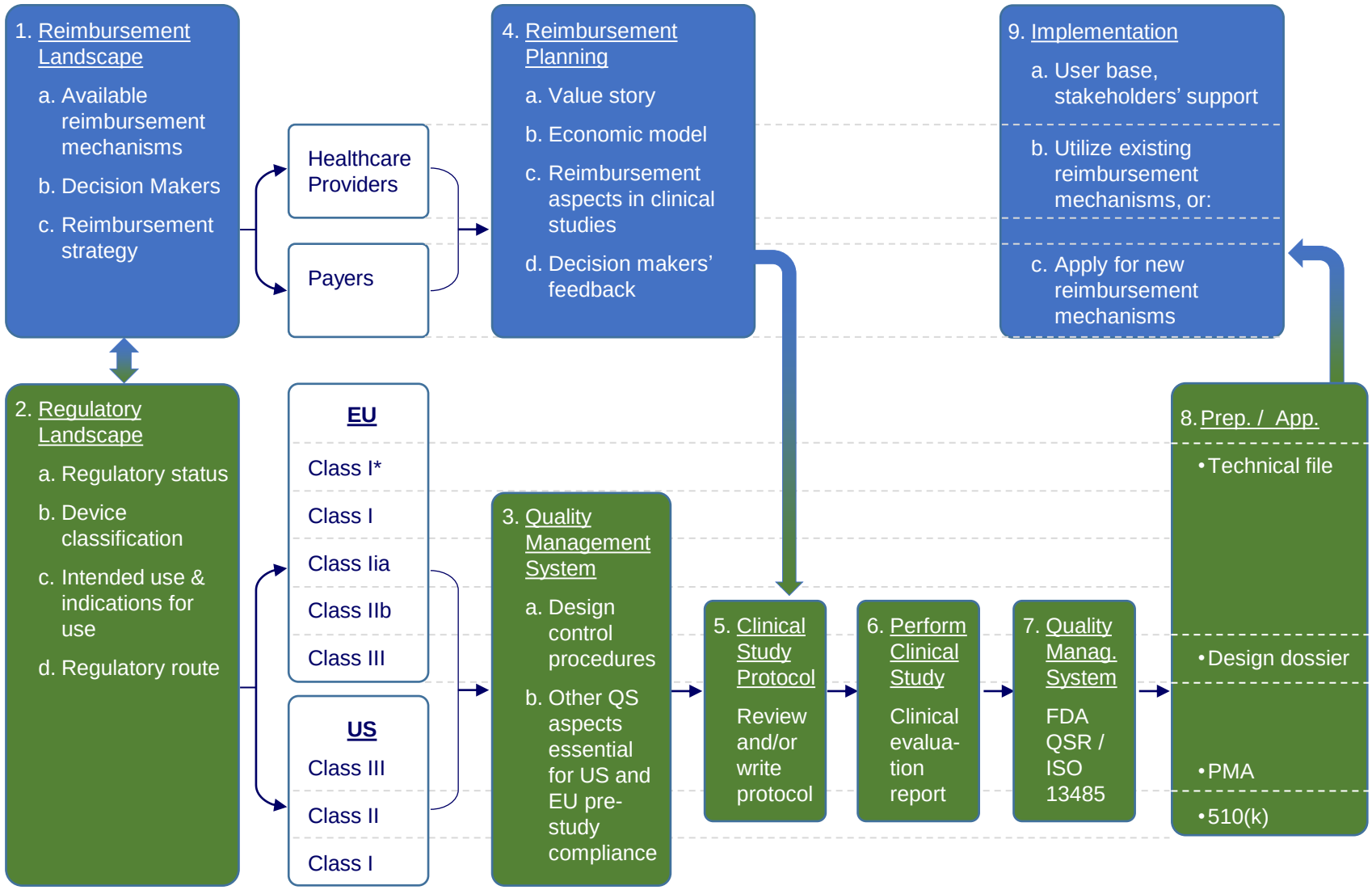

The End

To access additional articles, speak with one of our reimbursement consultants or receive a formal quote for our services, use the links on the top right corner.

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