|  | **Site PI workload***Consider chart review, queries, follow-up, safety reporting (AEs)* | **Site RA screening** | **Site RA enrolment workload** | **Site RA data entry workload** | **Site RA safety screening and reporting workload** | **Data monitoring workload**Consider frequency,% of cases, who is needed  | **Site RA follow-up workload** | **Anticipated patient volume***(may be different for RA and PI***)** | **Clinician workload (nurses and doctors)***How much will the study impact on clinicians working in the ED?* | **Clinician education workload***Consider which staff need education (Nursing? Medical? ED only? Inpatient units?)* |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Minimal | <5 minutes per patient | Minimal screening load<30 min per day | <5 minutes per patient | <15 minutes per patient | N/A  | Minimal  | <15 minutes per patient | <1 per week | No direct clinician involvement | No direct education as no clinician involvement |
| Low | 5-15 minutes per patientMinimal safety risk | Minimal screening load30-60 min per day | 5-15 minutes per patient | 15-30 minutes per patient | Only required when safety concern reported | <20% of patientsand/or<50% of data points | 15-30 minutes per patient | 1-7 per week | Clinician screens and identifies potential patients for research staff | Education for clinicians who screen / identify patient onlyEducation for non-ED/inpatient clinicians FYI only |
| Moderate | 15-30 minutes per patientModerate safety risk | Moderate screening load1-3 h per day | 15-30 minutes per patient | 30-60 minutes per patient | Reviewing every patient enrolled at multiple time points and as safety concern reported | 20-50% of patientsand/or>50% of data points | 30-60 minutes per patient | 1-3 per day | Clinicianfills in brief CRF  and/orenrols (without needing to do consent) | Education for clinicians who complete CRFs and/or enrol *without* written consentEducation for non-ED/inpatient clinicians to adhere to study protocol (e.g. PROMPT fluid arm) |
| High | 30+ minutes per patientHigh safety risk (or high risk population) | Large screening load4+ h per day / constant RA presence required | 30+ minutes per patient | 60+ minutes per patient | Reviewing every patient enrolled at multiple time points and as safety concern reported, plus liaising with Data Safety Monitoring committee / ethics | >50% of patientsand/orAll data points | 60+ minutes per patient  | >3 per day | Clinician fills in long CRF Clinician obtains informed consent and enrols | Education for all clinicians who complete CRFs, *obtain* informed written consent and enrol |

This tool is designed to be used to estimate study workload. However, systems and processes differ between hospitals.

Shading / highlighting indicates an estimate of workload from the lead study site **[insert site name]**.

Please make an assessment of work at your site using this as a guide