“If a tree falls in a forest…”: Abstract view statistics as a measure of research impact

Andrew Embleton, Deborah Ashby, Ella Flemyng, Peter Langhorne, William J. Meurer, Annabelle South, Matthew Sydes
Motivation
Motivation

Conference abstract
Motivation

Conference abstract

Impact
Motivation

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Viewing figures
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Patterns
Impact of retrospective data verification on the results of the academic-led ICON6 trial

Background

ICON6 (NCT02333271) is an international three-arm, double-blind, placebo-controlled, randomised trial which recruited 451 patients.

Path was performed to identify whether chemotherapy and radiotherapy with paclitaxel and carboplatin induced deconditioning (Arm A), chemotherapy and radiotherapy with concurrent oxaliplatin, followed by maintenance (Arm B), chemotherapy and radiotherapy with concurrent oxaliplatin, followed by maintenance (Arm C). Maintenance therapy is shown in Figure 1.

The primary endpoint was progression-free survival (PFS) between Arms A, B and C. Secondary endpoints included overall survival (OS), toxicity and quality of life.

A substantial improvement in terms of PFS was seen with Arm B, and the primary endpoint was met. ICON6 was conducted using a long-established monitoring model that is common in academically supported CTAs and is consistent with recent approaches advanced by FDA/EMA.

Following positive results, ICON6have submitted a marketing application to EMA using ICON6 as the single pivotal trial.

Figure 1: Study schema

Quality Checking

Quality checking (QC) of the database against the CRFs collected at the site was performed in the following domain:

- Arm B: histograms for all patients for all 176 variables, 765 data points were QC'ed and 11 errors were identified, wth an error rate of 0.108%
- Arm C: histograms for all patients for all 176 variables, 765 data points were QC'ed and 13 errors were identified, with an error rate of 0.105%
- Arm D: histograms for all patients for all 176 variables, 765 data points were QC'ed and 12 errors were identified, with an error rate of 0.100%
- Arm A: histograms for all patients for all 176 variables, 765 data points were QC'ed and 12 errors were identified, with an error rate of 0.100%
- All QA/QC were considered acceptable. All identified errors were corrected.

Blinded Independent Clinical Review

The basis for this study was to examine the eligibility criteria for patients with metastatic colorectal cancer, to determine whether patients would meet the criteria for study entry.

The review conducted by an independent panel of experts to identify which patients met the eligibility criteria for the study. The results of the review were compared to the original CRFs and a 95% confidence interval was calculated.

Results

Efficacy

- As compared to the primary analysis, the final results showed a statistically significant improvement in overall survival.
- The results were consistent with the primary analysis, showing a significant improvement in overall survival.

Safety

- The most common adverse events were diarrhea, nausea, and vomiting.
- No new safety concerns were identified.

Conclusions

- ICON6 met the primary endpoint of overall survival.
- The study results were consistent with previous studies.
- The results were consistent with the primary analysis.

References

Motivation (honest version)
Motivation (honest version)

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Motivation (honest version)

No talk

View metrics
Methodology
Methodology

Trials journal
Methodology

Trials journal

Snapshot
Methodology

Trials journal

Snapshot

‘Scrape’
Methodology

Trials journal

Snapshot

‘Scrape’
import.io
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Methodology

Impact of retrospective data verification on the results of the academic-led ICON6 trial

Andrew Embleton, Elizabeth Clark, Stephen Townsend, Laura Farrelly, Cheryl Jones and Richard Kaplan

Published: 16 November 2015

ICON6 (ISRCTN68510403) is a phase III academic-led international double-blind placebo-controlled randomised trial of the addition of cediranib to chemotherapy in recurrent ovarian cancer. The trial established a beneficial gain in progression-free survival (PFS), conducted using the long established risk-based monitoring model as advocated by FDA/EMA as an alternative to the traditional monitoring-intensive industry approach. AstraZeneca are currently considering regulatory submissions using ICON6 as the single pivotal trial.

Given the lower level of on-site monitoring performed AstraZeneca mandated the CTU implement retrospective Source Data Verification (SDV) of medical records against Case Report Forms (CRFs), and complete Quality Control (QC) checks of single data entry. Additionally, Blinded Independent Central Review (BICR) of imaging studies to assess investigator ascertainment bias was performed. We summarise changes resulting from additional monitoring and the impact on reported results.

Amongst 253 events in 282 patients in the primary comparison two additional progressions were reported, one in each arm. The result of the log-rank test changed marginally, remaining p<0.001. No change in a hazard ratio of 0.57, with minor confidence interval adjustment from 0.45-0.74 to 0.44-0.73. Reference median time-to-event remained at 8.7 months, with the comparator revised from 11.1 to 11.0. Within those progressions assessed radiographically, BICR identified differences as expected given the subjective nature of scan assessment. However these differences were slight.
Methodology
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Overall

55 days post-meeting
median of 79 views
Overall

55 days post-meeting
median of 79 views

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Innovative considerations on a phase 2a dose-finding strategy using Bayesian methods and MCP-MOD

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Preliminary results (lack of…)

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Abstract publication
ICTMC/SCT 2017

Meeting abstracts from the 4th International Clinical Trials Methodology Conference (ICTMC) and the 38th Annual Meeting of the Society for Clinical Trials

Liverpool, UK. 07–10 May 2017

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Published: 8 May 2017
ICTMC/SCT 2017

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It is possible to assess impact
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