White Paper

Test Protocol Development

When planning any testing project, it is critical you develop a test protocol. Understanding the study objectives and methods will help ensure a successful testing project and mitigate risk. The protocol should convey a clear understanding of why and how the test will be completed, what the necessary materials are and most importantly, how the data will be presented and analyzed.

We often get asked: “Do I need a test protocol?” or “How do I develop one?” This document outlines the common sections of a protocol. We highly recommend having test protocols in place prior to starting any study and work together to develop your testing strategy.

Why Is Having a Protocol So Critical?

Whether you are performing your testing internally or outsourcing it to a trusted partner, the protocol serves as the main communication tool for capturing expectations, acceptance criteria, regulatory requirements and applicable standards, and walks you through the steps to create a plan for the project. It’s almost like a map. A protocol also documents this information accordingly for repeatability in the future, and for keeping the team on the same page with revision control.

How Do You Start?

There are several common sections to test protocols and depending on your regulatory strategy, you may want to include all of them or modify as needed to align with your design history file. Some of these items may be outlined in other documents and may be redundant to have in both places.

Typical protocol sections are outlined below:

1. Scope
2. Objective
3. Specifications/Standards
4. Materials and Worst Case Analysis
5. Equipment
6. Methods
7. Data Interpretation and Results
8. Acceptance Criteria
9. References
10. Signatures

Good protocols can take time to develop, and adequate resources should be allocated at the beginning of the projects. Writing protocols retroactively or mid-way through the project because you are trying to save time often results in delays and unclear expectations and test reports. Delays can be easily been prevented if the correct steps are mapped out, particularly if you don’t perform testing routinely. In our experience, the most successful

customers are the ones that put in the forethought to identify the regulatory needs and risks at the beginning, then mitigate it through the protocols instead of doing it on the fly.

Scope, Background and Objective – What is the Goal and Why?

Most protocols start with a scope or background for the project. It lays the groundwork for the device and why it is being evaluated. The objective or purpose define the output. A clear objective sets the tone for the project and identifies what questions are being answered or what hypothesis is being made. Several examples are listed below in order of impact and clarity:

1. To perform testing to evaluate the strength of the partial knee replacement.
2. To characterize the antero-posterior, medio-lateral, and rotational constraint behavior of a unicondylar knee replacement system.
3. This testing covers the means by which unicondylar knee replacement constraint may be quantified according to motion delineated by the inherent articular design as determined under specific loading conditions in an in-vitro environment. This testing characterizes antero-posterior draw, medio-lateral shear, and rotary laxity in reference to ASTM Test Method F1223. The results will be compared for substantial equivalence to a predicate.

Specifications/Standards

The first question we ask a new customer is “Do you have a test standard that you are looking to test to?” Often times the answer is yes. If not, then there may be a similar standard to reference or deviate from. This part of the protocol should list any relevant standards and comment on any expected deviations. The FDA Guidance documents can also be references as they can outline the required testing.

Materials

The materials section should outline all of the components that are needed for testing, quantities, and any other relevant information. Maintaining traceability to ensure a clear expectation of what is to be tested is also important. An example table is shown below:

P/N	Lot #	Description	Quantity	Material

Another item that is helpful in the materials section is the worst case justification. For the medical industry, it is critical to identify the worst case configurations for testing. It is helpful to include this in the protocol along with any finite element analysis results because this is often the only insight the testing laboratory or future team members have into why this specific device size was selected. Being able to understand this information helps quickly identify issues or additional risks and address them at the beginning of the projects.

The materials section also contains the test equipment or apparatus that will be used. Identifying the load capacities and type of test frame can help ensure that the expected loads are within the calibrated ranges and minimize any equipment variability. General tuning parameters can also be included to minimize any risk. Fixtures and testing environments can be outlined, although they can also be listed in the Methods sections.

Methods

The methods or procedure sections outline the actual testing steps. They often align with the applicable FDA guidance documents and ASTM or ISO testing specifications. If you are not sure how to get started with this section, the Procedures section in the standards is often the best place to go. The methods section should outline the test parameters for the testing project:

1. Specimen Preparation - Customer specific assembly instructions
2. Test Configurations
3. Testing Frequency
4. Target Cycles
5. Target Load Data or Method for Load Selection
6. Testing Environment
7. Testing Rates
8. Control Modes (force/displacement)
9. R Ratios
10. Waveforms

This section should also reference any previous studies or test reports to ensure repeatability. If the methods section has several different test configurations, the parameter listed above should be outlined for each test type. A key area of the methods section is an outline listing any specific assembly, disassembly, or handling information. Test block or loading orientations, tightening torques, and fluid collection information should also be outlined.

Data Interpretation, Results & Acceptance Criteria

Defining the data you are looking for and what you are comparing against needs to be documented. Determining acceptance criteria based on previous or predicate testing up front helps everyone involved evaluate the data that is being generated, and quickly make adjustments if needed. It also drives the procedure section to make sure there is an “apples to apples” to predicates. If there are no predicates available for your device, clear definition of acceptance criteria is paramount.

This section should also include the reporting requirements from your company’s internal reporting procedures. Similar to the methods section, the ASTM or ISO test standards outline the common deliverables for the testing. However, if you also require raw data, specific photographs or inspections, these should be clearly outlined in this section. Statistical analysis information should also be outlined here for data evaluation.

References

The references section should list any appropriate references such as: test standards, regulatory gruidance, previous test reports, published literature, etc. This section helps identify where the information in the protocol came from and where to access that information for more details.

Signatures & Revisions

Once the protocol is completed, we recommend having signature and revision control to ensure that all parties are aware of any changes and to get everyone is on the same page. The study owner, local management, and the testing laboratory sign off are common. Additional signatures can be added as required. This ensures multiple people have eyes on the program. A sample signature block is below. Depending on internal processes, some protocols have signature blocks on the front page, while others have them at the end.

Element Materials Technology			
Protocol Name: ASTM F1717 Testing of pedicle screw system			
Protocol ID:			
Author:		**Title:**	
Signature:		**Date:**	
Management Review:		**Title:**	
Signature:		**Date:**	
Approval:		**Title:**	
Signature:		**Date:**	
Revision	**Signature:**	**Date:**	**Description of Change:**
0			**Initial Protocol Release**

Conclusion

Often customers have purchased or developed a set amount of parts and have one opportunity to get testing programs right. There is a substantial difference in testing programs that have testing protocols implemented and those that do not. Always invest in a protocol and test plan. A protocol and plan will mitigate your risk, prevent confusion, set clear expectations, and preserve the necessary information for future reference and use.

Element Materials Technology is ISO 17025 accredited and has one of the most expansive medical device testing scopes in the world ranging from orthopedics and cardiovascular implants testing to EMC/EMI/product safety testing to biological and packaging evaluations. Contact us to discuss how we can help with your test project.