

Spring brings with it the feel-good factor (and better weather!) and we are all looking forward to a better year both in the workplace and at a personal level. ATNEC reached important milestones, more than 100 participants recruited, and more than 50 hospitals open to recruitment. This is no modest achievement considering the staffing issues and reduced research capacity at sites. You have made it possible, and I believe we together can deliver this large, randomised trial to improve patient outcomes and reduce the debilitating side effects of axillary node clearance.

To support sites, we will be conducting a FREE 'hands-on' axillary node marking training workshop at Association of Breast Surgery annual meeting on 17<sup>th</sup> May 2022. Looking forward to a summer of growth in recruitment rate, more sites and lots of sunshine.



Associate Professor  
Amit Goyal - CI



## Thoughts From Our Participants...

The following quotes are taken from interviews with ATNEC participants and our qualitative researcher Sophie Gasson, as part of the Participant Experience Sub-Study:

*'I didn't have any cancer left in my armpit.... I was actually quite pleased I wasn't selected to have armpit.....radiotherapy only because I understood that there was a tiny risk that you know it could affect your flexibility in your arms.'*

*'I agreed to it having understood everything that the Research nurse told me because she explained it so brilliantly and so did the Consultant Surgeon.'*

*'I just thought well I've got nothing to lose by doing it..... You know things progress by people being on trials.'*

If any of your ATNEC patients would be interested in speaking with our qualitative researcher to share their thoughts on the trial, please contact [ATNEC@warwick.ac.uk](mailto:ATNEC@warwick.ac.uk) for more information.

### Top Recruiting Sites

University Hospitals of Derby and Burton:

27 Enrolled

NHS Grampian:  
20 Enrolled  
7 Randomised

10 Randomised

University Hospitals Leicester:  
15 Enrolled  
4 Randomised



**ATNEC IS OPEN TO NEW SITES!**

### Trial Update

- 114 participants enrolled, 35 randomised
- 43 NHS Trusts open to recruitment (52 recruiting hospitals)
- 52 SIVs scheduled to date

Welcome on board to the following Trusts who opened ATNEC this month:

North Middlesex University Hospital NHS Trust  
NHS Dumfries and Galloway

Congratulations to the following sites for recruiting their first participants in March 2022:

Clatterbridge Cancer Centre  
NHS Borders  
North Manchester General



## Patient Screening Log Guidance

The ATNEC Patient Screening Log was recently amended to **v3.0 dated 05-Jan-2022**.

The amendment included the addition of a new coded option for 'Has the eligible patient been approached about the trial?':

**'e—Patient ineligible after initial identification'**.

If a patient is initially identified as eligible for ATNEC by the MDT, and is therefore added to the screening log, but further investigations (e.g. MRI scan) deem the patient to be ineligible for the trial, this coded option should be selected. Option 'd— patient medical/mental health reasons—not appropriate to approach' should only be selected for patients if the MDT make the decision not to approach them due to an unrelated medical/mental health reason (s).

|  |                          |
|--|--------------------------|
| <b>Has the eligible patient been approached about the trial?</b><br>(Please tick one appropriate response below) |                          |
| Yes  | <input type="checkbox"/> |
| <b>No, why not?</b><br>(Tick relevant coded option below)  |                          |
| a. MDT/clinician decision - prefer axillary treatment (axillary node clearance or axillary radiotherapy)         | <input type="checkbox"/> |
| b. MDT/clinician decision - prefer NO axillary treatment (axillary node clearance or axillary radiotherapy)      | <input type="checkbox"/> |
| c. Staff not available to discuss trial/consent  | <input type="checkbox"/> |
| d. Patient medical/mental health reasons - not appropriate to approach   | <input type="checkbox"/> |
| <b>e. Patient ineligible after initial identification</b>  | <input type="checkbox"/> |

**Reminder—A copy of your local screening log is requested via email in the second week of each calendar month.**



## Meet the Team

**Natalie Hammonds**  
ATNEC Trial Coordinator

Natalie graduated from The University of Sheffield with a degree in Biomedical Science BSc in 2019. Natalie went on to work at a clinical trial management organisation before joining Warwick CTU and the ATNEC trial in January 2021.

Natalie enjoys travelling (going on holiday 😊), skiing, gymnastics and shopping—particularly for clothes!



## Current Document Versions

Please ensure you are using the correct versions of the following documents:

|   |   |
|---|---|
| Protocol<br>v3.0 07-Oct-2021                        | Informed Consent Form<br>v5.0 18-Feb-2022 |
| PIS Pathway 1<br>v4.0 07-Oct-2021                   | PIS Pathway 2<br>v3.0 25-Feb-2021         |
| Site Signature & Delegation Log<br>v4.0 07-Mar-2022 | Patient Screening Log<br>v3.0 05-Jan-2022 |

A new document

**Example Patient Management (v1.0 08-Mar-2022)** was recently circulated to sites which can be used as a guidance tool for how to manage patients being approached through both Pathway 1 and Pathway 2.

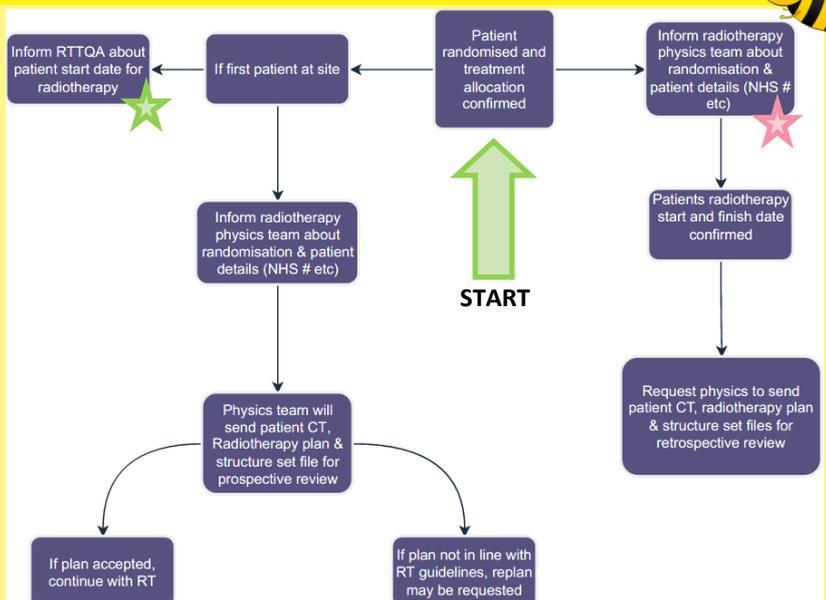


## Collection of RT QA Data in ATNEC

When a patient is randomised to ATNEC (regardless of which arm they are randomised to) it is important that the research team communicate with the physics department to ensure they are aware that an ATNEC patient is being referred to them. Please see guidance on how to do this in the flow chart.

The physics team will need to know the patient's personal details, as well as their trial number and treatment allocation ★

If the patient is the first patient randomised to axillary treatment at your site, the RTTQA team will be undertaking a prospective review of the treatment plan. They will therefore need to be informed of the patient's start date for radiotherapy. ★



| Site                                  | Months Open | Enrolled | Enrolment Rate | Randomised | Randomisation rate |
|---------------------------------------|-------------|----------|----------------|------------|--------------------|
| ROYAL DERBY HOSPITAL                  | 15.4        | 17       | 1.10           | 8          | 0.52               |
| QUEEN'S HOSPITAL BURTON               | 15.4        | 10       | 0.65           | 2          | 0.13               |
| ROYAL CORNWALL HOSPITAL               | 14.4        | 3        | 0.21           | 3          | 0.21               |
| THE ROYAL MARSDEN HOSPITAL            | 14.0        | 3        | 0.21           | 1          | 0.07               |
| ABERDEEN ROYAL INFIRMARY              | 11.8        | 20       | 1.69           | 7          | 0.59               |
| ST ALBANS CITY HOSPITAL               | 11.8        | 3        | 0.25           | 0          | 0.00               |
| ROYAL ALBERT EDWARD INFIRMARY         | 11.3        | 6        | 0.53           | 1          | 0.09               |
| GLENFIELD HOSPITAL                    | 11.2        | 15       | 1.34           | 4          | 0.36               |
| LUTON & DUNSTABLE HOSPITAL            | 10.8        | 5        | 0.46           | 3          | 0.28               |
| FORTH VALLEY ROYAL HOSPITAL           | 10.3        | 1        | 0.10           | 1          | 0.10               |
| ST HELENS HOSPITAL                    | 10.3        | 4        | 0.39           | 1          | 0.10               |
| BORDERS GENERAL HOSPITAL              | 10.1        | 1        | 0.10           | 0          | 0.00               |
| MUSGROVE PARK HOSPITAL                | 10.0        | 5        | 0.50           | 1          | 0.10               |
| YEOVIL DISTRICT HOSPITAL              | 9.9         | 0        | 0.00           | 0          | 0.00               |
| HAIRMYRES HOSPITAL                    | 9.9         | 0        | 0.00           | 0          | 0.00               |
| THE JAMES COOK UNIVERSITY HOSPITAL    | 8.9         | 1        | 0.11           | 1          | 0.11               |
| ROYAL FREE HOSPITAL                   | 8.7         | 1        | 0.11           | 0          | 0.00               |
| MILTON KEYNES HOSPITAL                | 8.5         | 3        | 0.35           | 0          | 0.00               |
| UNIVERSITY HOSPITAL OF NORTH TEES     | 8.3         | 0        | 0.00           | 0          | 0.00               |
| ADDENBROOKE'S HOSPITAL                | 7.7         | 2        | 0.26           | 0          | 0.00               |
| WESTERN GENERAL HOSPITAL              | 7.5         | 1        | 0.13           | 1          | 0.13               |
| THE ROYAL VICTORIA INFIRMARY          | 7.1         | 0        | 0.00           | 0          | 0.00               |
| CASTLE HILL HOSPITAL                  | 6.2         | 1        | 0.16           | 0          | 0.00               |
| UNIVERSITY COLLEGE HOSPITAL           | 5.7         | 0        | 0.00           | 0          | 0.00               |
| COUNTESS OF CHESTER HOSPITAL          | 5.7         | 0        | 0.00           | 0          | 0.00               |
| CHARING CROSS HOSPITAL                | 5.3         | 0        | 0.00           | 0          | 0.00               |
| HUDDERSFIELD ROYAL INFIRMARY          | 5.3         | 0        | 0.00           | 0          | 0.00               |
| PINDERFIELDS GENERAL HOSPITAL         | 5.1         | 0        | 0.00           | 0          | 0.00               |
| THE CLATTERBRIDGE CANCER CENTRE       | 5.1         | 1        | 0.20           | 0          | 0.00               |
| ROTHERHAM DISTRICT GENERAL HOSPITAL   | 5.0         | 3        | 0.60           | 0          | 0.00               |
| QUEEN MARGARET HOSPITAL               | 3.9         | 0        | 0.00           | 0          | 0.00               |
| ST LUKES HOSPITAL                     | 3.6         | 0        | 0.00           | 0          | 0.00               |
| PRINCE PHILIP HOSPITAL                | 3.6         | 0        | 0.00           | 0          | 0.00               |
| CITY HOSPITAL                         | 3.5         | 6        | 1.71           | 0          | 0.00               |
| HEREFORD COUNTY HOSPITAL              | 2.9         | 0        | 0.00           | 0          | 0.00               |
| CHURCHILL HOSPITAL                    | 2.3         | 1        | 0.43           | 1          | 0.43               |
| ROYAL DEVON & EXETER HOSPITAL         | 2.3         | 0        | 0.00           | 0          | 0.00               |
| CLATTERBRIDGE HOSPITAL                | 2.1         | 0        | 0.00           | 0          | 0.00               |
| KING'S COLLEGE HOSPITAL               | 2.0         | 0        | 0.00           | 0          | 0.00               |
| DARLINGTON MEMORIAL HOSPITAL          | 2.0         | 0        | 0.00           | 0          | 0.00               |
| WYTHENSHAW HOSPITAL                   | 1.5         | 0        | 0.00           | 0          | 0.00               |
| SOUTHEND UNIVERSITY HOSPITAL          | 1.4         | 0        | 0.00           | 0          | 0.00               |
| NORTH MANCHESTER GENERAL HOSPITAL     | 1.3         | 1        | 0.77           | 0          | 0.00               |
| BROOMFIELD HOSPITAL                   | 1.1         | 0        | 0.00           | 0          | 0.00               |
| NORTH MIDDLESEX HOSPITAL              | 0.9         | 0        | 0.00           | 0          | 0.00               |
| DUMFRIES AND GALLOWAY ROYAL INFIRMARY | 0.4         | 0        | 0.00           | 0          | 0.00               |

Key = Recruitment rates from Pilot Study progression criteria (Grey = No Recruitment, Red = <0.30 p/m, Amber = ≥0.30 p/m < 0.36 p/m, Green = ≥ 0.36 p/m)