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| 3 Months | |
| Goal: | Actionables/deliverables: |
| Speak with physicians, patients, and insurance. | Questionnaire/survey  Phone calls/zoom  5/stakeholder  Find out about other stakeholders |
| Formulate a clear regulatory path. | Look through FDA website to determine classification under class II- 510K claim.  Find out equivalent license.  Determine intended use.  Speak to regulatory official. |
| IP | Address the comments from the lawyers on our provisional patent.  Add additional information.  Send draft back to our lawyers for a second revision. |
| Funding alternatives.  Submit Merck grant. | Investigate funding sources.  Fill out form. |

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| **6 Months** | |
| Complete and submit SBIR and DARPA grants. | Work with grant specialist to complete and submit grant. |
| Demonstrate product concept (productization, **requirements and specs**). | Model our product either using software or show a real-life non-working prototype.  Clearly state intended use and ensure that design fits intended use. |
| Business and go to market plan. | Talk to stakeholders to get an idea of the distribution channels, manufacturing, pricing, cost of manufacture, QMS system, etc. |