STUDY INTENSITY TOOL (SIT) V14:

Frequently Asked Questions

1) **How do I access training?**
   Training is accessed via UKCRF Network Website:
   https://www.ukcrfnetwork.co.uk/training-opportunities/study-intensity-tool/

2) **What format is the training?**

   Training is accessible in pre-recorded webinar format. There is short presentation summerising the changes with V14, this is aimed at existing users. There is a longer presentation for new users or those who would prefer a more detailed training update.

   There is also monthly live Q&A and demonstration sessions which are accessible via Microsoft Teams. These dates will be publicised on the UKCRF Network Website: https://www.ukcrfnetwork.co.uk/training-opportunities/study-intensity-tool/ and via email updates from the UKCRF Network Operations Team.

   There will be a number of short 'bitesize' video demonstrations available on the SIT webpage. These will be uploaded in response to queries and feedback from the monthly Q&A sessions.

   You can access the training as often as you require.

   There are also additional learning materials available on the website which includes a Study Intensity Tool V14.0 Summary of Changes document.

3) **How do I sign up to attend a live Q&A session?**

   We recommend that you watch the online pre-recorded training and read this FAQ document in advance of attending a Q&A and demonstration session.

   The sessions are open access with the dates published on the SIT webpage https://www.ukcrfnetwork.co.uk/training-opportunities/study-intensity-tool/

You can request the meeting invites using the request form on the website, or by contact your CRF Manager. Non-CRF staff are also welcome. These sessions may be recorded for training purposes.

4) **Where can I download the SIT and supporting documents?**

The documents can be downloaded from the UKCRF Network website, https://www.ukcrfnetwork.co.uk/training-opportunities/study-intensity-tool/

5) What do I need to do before I start to complete the SIT?

Complete SIT Training, have access to excel programme on laptop/ PC / tablet, most recent protocol, recruitment target, study duration figure and information on recruitment strategy for the study.

6) What if I don't know the start date for the study?

A start date is not required for the tool to work correctly.

7) How do I record the study duration in V14?

In V14, add the overall study duration in years and months on the summary page in cells C9 and D9 (Cell E9 will automatically decimalise).

You then add the duration of the page activity on the individual pages (1-5 & admin).

The page will then give you calculations specific to that page activity whereas the summary page will calculate on the entire study duration.

8) When do I start to complete the SIT for individual studies?

Many people find it useful to complete a provisional intensity calculation at feasibility. We advise that you start to use the tool as soon as you have completed your training.

9) Do all team members need to be trained on the SIT?

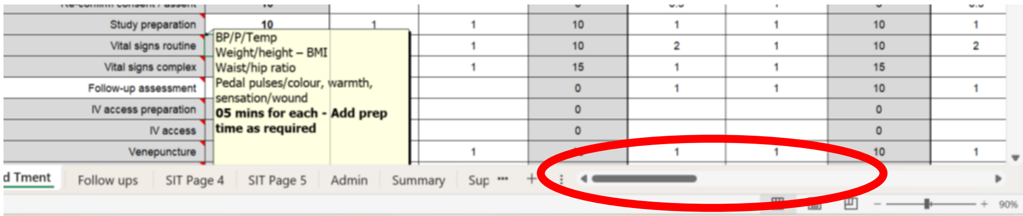
That is a decision that is specific to your team members and their role within the team. We recommend that clinical staff members confirm the timings / procedures for clinical activities.

10) **The data in the cell is showing as #####?**

If this happens, it means the font or zoom is too small, increasing the percentage of the zoom may resolve the issue. Users can also make the row height larger.

11) I can't see the guidance comments in the 'procedures' column?

This can happen in 'fixed screen' view, to see the comments fully – scroll the bottom bar along to the left-hand side of the screen. You will now be able to see the guidance comments. See screenshot below:



12) Why do we need to complete a SIT calculation?

NIHR funded infrastructures (e.g. CRF / BRC) need to include an average intensity calculation for each study in the metrics / annual reports submitted to NIHR. Completing the training will help ensure that the calculations are accurate.

The Intensity Calculations including Whole Time Equivalent (WTE) will also support work force planning for your teams.

13) I have a study which does not stop recruiting until we meet the target - what if I don't know how long recruitment is for?

Consider using one page to calculate recruitment activities for 12 months and the other pages for screening / study visits. The protocol driven activities are unlikely to change (unless you under or over recruit or there are protocol amendments which alter study visit schedule) and you can then update the recruitment calculation as target and timeline changes. It would be advisable to make it clear that the recruitment calculations are based on 12-month (rolling) period.

14) What if I have a complex oncology study where treatment is administered until there is disease progression or unacceptable toxicities?

Consider calculating treatment activities for a 12-month (rolling) period per patient. You may need to use different pages for different arms of the study. Using one page for recruitment, another for treatment and another for long term follow-up can help you accurately assess staffing requirements for each stage of the study. It would be advisable to make it clear that the treatment calculations are based on 12-month (rolling) period.

15) What if I don't agree with the 'suggested' timings on the spreadsheet?

Use your experience and the specific demands of the protocol and knowledge of the patient group to guide your timings.

If you predict that an activity will take longer than the suggested time and the data in the 'Procedure (Mins)' cell is protected (coloured grey) you can amend the timing of the activity by increasing the 'number per visit' and checking that the 'Study Time (mins) per visit(s) e.g. F53 reflects your amended timing.

16) What if I don't know how long things will take to complete?

Speak to your colleagues who have worked on similar studies or who are experienced in the specific procedure, refer to the IRAS form, speak to the Sponsor, PI and R&D costings team (who may have this information from previous studies).

You can always ask to speak with other sites already running the study.

Remember that the intensity calculation should be updated once the patient activity has commenced.

The actual timings might differ from the predicted (provisional) calculations. You can also refer to NCVR costing completed by the lead site for commercial studies.

***17)* What do I estimate as length of the study if it is not stipulated or is a rolling design?**

Consider calculating it on a 12-month duration and review it annually or as recruitment activity changes.

18) Can the comments be removed if tasks are overwritten?

No, the red triangles within the cell and the comments are protected and cannot be removed. You can add a comment to any of the 'white' cells.

***19)* Where can I add comments?**

Comments can be added in column 'S' on pages 1-5, or you can add a comment to a specific cell by 'right clicking' on a cell and selecting 'new comment'. You can then add your comment and click on the green arrow underneath the comment to post it to the cell. A purple triangle within the cell will indicate that the user has entered a comment.

***20)* Are there validated timings for the admin page?**

The timings have been updated with support from research project management staff from other CRFs and some activities mirror NCVR costings.

These activities can be adjusted by the user according to the size and complexity of the study.

All of the admin role activities have been standardised and these calculations are now automatically included in the summary page.

21) **Can we add in more lines?**

Additional lines cannot be added, the format is protected to ensure the tool functions correctly.

22) Will this link to the costing template?

It complements the costing template but does not link to it or replace it.

23) What happens if there are more than 5 visits?

Version 14 has 5 pages (each page has 5 visit type columns), you can have up to 25 different visit types in one workbook and can link include similar visits (e.g. standard follow-up) into one type of visit.

24) What happens if the study has more than one arm or has more than 5 arms?

There are now 5 pages per workbook, you can use one arm per page or group similar arms together on one page.

25) What happens if I get it wrong?

It's ok! Just review the information you have entered and compare it to the protocol driven activities, study duration and participant target. You can either amend the data you have entered or (if you prefer) start again with a fresh spreadsheet.

26) Can someone check my work?

The Intensity Workgroup host monthly 'live Q&A sessions' which you can join and discuss your query. Due to confidentiality agreements with the Study Sponsor, we may not be able to check your work against the specific protocol but one of the workgroup may be able to have a telephone call with you to address any queries you might have. Please direct any queries to :studyintensitytool@nihr.ac.uk

27) What happens if I can't get the information which is needed to complete the SIT?

The intensity calculation will be inaccurate, but you can update the SIT when you have more information available.

Make sure your team are aware if the SIT is incomplete or information is outstanding.

28) Can I use page 2 for patients crossing over into extension studies if they have a separate protocol?

Extension or 'cross-over' studies with a separate protocol should be set-up as a new study and have a new intensity calculation completed specific to the new protocol.

29) Can you change the banding of the nurse / staff member for costing purposes?

You can alter the cost per hour (inc overheads) for the specific grade of staff that will be undertaking activities. You need to ensure that the activities allocated to the corresponding nursing / MDT section of the tool corresponds with the staff details included in the costing section. (E.g. band 6 nurse included in the main nursing section and band 5 nurse activities added to MDT1 with band 6 costs per hour added to nurse 1 and band 5 nurse added to MDT1 costs).

30) Why isn't there a 'master intensity' completed by the lead site for multi-site studies?

This is because each site will work slightly differently, the team roles may differ. Some sites may be participating in sub studies / different cohorts / treatment arms. The timings for protocol driven activities would be similar - it might be a helpful to check timings with other sites.

The calculation should reflect the specific activities conducted by your team at your site. However, there is nothing to prevent you from sharing your SIT with another site delivering that study.

31) Is SAE reporting a study specific procedure?

This is usually recorded in the 'Follow-up Assessment' cell.

32) Where can I add time for monitoring visits?

If you have a monitoring plan confirmed e.g. 1 day of monitoring every 8 weeks, you can add the (expected) total amount of time spent with the monitor on the admin page, or as a 'other study specific activity' (row 76).

Alternatively, a few minutes can be added to each visit in row 59 'Indirect Nursing Care'. Remember – do not duplicate time for monitoring as this will make your SIT inaccurate.

33) How often should I revise my SIT calculations?

We advise that the SIT is reviewed once the study is actively recruiting, when recruitment is extended or closed, or when there is an amendment that changes the duration or delivery of the study.

34) How can the SIT reflect fluctuation in study activity? Recruitment and treatment is more intensive then longer term follow up.

Using one page to calculate recruitment, another to calculate treatment and another to calculate long term follow up will show how you will need more staff during recruitment and treatment period and less staff when the patients enter the long-term follow up stage.

35) What are the intensity calculation levels 1-6?

Intensity Level (Numerical)	***Duration of visit***	***Intensity Level (Descriptive)***
1	*Visit less than 1 hour*	*Low*
2	*Visit at least 1 hours but <1.6hrs*	*Low*
3	*Visit ≥1.6hrs but <3.6hrs*	*Medium*
4	*Visit ≥ 3.6hrs but <5.6*	*Medium*
5	*Visit ≥ 5.6 but <10hrs*	*High*
6	*Visit ≥10hrs or more*	*High*

36) What is WTE?

WTE means 'Whole Time Equivalent'.

You may see this abbreviated elsewhere as 'FTE' – Full Time Equivalent.

A WTE is a unit of measurement that is used to indicate the workload of a person or staffing requirements for a project. It is calculated by dividing the number of required hours for the role / project by the WTE (37.5hrs).

The SIT calculates 1.0 WTE on Agenda for Change contracts = 1560hrs per year / 37.5 hours per week. This allows for 8 weeks annual leave, average NHS sickness absence percentage, training time and other types of leave.

On the SIT summary page, the 'Study WTE' calculation is the total staffing requirement for the entire duration of the study across pages 1-5.

The WTE/A (whole time equivalent per annum) can be used to calculate the annual, monthly (or weekly) staffing needs for a specific duration of the activity included on an SIT page, this figure helps with workforce planning and when trying to identify periods of more intense activity within a study.

37) How do I calculate out of hours costs?

This is an explanation of how to do this for nursing, but the principles are the same for any MDT section.

Ensure that you have included the standard hourly rate in row 31 e.g. £30.56. Then add in the additional cost for out of hours payment (e.g. 25% extra per hour = £38.20).

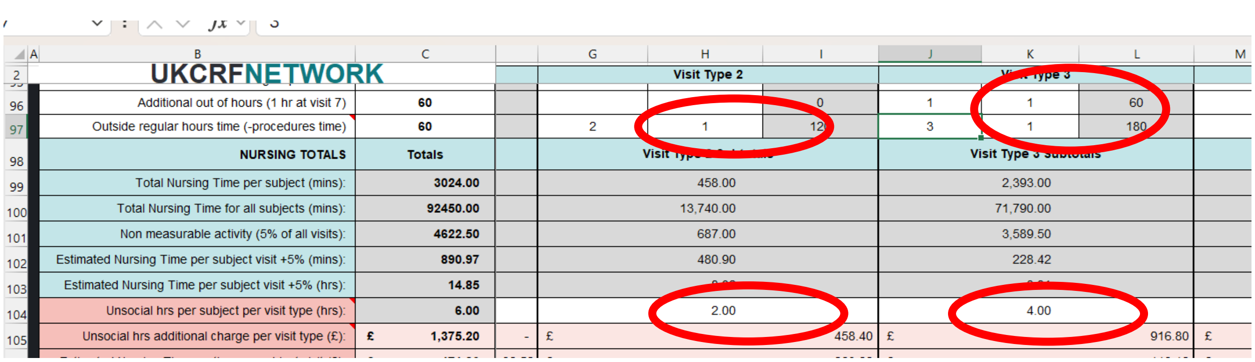
Add your out of hours minutes in row 97, this should not include any out of hours procedure time that you have included in any other cell for that visit type for that staff group (to avoid double counting). Essentially, if you have two nurses in the unit for 4 hours 'out of hours' it is 120 mins x 4. During that time, you do not need to calculate any other activities that are undertaken during that 4-hour period as you have already allowed for 2 staff to be with the patient.

Row 97 will automatically update your basic staff costs and WTE.

To calculate excess costs associated with unsocial hours payment (as per agenda for change contracts) you now need to enter the total amount of hours requiring unsocial hours payment in row 104.

This is the total hours per patient for that visit type.

In the example below, there are 2 hours pp on visit type 2 (Cell G97) and 4-hours pp (1hr in J96 & 3hr in J97) on visit type 3. The SIT will multiply the total hours for unsocial hours payment by the total number of patients within that visit type.



	B	C		G	H	I	J	K	L	M
2	UKCRFNETWORK			Visit Type 2			Visit Type 3			
96	Additional out of hours (1 hr at visit 7)	60				0	1	1	60	
97	Outside regular hours time (-procedures time)	60		2	1	12	3	1	180	
98	NURSING TOTALS	Totals		Visit Type 2 Subtotals			Visit Type 3 Subtotals			
99	Total Nursing Time per subject (mins):	3024.00		458.00			2,393.00			
100	Total Nursing Time for all subjects (mins):	92450.00		13,740.00			71,790.00			
101	Non measurable activity (5% of all visits):	4622.50		687.00			3,589.50			
102	Estimated Nursing Time per subject visit +5% (mins):	890.97		480.90			228.42			
103	Estimated Nursing Time per subject visit +5% (hrs):	14.85		[illegible]			[illegible]			
104	Unsocial hrs per subject per visit type (hrs):	6.00		2.00			4.00			
105	Unsocial hrs additional charge per visit type (£):	£ 1,375.20	-	£ 458.40			£ 916.80			£