Cancer Institute NSW

START: SiTe cApability Repository Tool

Quick Reference Guide

Version 1.0 | 10 May 2023

NSW
GOVERNMENT

Contents

1. INTRODUCTION & PURPOSE

Selecting a clinical site is one of the biggest challenges that Sponsors and Clinical Research Organisations (CROs) face during the study start-up process (SSU). Before selecting a site, the Sponsor or CRO performs a detailed feasibility assessment of the site's research capabilities, including past clinical trial experience, staff workload, qualifications and training, patient/participant population, site infrastructure, equipment, and accreditations to determine if the site would be a good fit to participate in the study. Depending upon the Sponsor or CRO, the feasibility assessment can be paper, electronic, or platform-based including cloud-based assessments, or the Shared Investigator Platform (SIP) a TransCelerate initiative.[1] While digital transformation progress has been made as a result of COVID-19, there is no single, uniform format or platform being used, leaving sites with the arduous, repetitive task of populating numerous assessments in several formats.

The feasibility assessment also provides an opportunity for the site to consider the suitability of the study relating to resource, capability, capacity, and alignment with the site's research strategy.

Requests for feasibility assessment completion are often tight requiring a significant collation of information and metrics from various sources.

This tool aims to facilitate feasibility assessments by adopting a proactive, dynamic approach to record and maintain a site's resource, capacity, and capability information. Praxis was commissioned by the Cancer Institute NSW to co-develop The **SiT**e c**A**pability **R**epository **T**ool (START).

The Cancer Institute NSW also acknowledges the contribution of Clinical Trials Unit managers and staff who provided valuable input in the START tool.

2. SCOPE OF START

START is not a clinical trial management system (CTMS), it is a facilitation tool, employing a centralised repository of the site's resources and capabilities, reducing administrative burden, improving workflows, and through shared access, aids efficient and informed decision-making.

NSW Health has secured licenses for four e-platforms; to support the delivery of clinical trials and research within NSW public hospitals The electronic infrastructure is designed to assist the state's clinical trials sector through the reduced administrative burden, increased visibility of clinical trial activity, and improved financial management.

3. NOMENCLATURE

For clarity and readability, START will also be referred to as the tool, and spreadsheet. The spreadsheet comprises of worksheets (tabs) which are called domains.

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[1] https://www.transceleratebiopharmainc.com/initiatives/shared-investigator-platform/

4. IMPLEMENTATION

The use of START is not mandatory. Each site should review its current needs and procedures to establish how START could benefit its SSU processes. START can be implemented as a standalone tool, utilising all, or specific domains depending upon the site's requirements.

The START domains can be employed to collate information, which can then be dovetailed (cut and paste) into elements of the sponsor's feasibility assessment questionnaire. In addition, information can facilitate resource needs and planning, and it provides an opportunity to conduct a 'stock take' of infrastructure, local services, expertise, and processes.

The initial version will require significant administrative input, which can be managed as a project, or delegated and allocated to the research teams. The format of the tool allows it to be shared with other organisational departments, allowing them to review the data or request them to populate their relevant domain.

The tool can also facilitate staff onboarding by highlighting key personnel, processes, and resources at the site. In addition, filtering **Unknown** outcomes (see Section 4) can drive fact-finding discussions and activities.

START is released as Version 1, 10th May 2023. It is a template allowing for the deletion, omission, or addition of domains or elements within each domain reflecting the site's resources and capabilities. Each site should implement its own document naming and version control procedures.

A **responsible person** (owner) should be identified, and their details included on the **Cover Page**.

The tool should be stored in a location that will allow identified users/collaborator access, for example, MS Teams, SharePoint, etc.

START is a 'living' document' with several domains requiring more frequent updates, than others, for example, **Site Personnel** versus **Haematology** Laboratory Services. Several, domains have an independent version control section (see below) which can be populated to indicate the domain's currency.

Version History			
Version #	**Date**	**Amendments**	**Name**
1	12-May-2023	N/A Initial Version	Susie Lee
1.1	15-May-2023	Updated NATA Accreditation - Biochemistry	Susie Lee

A review/update schedule should be implemented at the site, noting that some domains will require frequent amendments, but as a minimum, an annual review of each domain should be actioned and documented.

Excel functionality allows for hiding columns and rows, thereby limiting obsolete information from view, but remaining in the master copy. Additional conditional formatting can be included, i.e., an inactive status, and by employing a filer, limiting visibility.
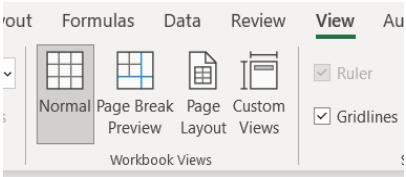
5. START FORMAT

START was developed in Excel to limit the need for advanced formatting and facilitate rapid data entry, retrieval, and filtering to produce top-line information and metrics to aid reporting and decision-making.
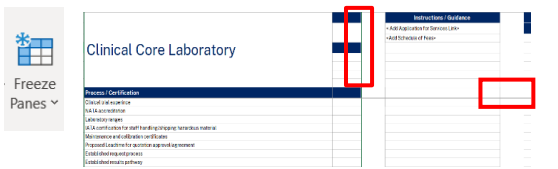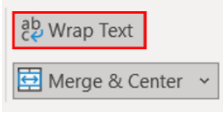
This Quick Reference Guide assumes that START users have pre-existing Excel skills and it will only provide guidance on how to populate, edit and manage the tool, as well as provide troubleshooting tips to address Excel formatting nuances.

5.1   Visual Layout and Navigation

The worksheets have variable quantities of data, requiring one or more pages in the worksheet.

To aid the visualisation and navigation of the spreadsheet and worksheets the guide below highlights the various VIEW formats and highlights the scalability functions.

Normal Page Layout Page Break NB: The worksheet will open in the view format of the previous user. Therefore, the view format may have to be changed to meet your needs.	Three view formats: **Normal, Page Layout,** and **Page Break** located on the bottom right-hand side of the screen. To facilitate visualisation of the contents of the worksheet, the magnification percentage can be increased or decreased.
	Or can access/change via the **VIEW** tab.
	Normal view is the standard visualisation method.
	Page Break are dividers that break a worksheet into separate pages for printing.
	Page Layout is used to describe the group of commands that control how a spreadsheet will appear when printed.
	To change the magnification on several or all worksheets at the same time, select the worksheets (**click and hold shift**) and change the magnification level required.
	To facilitate visualisation, the horizontal scroll bar will scroll the content of a window to the left or right (horizontal). The vertical scroll bar will scroll content vertically.
	The START spreadsheet has several pre-defined worksheets (tabs). They are not all visible on opening. To scroll to visualise the domain (worksheet) names (domains), click on either the right or left arrow to move the scroll bar.

Tip: Grey lines indicate freeze panes: vertical, first column, and horizontal first row.	To enable an area of a worksheet to remain visible while you scroll to another area, go to the **VIEW** tab, and **Freeze Panes** to lock specific columns in place, or **Split Panes** to create separate windows of the same worksheet.
	To contain text within the designated cell, use the **text wrap** function on the **Home tab**. Also, add text to the cell by **ALT and Enter**.

6. WORKSHEETS AND DOMAINS

START is a spreadsheet template, which provides worksheets (tabs) with pre-defined categories (domains) related to the site's resource, capacity, and capability that can be populated, or amended to reflect site-specific requirements.
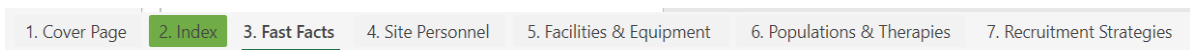
- Cover Page
- Index – coloured green with embedded hyperlinks to facilitate navigation
- Fast Facts – a summary sheet to summarise experience, capabilities, and metrics
- Site Personnel
- Facilities & Equipment
- Populations & Therapies
- Recruitment Pathways & Support Services – Consumers/Committees
- Clinical Laboratory
- Histo & Cyto Pathology
- Research Laboratory
- Medical Imaging
- Pharmacy
- Systems & Platforms
- Source Documents, Monitoring & Audit
- External Vendors
- Current Studies
- Pending Studies
- Completed/Terminated Studies
- HREC & Governance - Contacts & Process
- Budget & Contracts - Contacts & Process
- Satellite Sites - Contacts & Details

7. WORKSHEET FORMAT

Each worksheet has a header with the worksheet name and a location to add the site's name/logo.

Each worksheet has been prepopulated with a comprehensive list of considerations related to the category, but these can be edited, by 'hiding', deleting items, or including additional factors. An example of one section from the Medical Imaging domain is provided below.

In addition, colour-coded drop-down lists (conditional formatting function) have been included to allow for rapid data entry, providing a visual map of status.

Medical Imaging

	Name
	First Name

Imaging Equipment	Capability / Outcome
Digital Radiography	Yes
X-Ray	Yes
MRI: 1.5T	Yes
MRI: 3 T	No
PET	Yes
PET-CT	No
CT-Scan	UKN
Mammography	Yes
Echocardiography	Yes
Ultra-Sound	Yes
DEXA (Bone Scan)	No

Reporting Criteria	Capability / Outcome
RECIST	
RECIST 1.0	
iRECIST	
mod RECIST	
RANO	
Lugano	
LYRIC	

7.1   Formatting Actions

To accommodate the hybrid of text, numeral fields, and drop-down menus, several worksheet formats are required. To facilitate column (and row) formatting the **cell merge** function (below) has been extensively employed in the tool. While useful, adding rows and columns can remove formatting. Section 7.2 provides instructions on how to add a row to retain or reinstate formatting.
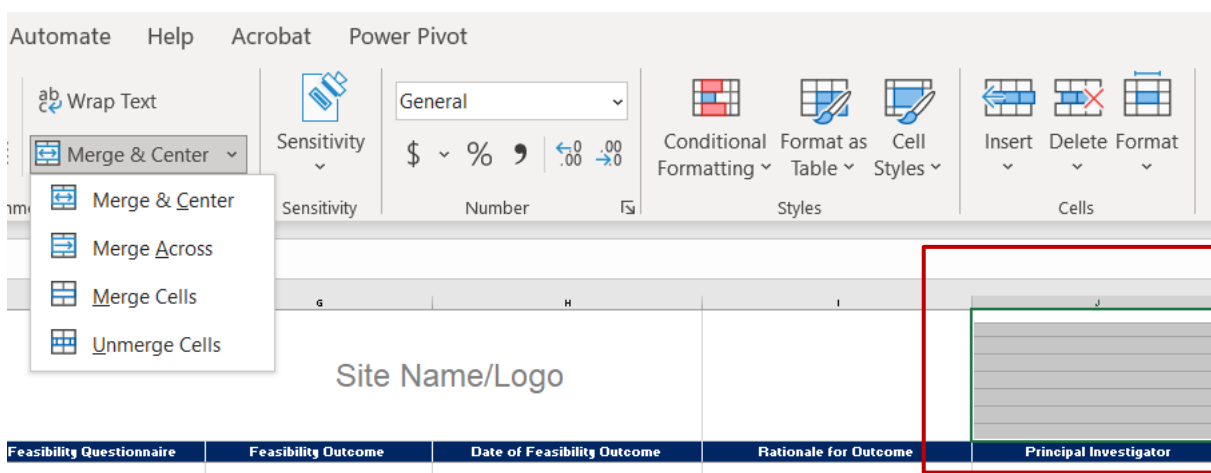
Tip: To copy merged formatting use the **Format Painter** tool, by highlighting the format to be copied, select **Format Painter**, and select the cells that have to merge.
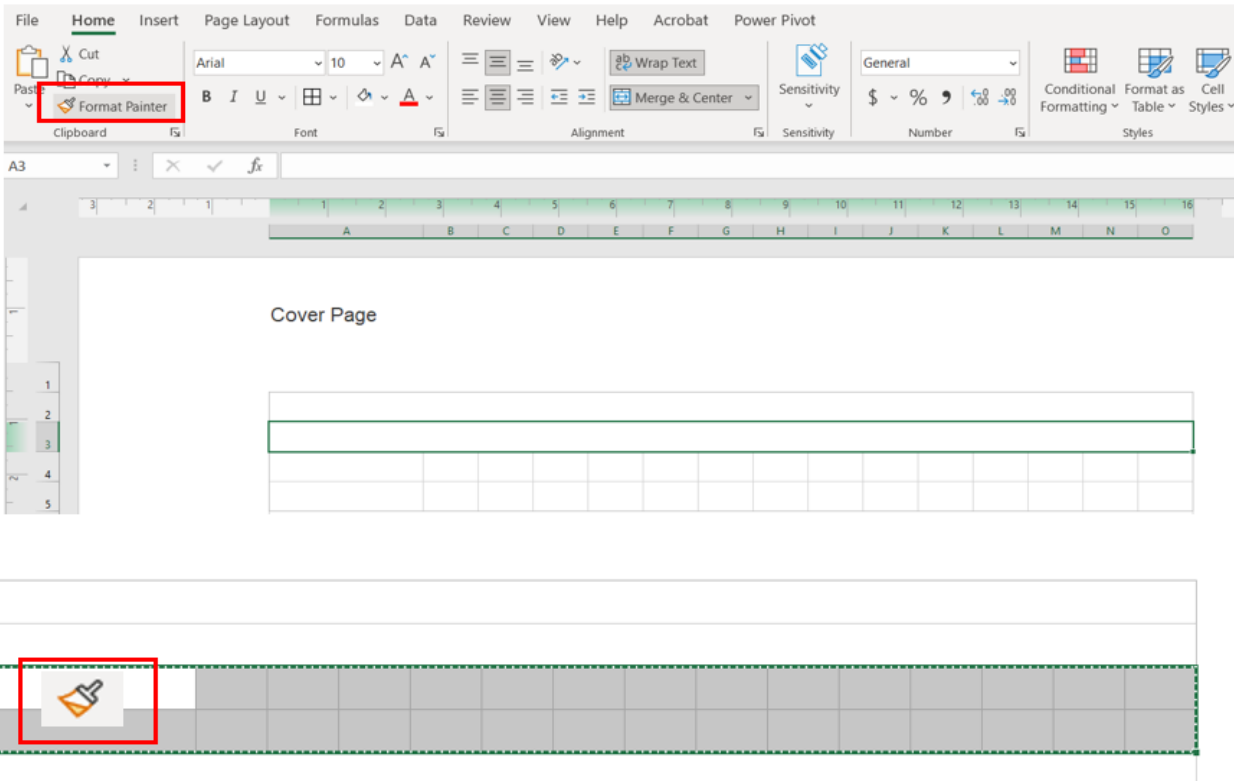
7.2   Add a Row

By using the traditional add row function in a merged cell area of a worksheet the inserted row will retain the original column formatting. Box A (below) highlights the new row with the original column formatting. There are two solutions, either highlight the new row and **merge cells** or highlight an unpopulated formatted row and **insert copied cells**, which will retain the merged cell formatting (Box B).

The new row will retain its original formatting, so if the section requires a drop-down option, copy and paste formatting to the new row (s) as described in 7.4.
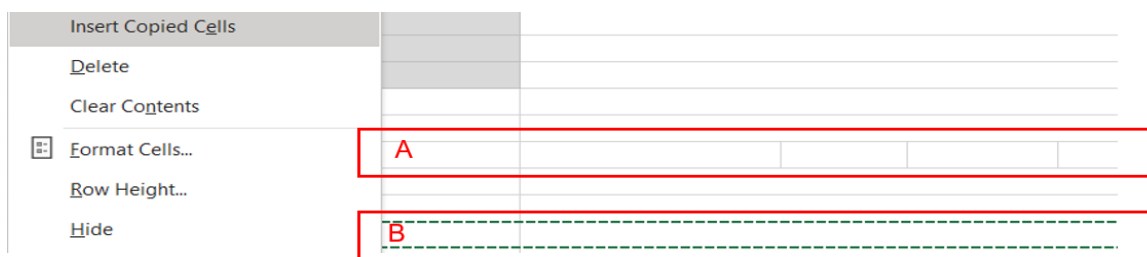
Tip: Ensure that each section has an extra row Box B, above) which can easily be copied and inserted.

7.3   Add Hyperlink within the Worksheet

To facilitate the centralised repository function of the tool, documents, including CVs, ICH-GCP Certificates, licenses, accreditations, website addresses, and images can be linked within the worksheet. Ensure that privacy laws, institutional policies, and procedures are followed concerning confidential and identifiable information.

7.4   Hyperlink a Document

Firstly, select the location or text that is to be displayed as a hyperlink, **right-click,** and select **Link.**

In this example, adding a link to include a PI's CV.

In the insert hyperlink box choose **Existing File or Webpage** and select the document from either the Site Trial File or a central repository file location. This will depend upon site document management and storage processes and access rights.
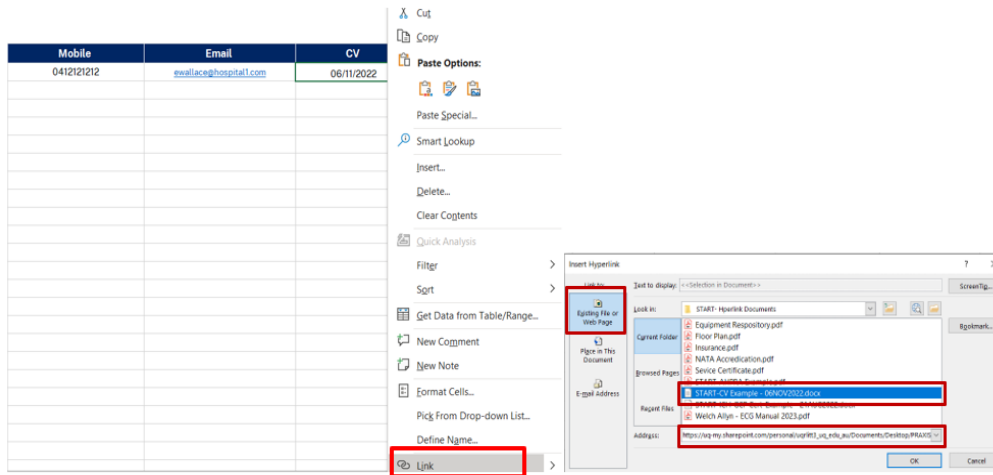
Tip: If CVs, certificates, and licenses are named using a date format, any updates would require the contents to be deleted and repopulated using the new date, and hyperlink as outlined above to include the new hyperlink

7.5   Hyperlink a Website (URL)

Follow the same process as hyperlinking a document (above) but include the web address (URL) in the **Address** box. The hyperlink will be visible.
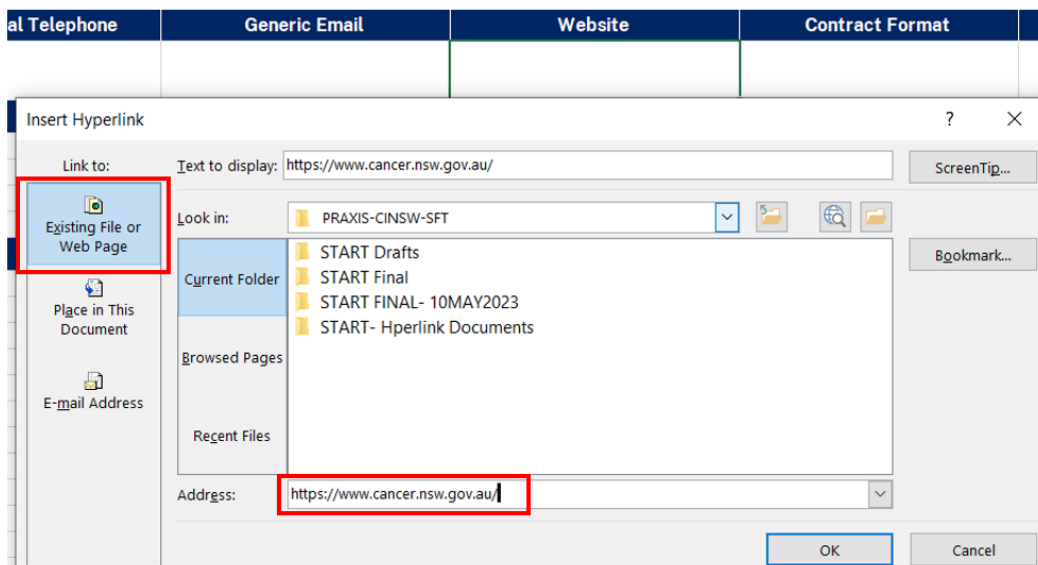
The hyperlink text can be reformatted but retaining underlining signals the presence of a hyperlink.

If the URL requires to be updated select the item hyperlinked **right-click** and **Edit Hyperlink** and replace the web address.
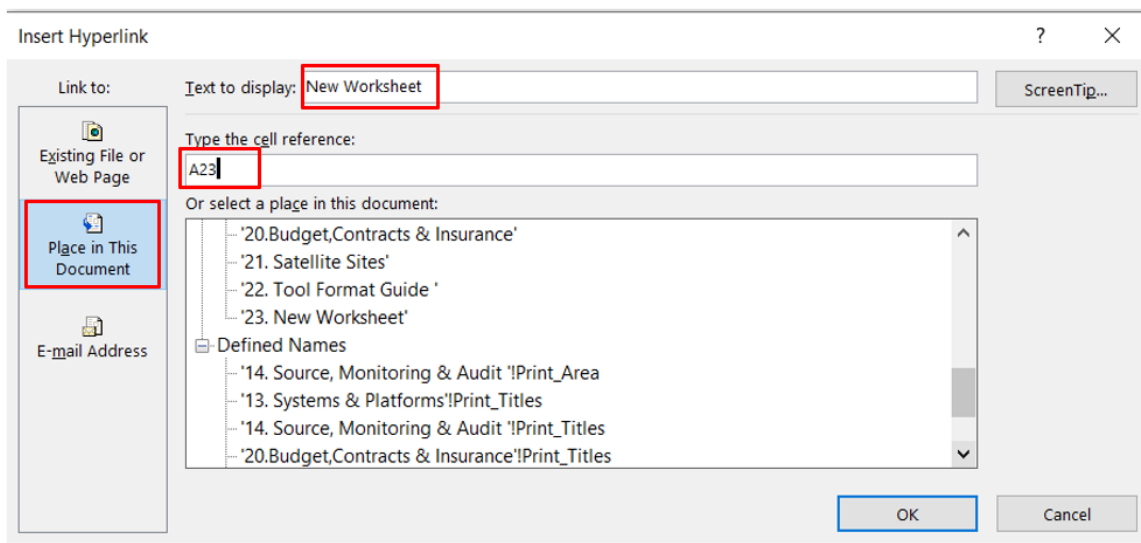
🔗	Edit Hyperlink…
	Open Hyperlink
⌧	Remove Hyperlink
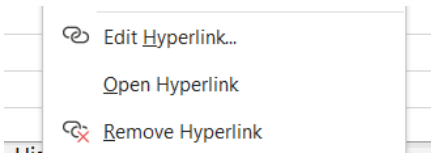
In several domains, there are options to add hyperlinks for instructions and guidance.

Instructions / Guidance
< Add Website/Application for Translation Services Link>
<Add Schedule of Fees>
<Add Consumer and Community Involvement Procedure>

7.6   Add New Tab and Hyperlink to Index Page

If a new worksheet (tab) is added to the tool and it is located after the final worksheet, the inclusion of the worksheet name in the Index page requires to be hyperlinked. In this case, it is hyperlinked by selecting **Place this in this Document** adding the name to **Text to display** and the cell location in the Index page.

By using **Format Painter,** the hyperlink will resemble the other Index page text.

> **Tip:** If the location of the new worksheet is within existing worksheets the index will require to be reformulated from the location of the new worksheet and establish new hyperlinks for the new locations of the affected worksheets.

Budget & Contracts - Contacts & Process
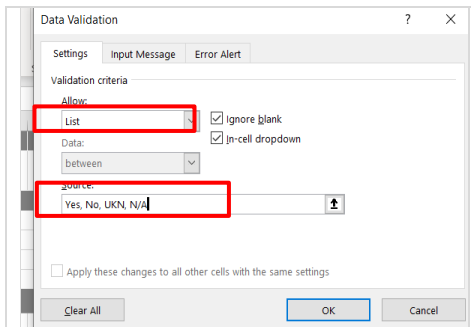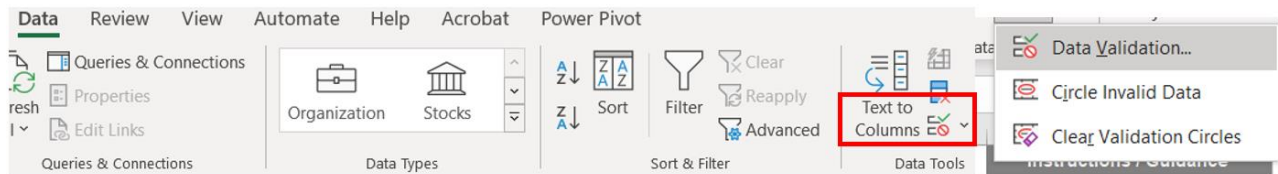Satellite Sites - Contacts & Details
Tool Format Guide
New Worksheet

Budget & Contracts - Contacts & Process
Satellite Sites - Contacts & Details
Tool Format Guide
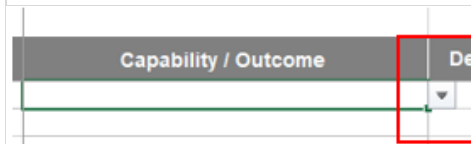New Worksheet

7.7   Colour Coded Drop-Down Lists

7.7.1   DATA VALIDATION

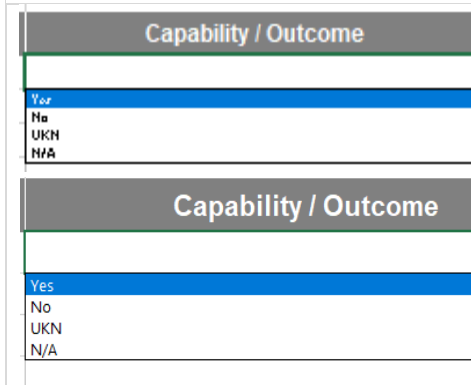To create a drop-down list a master **list** is required.

On the **Data** tab, click **Data Validation** and select **List.**

	The **source** can be a **List** populated directly by typing the list or generated within the spreadsheet. Pre-populated master drop down-lists are located in 22. Tool Format Guide.
	The presence of the drop-down list is indicated by an arrow.
	Note that the drop-down list is small. Unfortunately, the font size cannot be changed. However, for increasing the readability of the drop-down text, change the **zoom level** on the sheet.

Once established, the **Format Painter** can be used to copy formatting to another location in the worksheet.
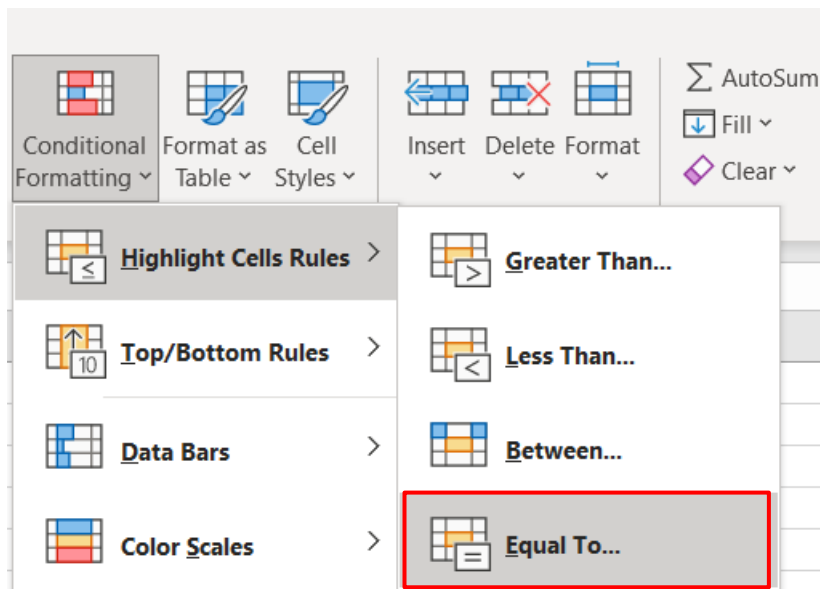
7.7.2   CONDITIONAL FORMATTING

Conditional formatting is a feature that automatically applies formatting to a cell when the data in that cell meets specific criteria.

To facilitate visual status, a traffic light colour system is applied, green for Yes, red for No, amber for Unknown, and grey for not applicable.

| Imaging Equipment	Capability / Outcome
Digital Radiography	Yes
X-Ray	Yes
MRI: 1.5T	Yes
MRI: 3 T	No
PET	Yes
PET-CT	No
CT-Scan	UKN
Mammography	Yes
Echocardiography	Yes
Ultra-Sound	Yes
DEXA (Bone Scan)	No

To establish colour-coded conditional formatting, on the **Home** tab select **Conditional Formatting**, then **Highlight Cells Rules** and **Equal To**…

By selecting each criterion and a corresponding colour (custom formatting can also be generated). For example:
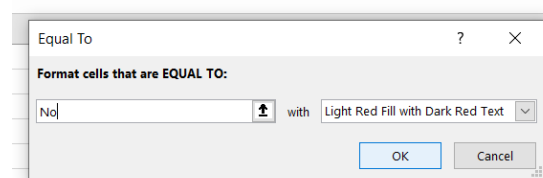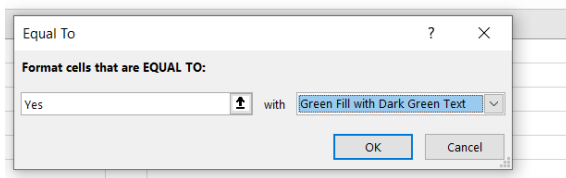

Once conditional formatting is established, the rules can be copied to other locations within the worksheet or the spreadsheet, by selecting **Copy**, **Paste Special, and Paste** and select the **Merge Conditional Formatting** option**.**
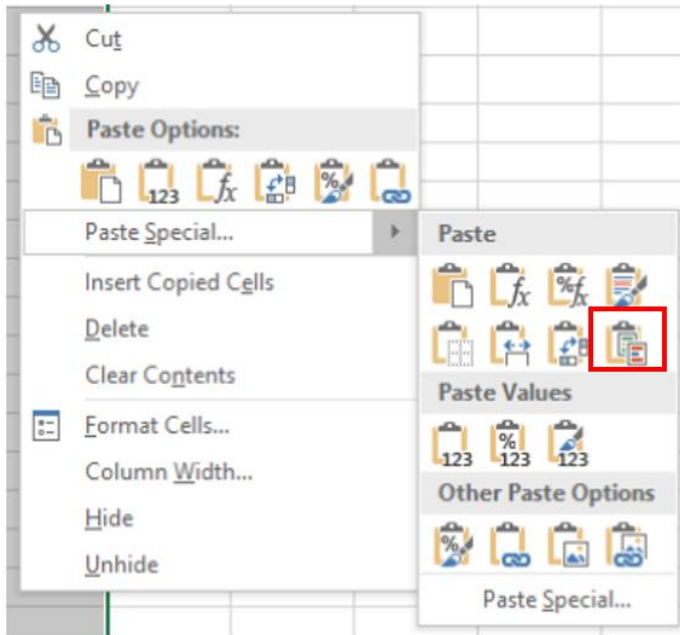
These hyperlinks will provide further instructions for generating [drop-down lists](#) and creating [conditional formatting](#).

To remove conditional formatting from specific cells, **select the cells, click the Quick Analysis button, and click Clear Format**.
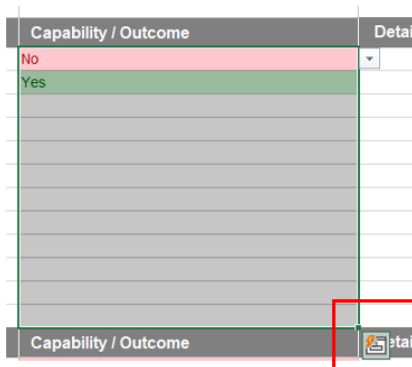
Tip: To select **Quick Analysis** at least one data item has to have been entered.

Excel functionality allows for hiding columns and rows, thereby limiting obsolete or not applicable information from view, but would remain in the master copy and would be visible when unhidden again.

Conditional formatting can utilise the **Not Applicable** (N/A) option to provide confirmation that the item has been considered and answered.

8. FILTERING DATA

To filter data on selected criteria, identify the data set to be filtered (1), on the **Home** tab, click **Sort and Filter** (2). Options will be presented to filter based on items in the drop-down list, for example, Yes, No, Unknown (UKN), N/A (A3), and Active/ Inactive (B3).

Filtering can facilitate fact-finding, by highlighting unknown items, and the filtered data can be shared with the relevant organisational group to assist in its completion (Example A). While status criteria can provide metrics for reports.

	1	2	3	4
A				
B				Tip: The filter icon will be visible in the column header when operational and non-filtered rows will be 'hidden' – noted by non-sequential row numbering and blue colour - until the filter has been inactivated. Tip: If the filter does not activate, the header may have to be unmerged to show the column to activate the filter.

9.   GLOSSARY

CINSW	Cancer Institute NSW
CRO	Clinical Research Organisation(s)
CTMS	Clinical Trials Management System
CTU	Clinical Trial Unit
CV	Curriculum Vitae
ICH-GCP	International Conference on Harmonisation Good Clinical Practice
NSW	New South Wales
PI	Principal Investigator
SIP	Shared Investigator Platform
SSU	Study Start-up Process