How to write and track Additional Requests using Excel/Word

Xavier Passera, Detour Solutions Ltd., Welwyn Garden City, Great Britain

ABSTRACT

Over the life of a project, numerous output and data requests, which are not part of the SAP process, are made from people outside the statistics department. A process that defines and allows statisticians to track these additional requests is essential for quality assurance, project management and documentation. Roche Products Ltd has a defined process for Additional Requests and this paper highlights how a tool, using Excel and Word, manages the different aspects of the process.

INTRODUCTION

Additional requests range from producing one output, to producing dozens, or can include providing datasets or subsets of data. In each case a formal requests has to be made to the statistician and needs to comply with the Roche Adhoc Request SOP. However the SOP doesn’t cover where documents should be stored, how they should be named and doesn’t provide a technical framework to track these requests. Individual projects manage this on their own. This paper covers what goes on afterwards, once the statistician and the client agree to what needs to be produced. This includes describing how requests are logged in a database to allow progress to be tracked, how to share information amongst team members and how to organize documentation. The database is saved in an Excel workbook and VBA macros are used to manage the different functions, which includes updating Word documents from Excel. These technical aspects are also covered in this paper.

ADHOC REQUEST PROCESS

The Adhoc Request process is covered by a SOP at Roche. The basics of the SOP are that any request from outside the statistics department must be written in a standard document and both parties must sign it. The document includes information such as delivery date, study name, requestor, project statistician and so on. There are different versions of the document indicating what state the request is in.

1.0: means the request is signed by both parties and is ready to be produced.
2.0: means the request has been delivered to the client and the client confirms that the request meets their requirements.

There are other stages but this is outside the scope of the paper.

The purpose of using a standard document is:
- to avoid loosing request information in Emails
- the signature indicates both parties know and agree to what is produced and when it should be delivered
- to provide enough information that the programmers know what is requested

However the SOP doesn’t cover where documents should be stored, how they should be named and doesn’t provide a technical framework to track these requests. Individual projects manage this on their own.

The following sections describe how a particular project manages this process with the help of the Adhoc Request Tracking Tool (ARTT)
DIRECTORY AND FILENAME STRUCTURE

The programming/statistic teams are split between efficacy and safety. As such each request is either a safety or efficacy request and is stored in different sub-directories.

Each request created has its own sub-directories. The sub-directory and the request document name are identical.

- **ReqID:** Request ID
- **Letter:** E for Efficacy, S for Safety
- **Numbers:** Unique number within project

The sub-directory and document are created by ARTT.

Example:

```
  Additional Requests 2006
  ▼ Efficacy
    ▼ ReqIDE001
    ▼ ReqIDE002
    ▼ ReqIDE003
    ▼ ReqIDE004
    ▼ ReqIDE005
    ▼ ReqIDE006
    ▼ ReqIDE007
    ▼ ReqIDE008
    ▼ ReqIDE009
    ▼ ReqIDE010
    ▼ ReqIDE011
    ▼ ReqIDE012
```

(only efficacy requests are shown here)

In the sub-directory ReqIDE001, there is the request document, ReqIDE001.doc but may also contain previous versions of the document. This is at the discretion of the statistician.

Although ARTT uses a network drive, statistician copy sub-directories to shareweb or RAPID once the request has been agreed. This complies with another Roche SOP which states that changes to documents need to be tracked and documented.
MODIFIED ADHOC REQUEST TEMPLATE

The standard template is modified and the text “&&xxxx” is added. This allows ARTT to communicate with the document. The special text is replaced by appropriate information entered by the user (usually the statistician) in ARTT. This information is particularly useful for information sharing, tracking and documentation summary. The rest of the template contains request specifics (section B and C), such as output shells with titles and footnotes.

A. SUMMARY OF INITIAL REQUEST

<table>
<thead>
<tr>
<th>1. Project Number (Project name)</th>
<th>2. Request ID Number</th>
<th>3. Version number*</th>
<th>4. Requestor</th>
</tr>
</thead>
<tbody>
<tr>
<td>PHuse &amp;&amp;ID</td>
<td>0.1</td>
<td>&amp;&amp;AUTHOR</td>
<td></td>
</tr>
<tr>
<td>5. Protocol Number(s)</td>
<td></td>
<td>&amp;&amp;PROTO</td>
<td></td>
</tr>
<tr>
<td>6. Date request submitted</td>
<td></td>
<td>&amp;&amp;DATREQ</td>
<td></td>
</tr>
<tr>
<td>7. When is the request needed?</td>
<td></td>
<td>&amp;&amp;DATDUE</td>
<td></td>
</tr>
</tbody>
</table>

8. What is the request?
&&DESC

9. Why is this request being made?
&&SOURCE

10. Attach the initial request in here

B. Outline Report Object Requirements

* The version number for Initial Requirement Document is 1.0. Any modification or changes version numbers 1.1, 1.2 etc. should be used. The Final Requirement Document will use 2.0.

C. Agreement

Agreed Delivery Date

ARTT - WRITE ADHOC REQUEST

The ARTT is an excel workbook with macros and two sheets. The only document ARTT needs is the modified Adhoc Request Template described above.

The example below (sheet REQUEST_FORM) is the form used to write and log new requests. ARTT has no menu bar but instead there are buttons (in blue) that perform the different tasks.

To create a new request, the user clicks on “New Request” button. The request number is filled in automatically as well as the user name and the current date. The rest of the form is filled in as much as can be done at this stage. Usually the completion section is done later on.
Once the request is filled in, the user clicks on "Save Request". This will create a sub-directory and a word document with all the information entered. A hyperlink to the word document is created and the user can follow it to complete the request with further detailed information.

The excel workbook has to be saved as it also acts as a database.

**DESCRIPTION OF REQUEST FORM**

The blue buttons perform certain tasks which are self-explanatory or are used to navigate between requests.

- **Column A:** brief description of information required to create, log, manage request
- **Column B:** user enters information in this column or uses drop-down menus to select options
- **Column C:** (V) indicates that a valid answer must be entered. Eg. a valid date.
- **Column D:** (!) indicates that the user must select answer from drop-down menu
- **Column D:** Provides further information for the user on how to fill in the form. Numbers indicate the corresponding item of the standard request document.
EXAMPLE OF A REQUEST

A. Summary of initial Request

<table>
<thead>
<tr>
<th>1. Project Number (Project name)</th>
<th>2. Request ID Number</th>
<th>3. Version number</th>
<th>4. Requestor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mathematica</td>
<td>67</td>
<td>1.0</td>
<td>Tim Toml</td>
</tr>
</tbody>
</table>

5. Protocol Number(s) : wa17942

6. Date request submitted : Wednesday 22 November 2006

7. When is the request need? : 1st December 2006

8. What is the request?

Repeat analyses of Sharp, Gianetti score, total erosion score and joint space narrowing score including ALL patients in the original ITT population (N=517) and using some conservative imputation methods.

9. Why is this request being made?

Answer CHMP questions for X-ray file

10. Attach the initial request here

Questions attached however requests were thoroughly checked during a meeting.

B. Outline Report Object Requirements

All the following should include ALL patients in the original ITT population (N=517) i.e. All randomised patients who have received any part of an infusion of study medication (excluding vial breakage patients and audit patients – see 24 week CSR DRAM for more details).

ARTT - LOG ADHOC REQUEST

When the user clicks on “Save Request” the request is logged in the database. This is another sheet on the workbook called “TRACKING”. All the information entered is copied on this sheet.

The sheet structured in different sections:

REQUEST HEADER SECTION

<table>
<thead>
<tr>
<th>ID Number</th>
<th>Date of Request</th>
<th>Author of Document</th>
<th>Author of Request</th>
<th>Due Date</th>
<th>Protocol Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>55</td>
<td>Friday 13 October 2006</td>
<td>willis16</td>
<td>Sarah Williams</td>
<td>11-Dec-06</td>
<td>HLS HAGU</td>
</tr>
<tr>
<td>56</td>
<td>Friday 13 October 2006</td>
<td>willis16</td>
<td>Matt Cruveric</td>
<td>11-Dec-06</td>
<td>HLS HAJSU</td>
</tr>
<tr>
<td>57</td>
<td>Friday 13 October 2006</td>
<td>willis16</td>
<td>Matt Cruveric</td>
<td>24-Oct-06</td>
<td>wa7643</td>
</tr>
</tbody>
</table>

All the information
REQUEST INFORMATION SECTION

<table>
<thead>
<tr>
<th>Brief description of request</th>
<th>Source of Request</th>
<th>Link to Request Details</th>
<th>Type of Request</th>
</tr>
</thead>
<tbody>
<tr>
<td>Summarized rate of SAE's per patient year</td>
<td>Additional request for the RNP from RMP</td>
<td>RmpR3065.doc</td>
<td>Safety</td>
</tr>
<tr>
<td>Produce all adverse events by treatment source at an additional request for the RNP request</td>
<td>RmpR3065.doc</td>
<td></td>
<td>Safety</td>
</tr>
<tr>
<td>Produce a summary of the duration of infections</td>
<td>Additional request for the RNP for the RmpR3065.doc</td>
<td></td>
<td>Safety</td>
</tr>
</tbody>
</table>

COMPLETION INFORMATION SECTION

<table>
<thead>
<tr>
<th>Programmer(s)</th>
<th>Request Version</th>
<th>Date</th>
<th>Unix directory</th>
<th>Program Name(s)</th>
<th>RAPID Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dassuhihika</td>
<td>2.0</td>
<td></td>
<td>sdlt235s</td>
<td>AFLSTripe.cac</td>
<td>Clinical Other S</td>
</tr>
<tr>
<td>Pavithra</td>
<td>2.0</td>
<td></td>
<td>sdlt235s</td>
<td>AFL_*</td>
<td>Clinical Other S</td>
</tr>
</tbody>
</table>

No particular protection/security exists on the workbook and cells can be modified by everybody. The precaution is to save all documents in a secure area for backup purposes on a regular basis. If word documents are modified then ARTT has to be modified manually.

ARTT - TRACK ADHOC REQUEST

A new request has been logged and the statistician informs the lead programmer (LP) that it needs to be dealt with. ARTT is used to find the information about the request and the LP enters information regarding the technical aspects of the request. They then dispatch the work to a programmer.

While the programming is ongoing ARTT doesn’t change. Once the request has passed QC, ARTT will be updated and the statistician will be informed.

If there are many requests overlapping the TRACKING sheet can be used to manage resources and set priorities.

ARTT - SHARE ADHOC REQUEST

An important aspect of ARTT is to share information amongst statisticians and programmers working on the project. The TRACKING sheet can be used to search for previous requests, to delegate work, to know the status of all requests on the project at a particular time.

The filters in excel can be used to search for groups of requests, such as requests written by a person.
TECHNICAL ASPECTS

VBA is used to perform tasks in ARTT. Creating basic VBA macros can done using the macro recorder function in Excel or Word. Press ALT-F11 and the actual code can be seen. Learning about VBA functions can be done using the VBA help and this is most useful for syntax checking and examples. But the internet is best for searching “how to do this and that”.

This section goes through a few macros used.

NEW REQUEST

This button is created using the Drawing toolbar. Right-click on the button and click on “Assign Macro”

This button is linked to the macro New_Requests which performs a certain task. It clear the cells in REQUEST_FORM and fills in rows 4 to 6

Sub New_Request()
'***************************************************************************
' Author        : Xavier Passera
' Name          : New_Request
' Date          : 31 August 2005
'***************************************************************************
Dim i           As Integer
Dim iMaxRow     As Integer
'*** Clear Request Form ***
Worksheets("Request_Form").Activate
For i = 5 To 24
    Cells(i, 2).Value = ""
Next i
PhUSE 2007

*** Get new request ID number based on number of records in TRACKING ***
iMaxRow = Worksheets("TRACKING").Cells(4, 1).CurrentRegion.Rows.Count - 3

*** Fill in rows 4 to 6 ***

*** New Request number ***
Cells(4, 2).Value = iMaxRow

*** Todays date ***
Cells(5, 2).Value = WeekdayName(Weekday(Date), False, vbSunday) & " " & FormatDateTime(Date, vbLongDate)

*** username. Usually windows log on name ***
Cells(6, 2).Value = Application.UserName

End Sub

SAVE REQUEST

This macro saves the request by copying the information in the TRACKING sheet, and fills in the word template. The template is saved as word document in a directory on the network drive. Finally, in Excel a hyperlink is created to the word file.

Sub Save_Request()
'***************************************************************************
' Author        : Xavier Passera
' Name          : Save_Request
' Date          : 31 August 2005
'***************************************************************************
Dim i           As Integer
Dim iMaxRow     As Integer
Dim sName       As String
Dim sDate       As String
Dim sText       As String
Dim sRequest    As String
Dim objFSO
Dim sWDtemplate     As String
Dim WordMyDoc       As Object
On Error Resume Next

*** Last row in Tracking sheet ***
iMaxRow = Worksheets("TRACKING").Cells(4, 1).CurrentRegion.Rows.Count + 1

*** Check that Request ID number is within range ***
If Cells(4, 2).Value > (iMaxRow - 4) Then Cells(4, 2).Value = iMaxRow - 4
If Cells(4, 2).Value < 1 Then Cells(4, 2).Value = 1
sName = "TRACKING"
Worksheets("Request_Form").Activate
*** Due Date / Type of Request must be filled in ***
If Cells(8, 2) = "" Then
    MsgBox "Due Date must be entered to save the request"
    GoTo fin
End If
If Cells(15, 2) = "" Then
    MsgBox "Please select type of Request, either Efficacy or Safety"
    GoTo fin
End If

iMaxRow = Cells(4, 2).Value + 4

*** Fill in TRACKING with information on REQUEST_FORM ***
With Worksheets("Request_form")
    Worksheets(sName).Cells(iMaxRow, 1).Value = Cells(4, 2).Value
    Worksheets(sName).Cells(iMaxRow, 2).Value = Cells(5, 2).Value
    Worksheets(sName).Cells(iMaxRow, 3).Value = Cells(6, 2).Value
    Worksheets(sName).Cells(iMaxRow, 4).Value = Cells(7, 2).Value
    Worksheets(sName).Cells(iMaxRow, 5).Value = Cells(8, 2).Value
    Worksheets(sName).Cells(iMaxRow, 6).Value = Cells(9, 2).Value
    Worksheets(sName).Cells(iMaxRow, 7).Value = Cells(12, 2).Value
    Worksheets(sName).Cells(iMaxRow, 8).Value = Cells(13, 2).Value
    Worksheets(sName).Cells(iMaxRow, 9).Value = Cells(14, 2).Value
    Worksheets(sName).Cells(iMaxRow, 10).Value = Cells(15, 2).Value
    Worksheets(sName).Cells(iMaxRow, 11).Value = Cells(18, 2).Value
    Worksheets(sName).Cells(iMaxRow, 12).Value = Cells(19, 2).Value
    Worksheets(sName).Cells(iMaxRow, 13).Value = Cells(20, 2).Value
    Worksheets(sName).Cells(iMaxRow, 14).Value = Cells(21, 2).Value
    Worksheets(sName).Cells(iMaxRow, 15).Value = Cells(22, 2).Value
    Worksheets(sName).Cells(iMaxRow, 16).Value = Cells(23, 2).Value
End With

*** Directory path is stored in workbook properties ***
sText = ActiveWorkbook.BuiltinDocumentProperties.Item(18)
sDate = Year(Mid(Cells(8, 2).Value, InStr(1, Cells(8, 2).Value, " ") + 1))
sIDnum = Cells(4, 2)
For i = 1 To 3 - Len(sIDnum)
    sIDnum = "0" & sIDnum
Next i

*** Store directory path and full filename in variables ***
sFolder = sText & sDate & "\" & Cells(15, 2) & "\ReqID" & Mid(Cells(15, 2), 1, 1) & sIDnum
sFileName = sFolder & "\ReqID" & Mid(Cells(15, 2), 1, 1) & sIDnum & ".doc"

*** Create object ***
Set objFSO = CreateObject("Scripting.FileSystemObject")

*** Create Request Directory ***
If (objFSO.FolderExists(sFolder)) Then
    "*** Exists already, do nothing ***
Else
    If (objFSO.FolderExists(sText & sDate & "\" & Cells(15, 2))) Then
    Else
        MkDir sText & sDate & "\" & Cells(15, 2)
    End If
End If

MkDir sFolder

'*** Create template, if not found ***
If (objFSO.FileExists(sFileName)) Then
    '*** Exists already, do nothing ***
    'objFSO.DeleteFile (sFileName)
Else
    '*** location of request template ***
    sWDtemplate = sText + "2006" & "\Request_template.doc"

    If Not (objFSO.FileExists(sWDtemplate)) Then GoTo fin

    '*** Open word and load request template ***
    Set WordMyDoc = GetObject(sWDtemplate)
    WordMyDoc.Application.Visible = True
    WordMyDoc.Activate

    '*** Search for "&&" ***
        .Text = "&&"
        .Forward = True
        .Wrap = wdFindContinue
        .Format = False
    End With

    '*** Search for "&&" and replace word with information in REQUEST_FORM ***
        WordMyDoc.Application.Selection.MoveRight Unit:=wdWord, Count:=1,
        Extend:=wdExtend

        Select Case Trim(WordMyDoc.Application.Selection.Text)
            Case "&&ID"
                sRequest = Cells(4, 2).Value
                WordMyDoc.Application.Selection.TypeText Text:=sRequest
            Case "&&AUTHOR"
                sRequest = Cells(7, 2).Value
                If sRequest = "" Then sRequest = "Unknown"
                WordMyDoc.Application.Selection.TypeText Text:=sRequest
            Case "&&DATREQ"
                sRequest = Cells(5, 2).Value
                If sRequest = "" Then sRequest = "Unknown"
                WordMyDoc.Application.Selection.TypeText Text:=sRequest
            Case "&&DATDUE"
                sRequest = Cells(8, 2).Value
                If sRequest = "" Then sRequest = "Unknown"
                WordMyDoc.Application.Selection.TypeText Text:=sRequest
        End Case

    GoTo fin:
End If

fin:
CONCLUSION

Overtime a project has a number of outputs and data requests which are not covered in the SAP process. These follow the Adhoc Request process when it’s defined. ARTT can be used with this process and help organize, manage and track these requests.

The key points are to define a directory structure, use a file naming convention, log and track the requests using ARTT. This system can be used to fit a SOP and provides valuable documentation to people involved in the project.
Lastly, it doesn’t require extensive training or use pharmware, allowing information sharing accessible to everyone.

GLOSSARY

SAP  Statistical Analysis Plan. Document written by Statisticians describing how a study is to be reported
ARTT  Adhoc Request Tracking Tool. Excel tool used to manage requests
LP  Lead programmer. Programmer responsible for managing programming resources
VBA  Visual Basic for Applications. Microsoft Office programming tool.
Pharmware  Pharmaceutical company software that is proprietary and not easily shareable.

CONTACT INFORMATION

Your comments and questions are valued and encouraged. Contact the author at:

Xavier Passera  
Detour Solutions Ltd.  
3 Sir John Newsom Way  
Welwyn Garden City, AL7 4FJ  
Great Britain

Mobile: +44 (0)7930 472 690  
Email: Xavier.Passera@detoursolutions.co.uk  
Web: www.detoursolutions.co.uk

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