

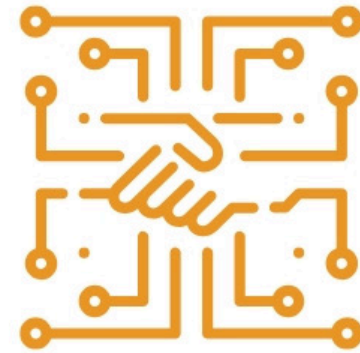
SCRS Digital Innovation Initiative

Connected Devices Workstream Meeting



For the Call Today...

- Deliverables Work Recap
 - Guidance
 - Consideration
 - Discussion Points
- Survey Data Review
- Next Work – Post Summit
 - Divide into groups
 - Content Development forward



SCRS
Digital
Innovation



Last Meeting

- Recommendations discussion
 - Guidance
 - Considerations for connected devices
 - Began Discussion points



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



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
- GDPR and like concerns

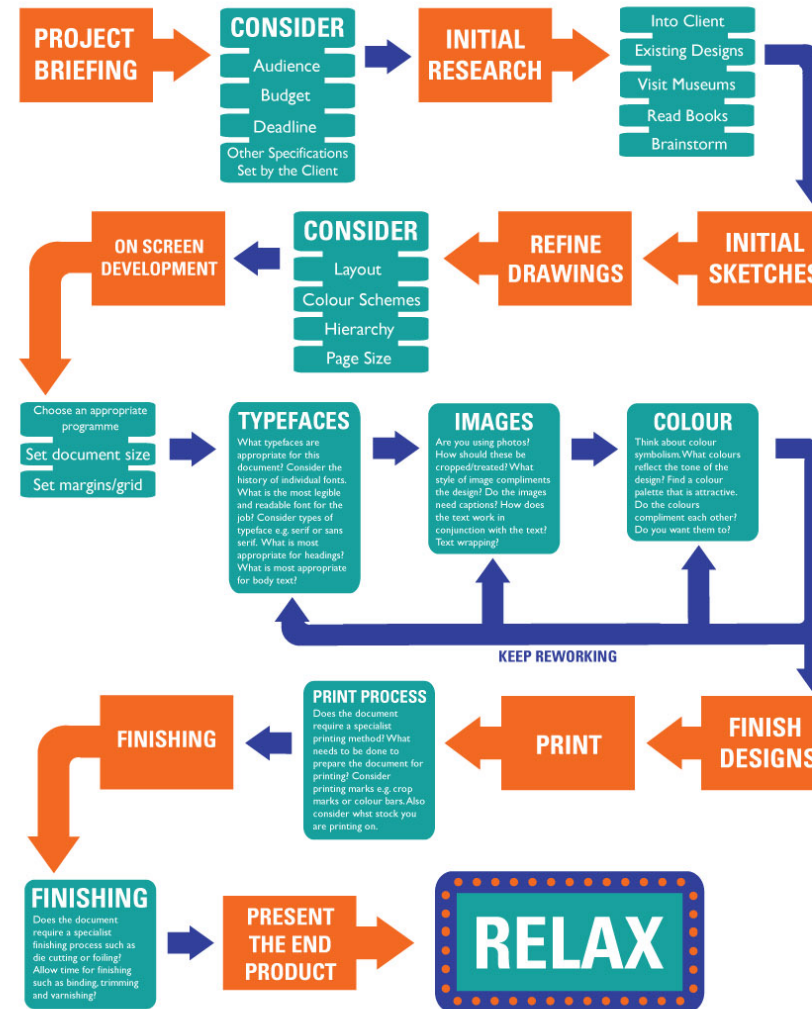


Example Layout

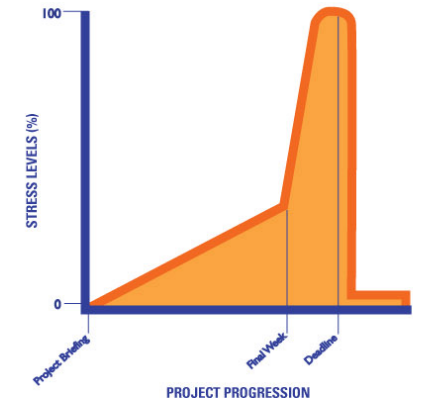
• STEP

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

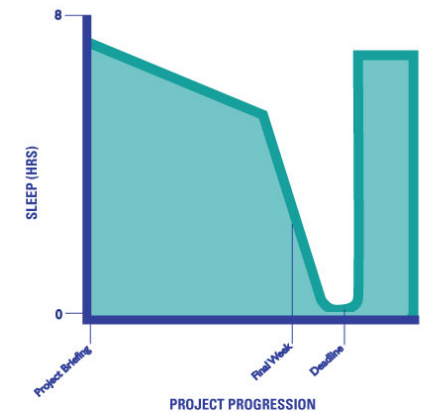
THE GRAPHIC DESIGN PROCESS



EXPECTED STRESS LEVELS THROUGHOUT PROJECT



EXPECTED HOURS SLEEP THROUGHOUT PROJECT

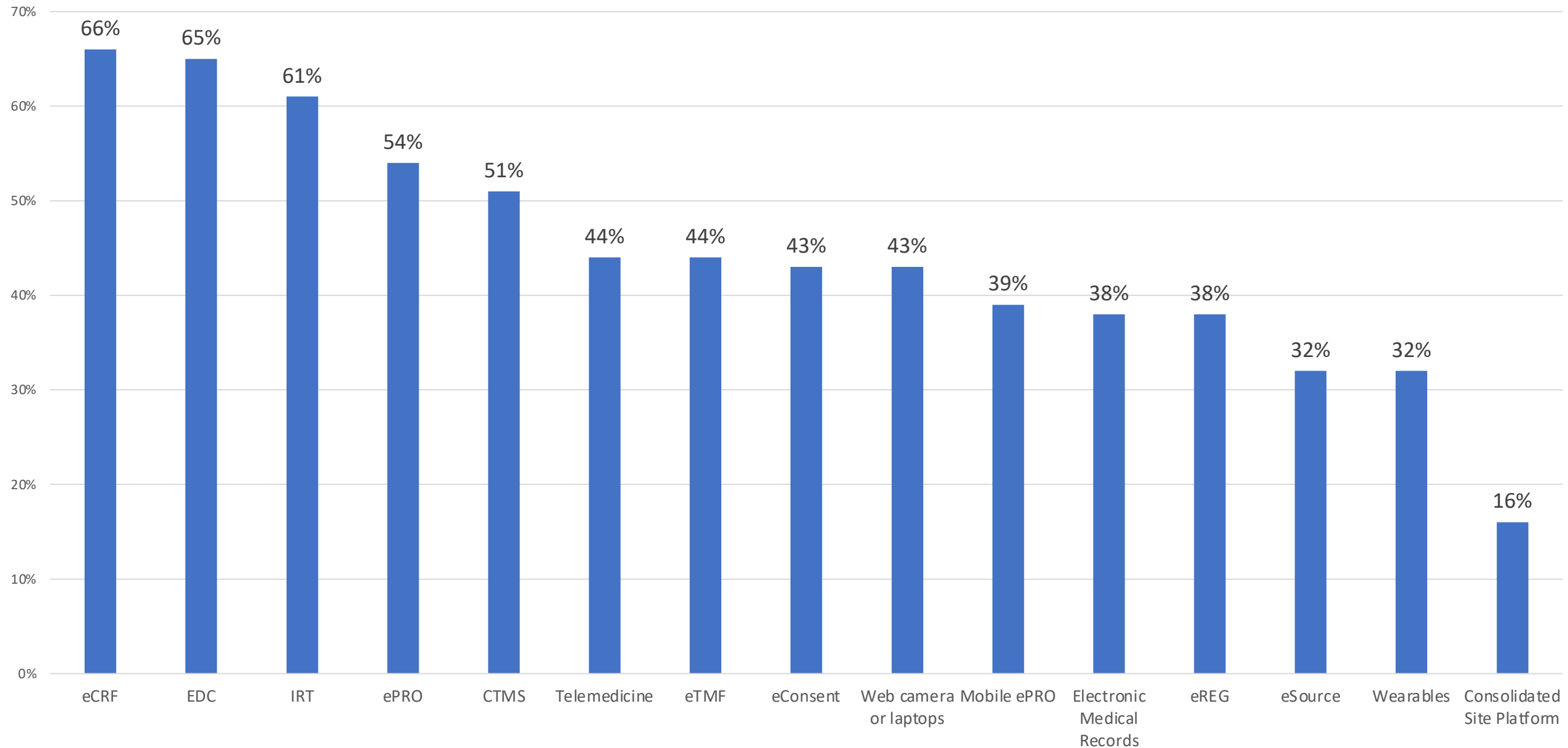


Discussion Point Recap

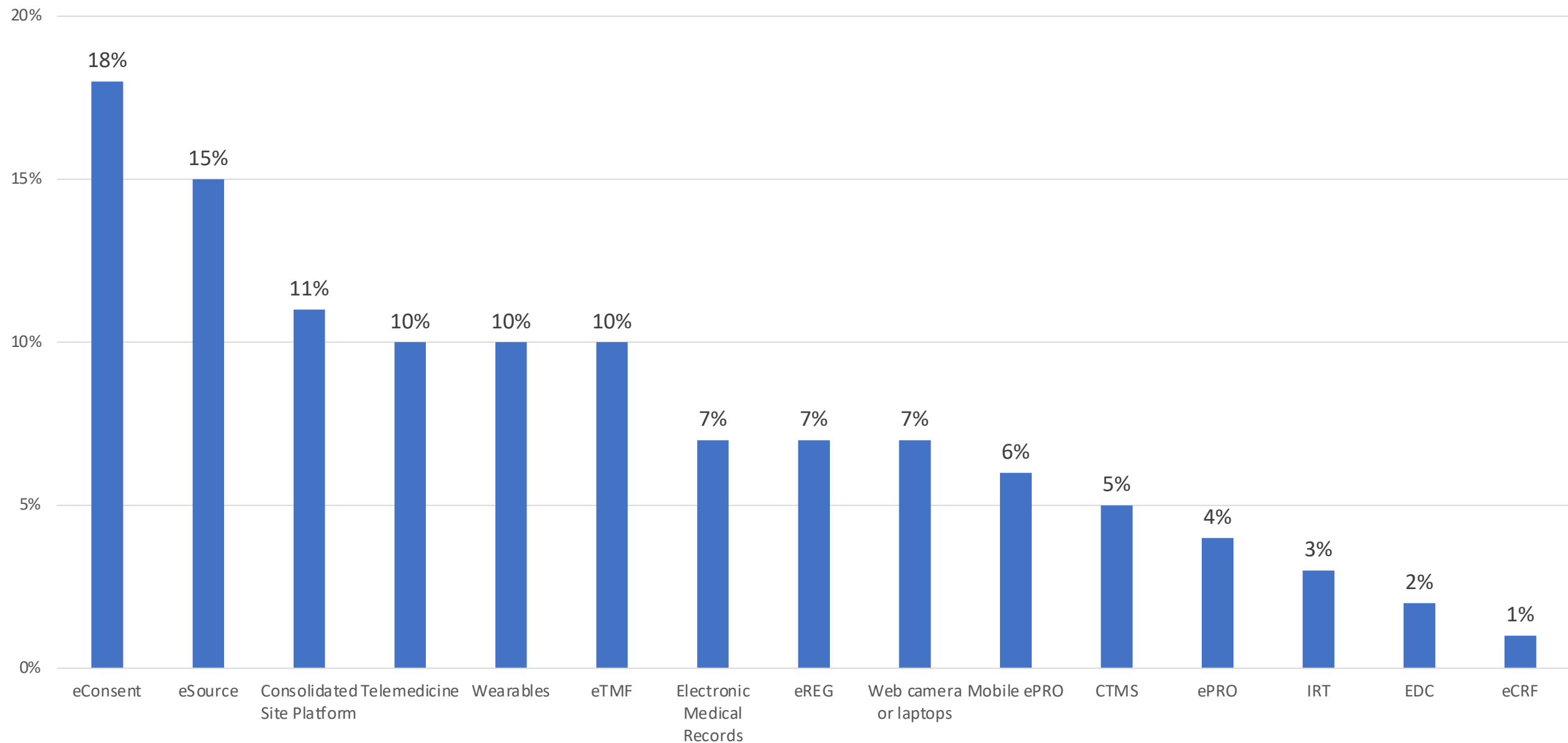
- Touch points between site and patient, site and sponsor/CRO
 - What those touchpoints look like
- Training Points
- Localization, GDPR, and other regulations
- Data consumption
- Hardware validation
- Costs and risks
- Support model



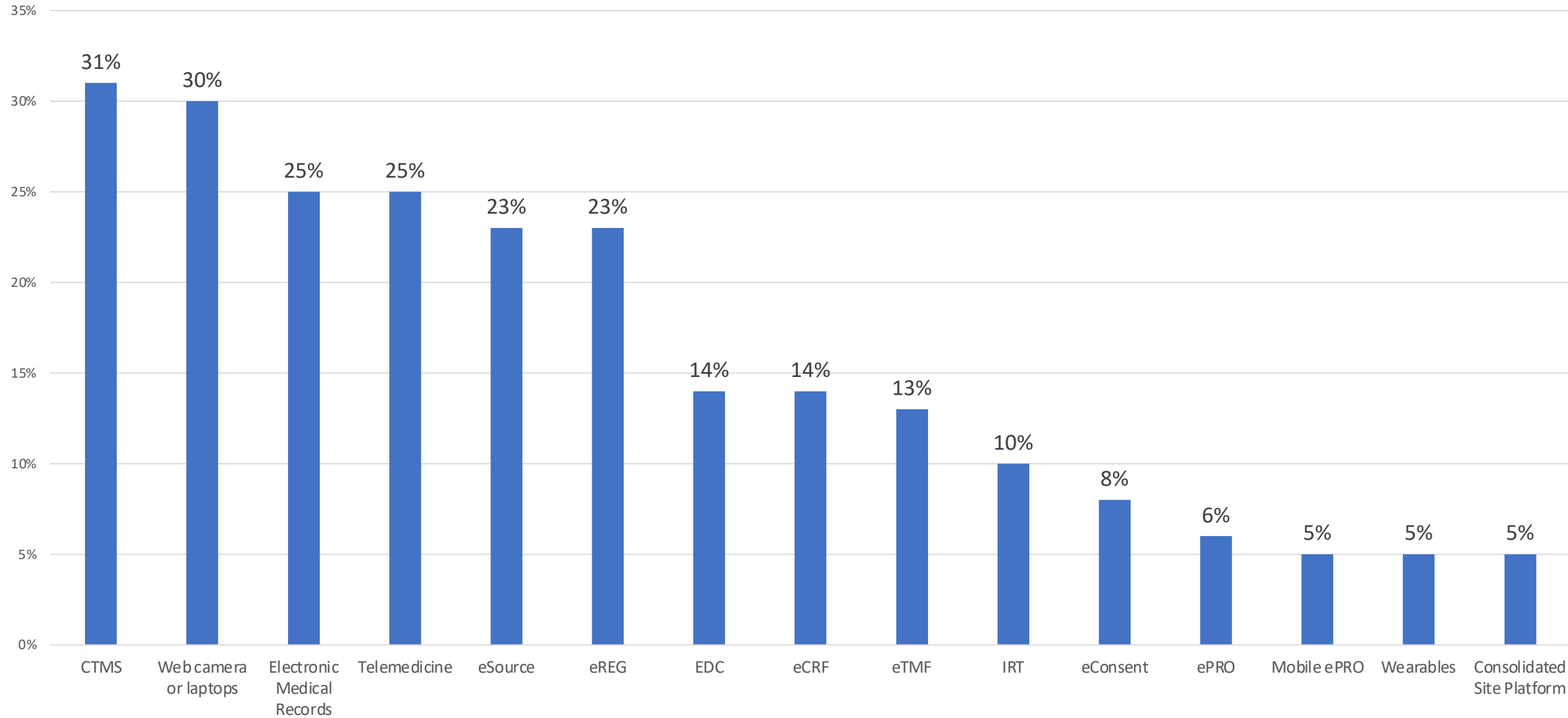
Which of the following technologies are you currently using, or have used, at your site? Select all that apply.



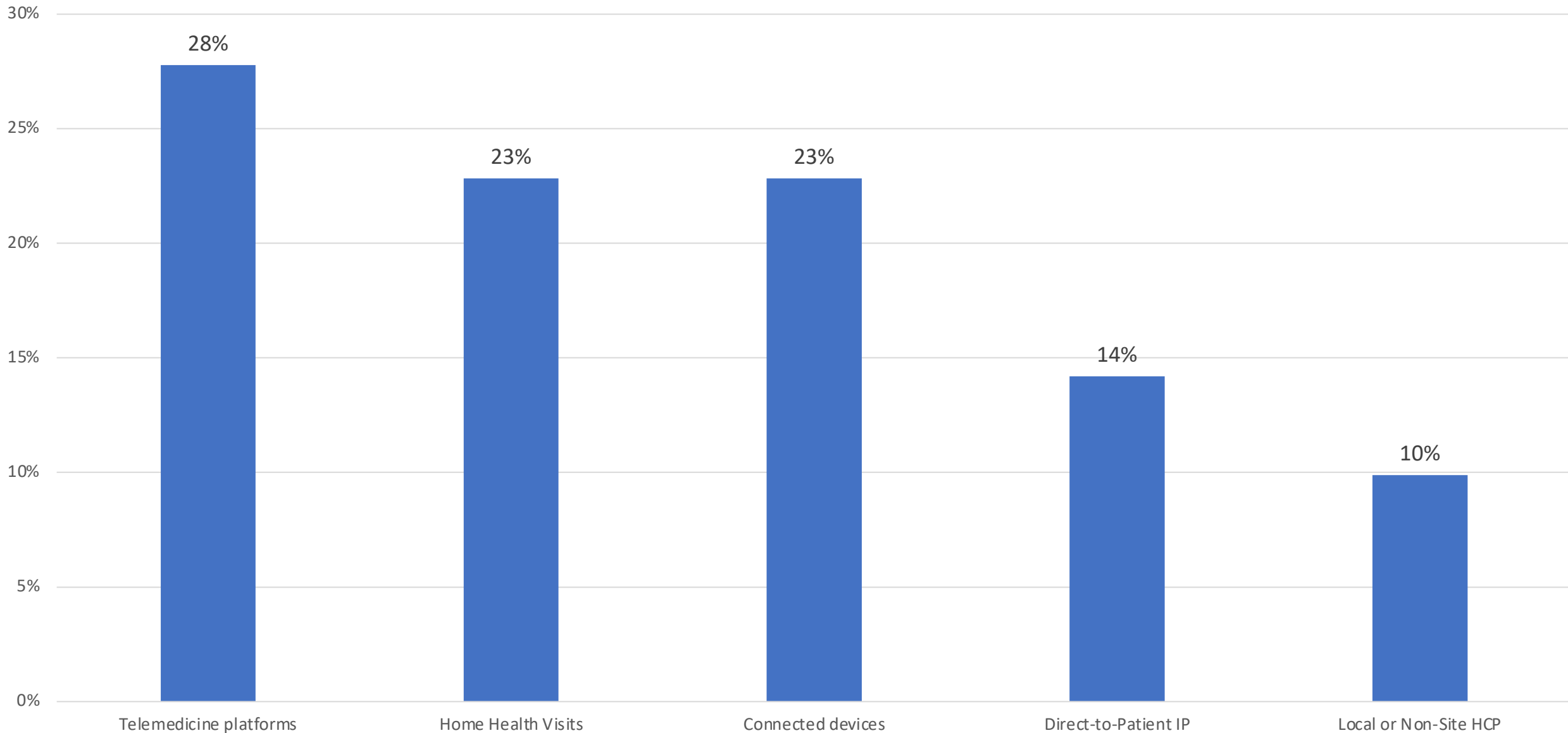
Which of the following technologies are you NOT using, that you intend to implement at your site? Select all that apply.



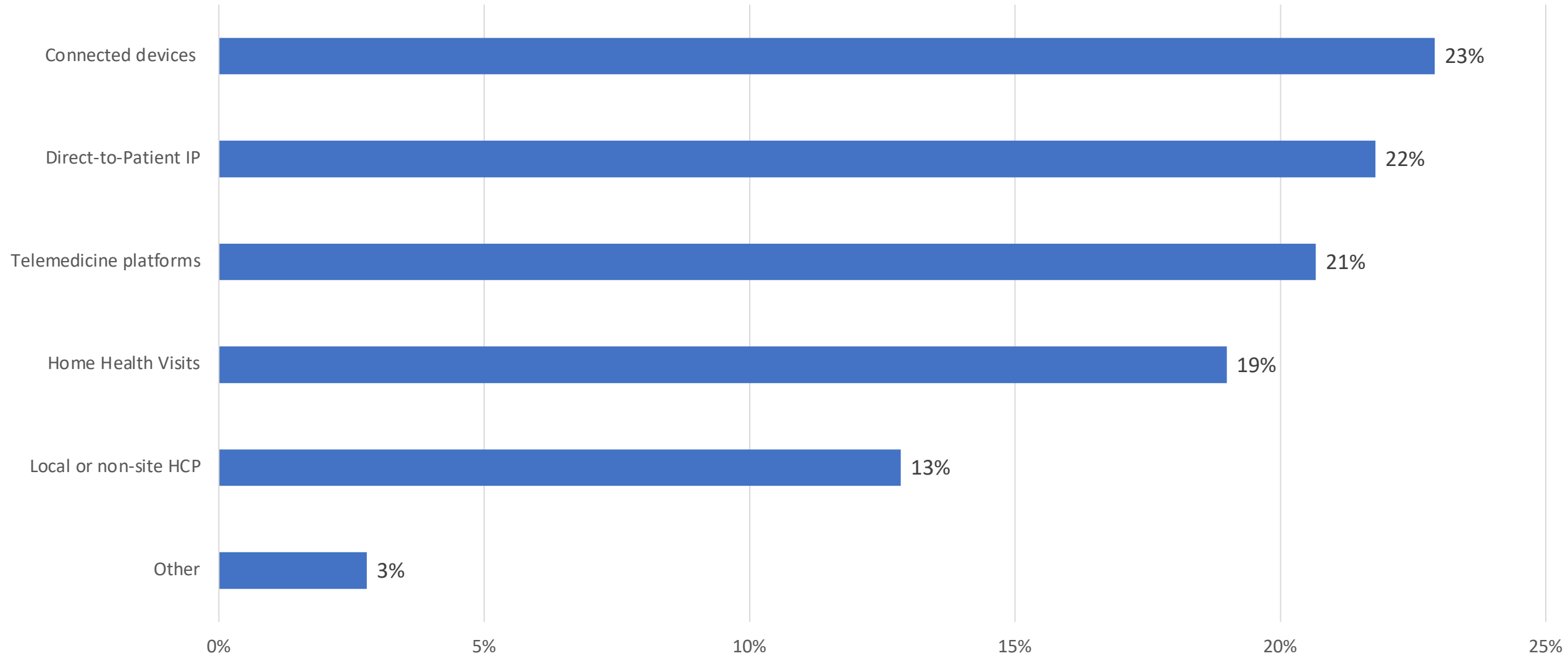
Which of the following technologies has your site invested in or adopted organizationally? This would be opposed to using just what a Sponsor or CRO requires. Select all that apply.



Which of the following elements or components of a decentralized trial are you willing or planning to utilize at your site? Select all that apply



Which of the following elements or components of a decentralized trial are you currently able to or have utilized at your site?



What role could SCRS play with regards to virtual / decentralized and hybrid trials that would have the greatest impact for your company? (Rank the top 3)

1. Provide Education to industry on how to include sites
2. Be a resource for sponsors looking for PI's to oversee/participate in Hybrid DCTs
3. Develop Feasibility tools for these types of trials
4. Develop best practices for sites pertaining to these types of trials

Group Work – Next Meeting

- Google Doc to start things off – get ideas
 - Goals for sites
 - What they need to understand
- Personas, incorporating the stages of the trial
 - Patient and Site groups
 - Weave in needs of the Sponsors, CROs



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 it as needed
- Move into group work to finalize



Thank you

Connected Devices Workstream Meeting

