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| **Execution Plan Pillar** | **Question / Consideration** | **Input / Response** |
| 1. **Clinical Trial Protocol** | | |
| What are the anticipated / potential changes to the current clinical practice in the therapeutic area ***during the clinical trial execution period*?** | |  |
| New devices, procedural techniques? Describe | |  |
| Potential impact to ability to execute clinical protocol? Describe – i.e., decreased enrollment, diminishing relevance, etc. **Subjective and Qualitative** | |  |
| Potential Mitigation Steps? Describe | |  |
| What **Tailwinds** exist today that should be *capitalized on* and will drive execution momentum? | |  |
| What **Headwinds** exist today and are anticipated during the clinical trial period that *potentially / will impact* clinical trial execution? | |  |
| Trial Site Start-up/Onboarding | |  |
| Enrollment:  Y1  Y2  Y3  Beyond | |  |
| **Trial Fatigue**- Potential actions to *mitigate* trial fatigue?  Note: Cross-reference **III. Stakeholder Engagement Plan** | |  |
|  | | |
| **Trial Design** – Can **Virtual Telehealth / e-Medicine** be incorporated into the trial protocol visit / assessment schedule?  **Y/N**  *How and with what considerations?* | |  |
| Any additional **considerations / opportunities** for less burdensome trial design elements and/or processes/procedures? | |  |
| 1. **Performance Metrics** | | |
| Forecasting Plan – Enrollment and Site Activation  Refer to Exemplary Templates | | (Repeat per quarter) |
| Enrollment Trending and forward looking calculated forecast - examples | |  |
| **Considerations:**  Solicit and validation assumptions from each site (inputs into Site Specific Performance Plan) | |  |
| Time to Sites Activation (for timing of accruing Trial Site contributions) | |  |
| Volume of Relevant procedures | |  |
| What are the Tailwinds at the local Trial Site? | |  |
| Headwinds at local Trial Site? | |  |
| What are known/anticipated impact periods during enrollment phase?  Known/anticipated seasonal impact (List)  Quantify/estimate impact – local Trial Site impact and overall Trial Progress | |  |

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| **Key Stakeholder / Partner Engagement** | |
| Identify Key Stakeholders critical to execution of the clinical trial   * Internal (Cross functional) * Field-based Partners – identify specific role in supporting / executing the clinical trial |  |
| Targeted Communication – Opportunities and Key Content |  |
| Milestones and Performance Goals |
| Stakeholders – including Trial Site Investigators & Research Team |
| Frequency / Cadence (Define) |
| Method (Webinar/Live Touchbase/Written/Electronic Updates |
| Engagement Roadshows/In person visits |
| Other (describe) |  |
|  | |