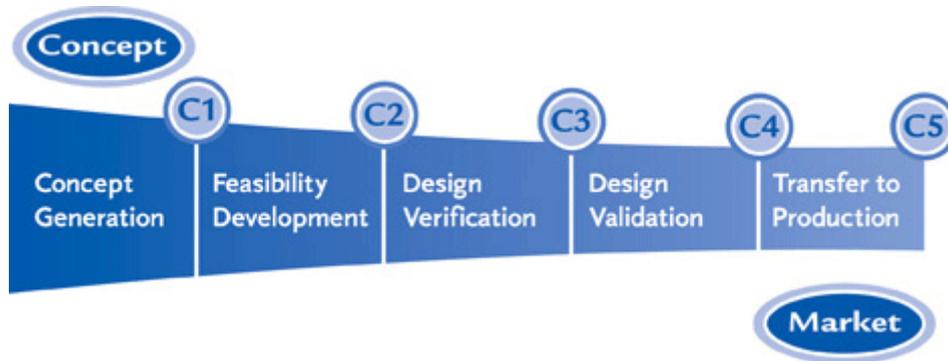


## Design & Development Process

The Creganna-Tactx Medical Design & Development process has five main stages.



\* C1-C5 Customer Reviews

The process is built around 5 key elements. These elements combine high levels of communication and customer interaction with structured processes.

- 1. Stage Gate Reviews**
- 2. Communication**
- 3. Dedicated Project Team**
- 4. Risk Assessment & Mitigation**
- 5. Change Control**

### 1. Stage Gate Reviews

At the end of each stage of development a stage gate review is conducted. This review is an opportunity to ensure that the commercial and technical objectives of the project continue to be achieved as agreed. Close co-operation and involvement from both customer and Creganna-Tactx Medical teams are key to the success of these reviews.

#### Benefits:

- Ensures each phase is complete and that the project objectives can still be achieved to schedule with the resources available.
- Both customer and Creganna-Tactx Medical teams have regular opportunities to review and discuss the project in a structured format.
- Objective evidence is presented at each gate, facilitating good decision making.

### 2. Communication

Both internal & external communication is key to the project's success. Internally the Creganna-Tactx Medical Design Team holds weekly meetings to review project progress. Externally, in addition to team customer reviews, frequent scheduled meetings are conducted and recorded as part of the formal project plan.

#### Benefits:

- Efficient flow of information to ensure the project continues to meet the clients ongoing objectives.

- Ensures the project works within and compliments the structure of the customer organisation.
- Frequent transfer of information means that issues can be dealt with as soon as they arise.
- Weekly conference calls ensure that updates are regular and consistent.

### **3. Dedicated Project Team**

For each client project, a dedicated Creganna-Tactx Medical Design project team is assigned. The project team is led by an experienced project manager. This team is given the responsibility and autonomy to ensure a successful outcome for the project.

#### **Benefits:**

- A single project team control the entire project with full responsibility for meeting milestones
- The project team are tasked with the objective of containing the costs of the project
- Each project team consists of a group of experts, ensuring cross-functional expertise
- Consistency for the client from project initiation to completion

### **4. Risk Assessment & Mitigation**

In any given project, risks may arise that are outside of the control of both team members. The key in controlling this is to identify risks before they develop and implement a plan to reduce them. At Creganna-Tactx Medical, all risks that will affect the timely completion of the project, both technical and commercial, are recorded and monitored in a standard format. This is reviewed with the customer on a weekly basis to assess the risk to the project and define the necessary actions needed to mitigate the risks. This will be a live document for the duration of the project.

#### **Benefits:**

- Constant visibility of the project risks leads to fewer 'surprises' later in the project.
- Actively, monitoring and assessing risks enables a proactive response to issues that have the potential to impact the project outcome.
- Information is shared to allow better, more efficient decision making.
- Ensures management of scope creep.
- Team members are encouraged to tell the 'bad news', which is often seen by companies as a failing.

### **5. Change Control**

If during the course of the project significant changes to the product, processes or testing are required, a change request form is completed. Both partners agree to the change and on its consequences. This is only required when there is a significant change to the project, which may affect its overall outcome. Day to day meetings and minor changes or requests are not involved in this system.

#### **Benefits:**

- Monitoring change in this way will allow both parties keep an accurate record of the project development and will help in evaluating the consequences of any decisions taken.
- Effective evaluation of potential changes is critical to ensuring the project goals are achieved and that the other aspects of the project are not compromised by the change.
- Our range of service capabilities span from concept generation to market. Because we offer a fully integrated service, we can advise you at each step. Even if you only require our help in one area of product development, you will still benefit from this knowledge and expertise.