

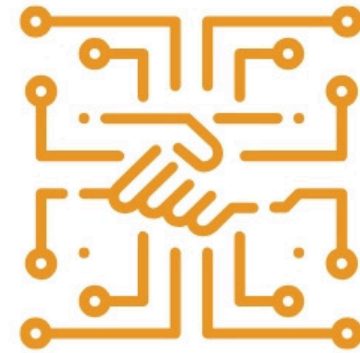
SCRS Digital Innovation Initiative

Connected Devices Workstream Meeting



For the Call Today...

- **Work Recap**
 - Guidance
 - Consideration
 - Discussion Points
- **Deliverables Continuation**
 - Discussion points and positions
 - Team Sessions - Design



SCRS
Digital
Innovation



Last Meeting

- Guidance and Recommendations Discussion

- Guidance and considerations

- Linear trial flow
 - Interoperability of technology
 - Based on Data flow

- Discussion Points

- Technical Support
 - Data ownership
 - Storage and backup
 - Subject training



Last Meeting

- **Visualization**

- Focus on images to support key messages
- Divergent paths



Guidance Discussion recap

- Standards and best practices
- Things to avoid and recommendations
- As a fully integrated tool
- Where is data going
 - Personal Information
- Being flexible
- The Package that is provided – how to interpret it and use it
- Where to allocate resources



Guidance Discussion Recap

- Data Flow Map
 - One component flows into another
 - Resource considerations at each step
- Incorporation of the Considerations along the way



Discussion Point Recap

- Take what we have done above and put it into discussion points.
 - What should be talked about?
 - What sites should be asking?
 - Clarifications they might need?
- Bring your major experiences
 - Come to the next meeting with these – ask your staff/teams



Considerations Discussion Recap

- How the consent process is affected
- How do we empower patients/how their role changes
- Security of data
- Data flow for empowerment
- Device selection – How
- Costing and understanding this
 - Standard Vs CPT
- Resourcing

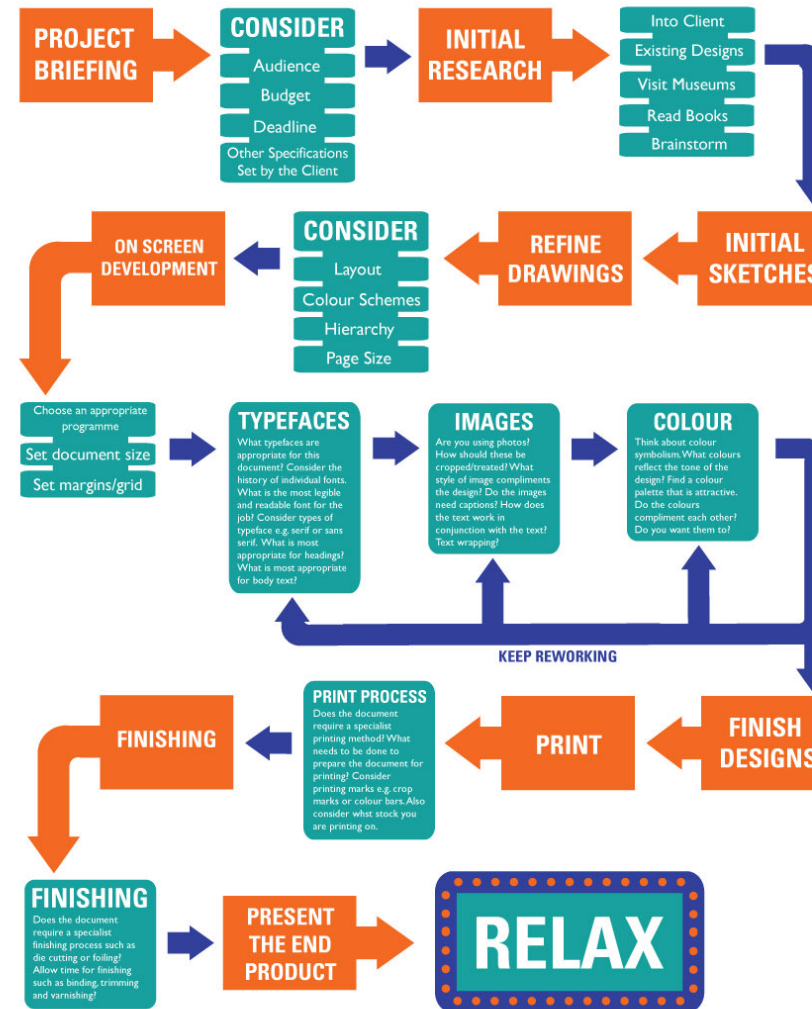


Example Layout

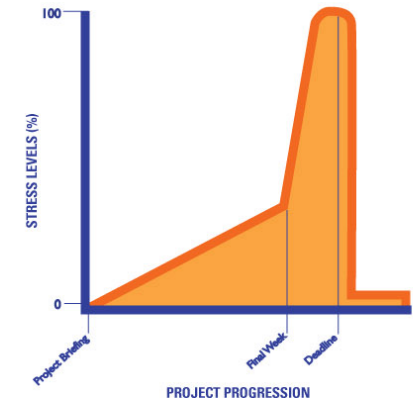
• STEP

- Data Flow
- List of Considerations
 - IE Resources, cost
- Discussion Points

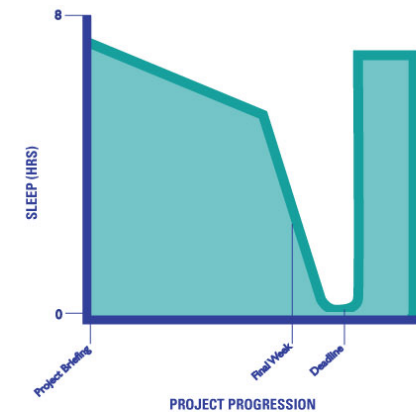
THE GRAPHIC DESIGN PROCESS



EXPECTED STRESS LEVELS THROUGHOUT PROJECT



EXPECTED HOURS SLEEP THROUGHOUT PROJECT



Group Work?

- Divide and Conquer various components
 - How should we divide in breakout groups?
 - Focus on building out what we want to have
 - Start with a baseline and a finish
- Stages?
 - Pre-Study, In Study?
- Journeys
 - Patient, Site, Data?



Tools

- What tools do we want?
 - Tangible resources that they can take from this?
 - Where are these tools used?
- Examples
 - Process checklists
 - Discussion points Guide



Project Work Progress

- Phase 1 – Definitions and Scope



- Settle on terms to define, where to find definitions

- Establish Scope and purpose of publication

- ➔ Phase 2 – Recommendations

- What sites need to do to be prepared for Connected Devices
 - Staffing, Finance, Operations, Technology

- Phase 3 – Recommendations Tool

- Checklist/reference guide

- Phase 4 – Resources Available



Recap and Next Steps

- Summarize the work done today, continue
- Break into groups at the next meeting
 - Focusing on divisions as we discussed today



Thank you

Connected Devices Workstream Meeting

