Outcome Report. Collaborative Working Project between Incyte Biosciences Ltd and Coventry and Warwickshire NHS Trust: Cholangiocarcinoma molecular testing audit programme, March 2026

Summary:

In partnership with Incyte Biosciences Ltd, Apodi Ltd, and Coventry and Warwickshire NHS Trust, this project aimed to identify potential improvements to the hospital cholangiocarcinoma (CCA) molecular testing patient pathway.

Background:

Molecular (genomic) testing for a range of gene targets in CCA is reimbursed by NHS England. However, despite this, many patients do not have their tumours molecularly profiled, or are not informed of test results in a timely manner.

This project aimed to support the Trust in reviewing its genomic testing data to identify barriers to optimal testing and to implement solutions to improve uptake and reporting.

Benefits of the project:

For Patients

- Increased access to molecular testing for CCA patients
- Reduced test failure rates due to improvements in the testing pathway
- More timely and informed treatment decision-making
- Greater equity of access to molecular testing across regions

For the NHS Trust

- More timely and informed clinical decision making
- Improved efficiency in service design and delivery
- Greater consistency in access to services across the Trust
- Enhanced understanding of biomarker prevalence and CCA patient characteristics to support patient management

For Incyte

- Enhance reputation through partnership working
- Potential improvement in patient access to innovative treatments in line with NICE guidance, which may or may not include an Incyte medicine

Methodology:

Using a pre-approved data collection template, an Apodi-employed auditor, who was also an employee of the Trust, reviewed patient records. The audit assessed whether patients had biopsy samples molecularly profiled and, where this had not occurred, the reasons why.

Project Outcomes:

The project supported Coventry and Warwickshire NHS Trust in reviewing patient records relating to molecular testing and identifying reasons why testing was not performed.

A total of 67 patient records were reviewed over a four year time period, including both intrahepatic and extrahepatic CCA cases. This distinction is important, as CCA subtype influences the likelihood of specific molecular alterations.

Approximately half of patients with extrahepatic CCA had a molecular test requested, compared with over three-quarters (76%) of patients with intrahepatic CCA. Reasons for not requesting testing included lack of biopsy material and poor patient condition.

The most common reason for test failure was insufficient biopsy material.

These findings highlight opportunities to improve biopsy collection techniques to increase tissue yield. In addition, optimisation of tissue utilisation for diagnostic and molecular testing purposes should be considered.

Conclusions and recommendations:

There are multiple reasons why patients with CCA may not undergo molecular profiling. These include insufficient or inadequate tissue obtained during biopsy, as well as delays in test requesting, processing, or reporting.

Retrospective review of patient records enables identification and analysis of barriers to molecular testing. While these barriers may vary between organisations, understanding local challenges can support the implementation of targeted improvements.

Addressing these issues may improve testing rates, reduce failures, and support more timely and effective patient management.