

UKCRF NETWORK

Study Intensity Tool v14.0 Summary of changes

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Introduction

Version 14 of the Study Intensity Tool has been developed by the Study Intensity Work Group, incorporating feedback from users.

The visual layout, functionality, and outputs (calculations) have been refined to increase usability and enhance resource and workforce planning. An overview of the changes is provided in this guidance document.

Version 14 has been released prior to the pending upgrade to CRFManager® software. At the time of launch, it is not yet possible to upload a completed V14 SIT directly into CRFManager®. If your site is required to do this, we recommend that you continue to use V13 until the additional CRF Manager work is completed.

Colour Scheme

Version 14 has a significantly different colour scheme. The new colours are aligned with the UKCRF Network branding and have been chosen to enhance accessibility and usability. Each colour now serves a specific purpose, making it easier for you to navigate and use the spreadsheet effectively.

	Dark Grey: Used as borders or dividers to separate tables or sections, with no functional purpose or data.
	White: Allows the user to enter data (except for the header in rows 1 and 2).
	Light Gray: Contains pre-populated procedure data or calculations (not related to costing, WTE, or intensity) that cannot be modified by the user.
	Light Aqua: This cell is a title or heading (not related to costing, WTE, or intensity).
	Yellow: This heading relates to WTE or intensity.
	Light Yellow: This cell calculates WTE or intensity.
	Coral: This heading relates to costing.
	Light Coral: This cell calculates costings.

Integrated Paediatrics and Adult Tool

Version 14 now merges the adult and paediatric versions into one tool. The user can switch between adult and paediatric version by selecting 'Paediatric' or 'Adult' from the drop-down box on pages 1-5 (row 50).

The only difference between the two specialties is the agreed procedure timings (which remain the same as previous V13). This is because some activities (such as measuring vital signs or consent) will take longer in a paediatric participant than for an adult.

Selecting 'Paediatric' in the drop-down box (cell E50, pictured on the next page) will change the relevant procedure times from adult to paediatric (e.g. consent, venesection, vital signs etc.). If using multiple pages (page 1-5), please remember to check that you have the correct version selected on each page and that the 'adult' or 'paediatric' procedures are showing in columns B and C.

Participant classed as recruited at visit number:		Adult or Paediatric?					
		Paediatric					
		Adult					
		Paediatric					
NURSING				Visit Type 2			
Procedures:	Procedure (Mins)	Number per visit	Number of visits	Study Time (mins) per visit(s)	Number per visit	Number of visits	Study Time (mins) per visit(s)
Admission documentation complex	60			0			0
Admission documentation routine	20			0			0
Paediatric informed consent / assent	45			0			0
Paediatric re-confirm consent / assent	30			0			0
Paediatric study preparation	15			0			0
Paediatric vital signs routine	20			0			0

Layout

The table below lists the key elements of the tool, where this information was in version 13, and where it is located in version 14. Previous users of the tool may find it helpful to open V13 and V14 of the tool and do a direct comparison of the changes listed.

Pages 1 to 5:

Section	V13 location	V14 location	Notes
Study and Page Title	C1 and G2	Row 5 and 6 (all pages)	The 'Study' title in row 5 will 'pull through' across all pages. The 'Page' title in row 6 is page specific and will not pull through.
Clinical Trial Summary Trial No: PI:	C2:C37	D9 and D10 (pg 1-5 & admin)	Row 9 now includes a section for you to add general comments on the study or data included.
Study Duration (page specific on V14)	C4	D12 to F12 (pg 1-5 & admin) C9 to E9 (Summary page)	This information is mandatory; the SIT will not calculate without it. V14 requires the duration of the activity to be added in years and months (not decimalised as per v13) and is specific to the duration of activities being recorded on the individual page. Total study duration (from opening to end of study) goes on the summary page (C9/D9).

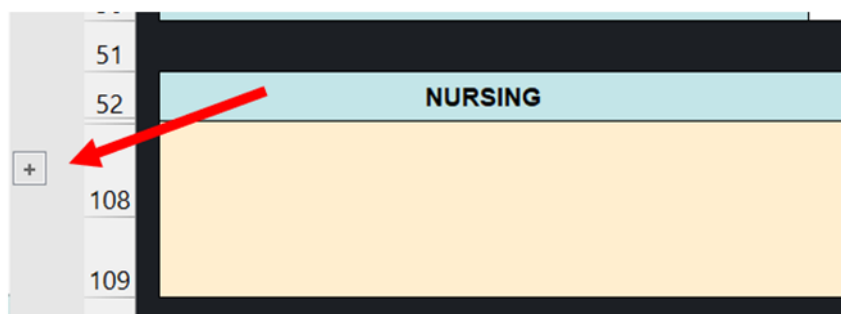
Section	V13 location	V14 location	Notes
Assessed by: Date Assessed: Costing Type:	O277 O278 O279	I12 to I14 (pages 1-5) H11 to H13 (Admin page)	The 'Costing type' wording has now changed to 'SIT calculated at' - enabling the user to give more information on the reason for the SIT calculation or review e.g. feasibility, accuracy check, extension to recruitment etc.
Recruitment Activity	Rows 8 to 12	Rows 16 to 23 (pages 1-5)	Now includes recruitment WTE and WTE per annum.
Set-up and Educational Activity	Was at the bottom of each staff group section, see B74 and C74 for an example	There is now a specific set-up and education section: see rows 25 to 28 (pages 1-5)	Grouping this together enables a more accurate assessment and overview of the time allocated per MDT.
Unsocial hours	At the bottom of each staff group section, see F72 for example	At the bottom of each staff group section, see row 104 for example	How the user enters the number of unsocial hours has changed. See section "calculations explained".
Costing Key	B274 to C282	Rows 30 to 32 (pages 1-5)	Includes out of hours cost for all disciplines
Costing Summary for recruitment and other costs	Part of recruitment Q9 to Q12; Part of each discipline, see D74	Rows 34 to 39 (pages 1-5)	Costs summarised in one table – pulls through from page 1 to all pages.
Study Information	Rows 14 to 19	Rows 41 to 47 (pages 1-5)	Visit type name (free text) is now underneath the descriptor in row 45.
Participant classed as recruited at visit number:	C19	C49 (pages 1-5)	
Procedures lists for Nursing	Started at Row 22	Starts at Row 52 (pages 1-5)	Same as V13, but includes both adult and paediatric procedure choices, with minor changes to suggested procedures and enhanced comments

Section	V13 location	V14 location	Notes
MDT sections			
MDT1:	MDT1 started Row 85	MDT1 starts Row 111	This section has been improved so that summary data for each visit type is clearly labeled and includes unsocial hours in time and costs. Enhanced comments to guide user WTE and total hours are on the far-right side of the summary section.
MDT2:	MDT2 started Row 121	MDT2 starts Row 145	
MDT3:	MDT3 started at Row 152	MDT3 starts at Row 175	
MDT4:	MDT4 started at Row 182	MDT4 starts at Row 204	
Lab:	Lab started at Row 212	Lab starts at Row 233	
Imaging:	Imaging started at Row 244	Imaging starts at Row 267 (pages 1-5)	
Pages 1-5 total WTE	Cell M275	Now included in a 'page summary' section C297 – C308	Enhanced page summary section includes page specific Intensity Rating, WTE and costs.
Pages 1-5 Study Intensity Rating	CELLS I280 – I281		

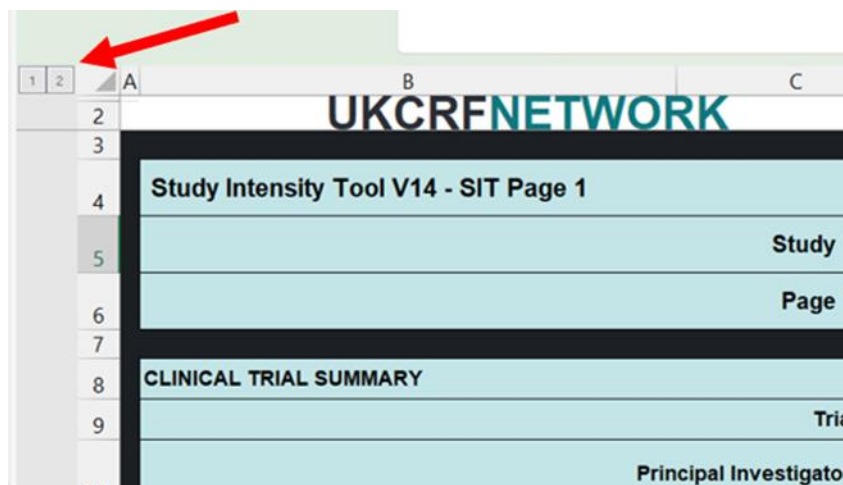
New Features

These will be shown in more detail in the training, but the following features have been added.

- **Minimise disciplines** that are not being used (such as MDT, Labs and Imaging) making it easier to scroll up and down pages 1 to 5. This can be done for each individual section by clicking the '+' (maximise) or '-' (minimise) sign on the left hand of the screen – shown below.



You can minimise or maximise all sections on the page by clicking on the small boxes labelled 1 and 2. These can be found in the top left-hand corner of each page – shown below.



- **Frozen columns A to C**, which means the headings remain in place when you are entering data into Visit Type 5 on pages 1-5.
- **'Visit Type' 1-5 header**, this will now remain at the very top of the screen – even if you scroll down to the bottom of pages 1-5.
- **MDT title sections**, Entering the MDT title into the relevant section (e.g. cell B112, page 1) will 'pull through' that title to the tables at the top of the tool (such as recruitment or costing key) as well as onto the summary page. This enhances consistency with workforce planning and summary page calculations.
- **Aligned data**, makes it easier to find the information you need, for example all Visit Type 1 subtotals are under one another.
- **Duration** for both study duration and recruitment activity can now be submitted as years and months, instead of a decimal (see additional comments in table above).
- **Procedure descriptions and timings** have been reviewed; the lab procedures have been aligned with NCVR guidelines with support from the UKCRF Network Laboratory Managers Group.

Admin Page

- **Admin procedures and timings** have been reviewed; the same activities are listed in each admin staff section for consistency. There are 3 admin and 1 nursing admin sections (four role types in total).
- **Nursing Admin** section has been included and can now be calculated separately to clinical nursing activities. Remember to capture nursing admin activity on either the admin page or on pages 1-5. Entering the same activity in both will 'double count' and cause inaccuracy in calculations.

Summary Page

- **An overall summary** table has been added to the top of the summary page.
- **Page descriptions and MDT titles** are now displayed to support comparisons between pages and disciplines.
- **Admin page** data automatically pulls through to the summary page and is included in overall figures.
- **A WTE comparison table** has been added to compare WTE and WTE per annum values across disciplines and pages.

Calculations Explained

Tool outputs remain consistent with Version 13 and are briefly explained here as a reminder.

- **WTE** is calculated by dividing the total number of minutes by 1560, which is the annual working hours for one full-time NHS staff member after accounting for 8 weeks of annual leave, average NHS sickness percentage, training and other types of leave. This provides a consistent measure of workforce contribution across studies, helping to estimate staffing needs and support resource planning.
- **WTE per annum** takes the WTE and divides it by the page or study duration entered at the top of the page. This provides an annualised measure of workforce effort required.

If the study duration is less than a year, the WTE/A will be higher than the WTE. If the study duration is more than a year, the WTE/A will be less than the WTE. It is a useful measure for workforce planning.

- **Study Intensity Rating:** Study Intensity is calculated using the average number of hours per study visit. The calculation excludes participant numbers, recruitment, and activity on the admin page, ensuring the rating reflects visit-driven workload per visit.
- **Total vs Estimate:**
 - **Totals:** A complete value based on known inputs, used when all visits and procedures are consistent.
 - **Estimate:** Used when procedures or timings may vary between visits. If all procedures are completed equally, the figure is effectively a total, but we label it “estimated” to reflect potential variation and guide interpretation.
- **Unsocial hours:** Please note that two pieces of input data used to calculate unsocial hours have changed from V13 to V14. In this new version:
 - **Cost for out of hours (per hour):** enter the full hourly rate, including both the standard rate and the out of hours enhancement (row 32).
 - **Number of unsocial hours:** enter the total hours per patient for that visit type. For example, if a visit type includes four visits with unsocial hours, enter the combined total hours for all visits. The SIT will then multiply this figure by the number of patients.

The additional cost is then calculated by multiplying the number of unsocial hours by the difference between the out-of-hours rate and the standard hourly rate. This is added to the total to reflect enhanced pay for work outside standard hours.