

Issue 1 HCF vs ECF ICER

Description of problem	Description of proposed amendment	Justification for amendment	ERG Response
<p>It is considered unlikely that the ICER for HCF vs ECF should have reduced from Roche's estimate of £50,838 to £31,765 (table 24) as a result of the minor revisions the ERG made to the economic model described in section 6.2. It is suspected that the Cost per life year gain was reported instead of the Cost per QALY.</p>	<p>We propose that the ICER in table 24 be confirmed as correct.</p>	<p>Possible correction of a factual inaccuracy</p>	<p>We accept that the ICER of £31,765 was factually inaccurate. This was a result of a transcription error in copying between tables. While the mean cost and QALY estimates were correctly reported, the estimate of the ICER was not. The ERG has amended table 24 in the report with the correctly calculated ICER of £47,907 per QALY.</p> <p>Following this query of factual accuracy the ERG has also double checked all other tables and calculations in the report. The ERG noted the following errors and has corrected these in the amended report:</p> <ul style="list-style-type: none"> In Tables 26, 28-31 HCF was incorrectly referred to as 'Extendedly Dominated'. HCF is actually dominated by HCF in these tables and so should read 'Dominated'. This has not material impact on the interpretation of the results. Table 12 was changed

			<p>from '625mg/m2' to '625mg/m2 x 2' for the dose of capecitabine. The correct dose was used in the model so does not affect any of the model results.</p> <ul style="list-style-type: none"> We also identified that the 0.96 HR adjustment used for ECX compared to CX applied in the "Alternative ERG base case scenarios" reported in pages 100-101 and Tables 30 and 31 had only been applied to PFS and not to OS as had been intended. These tables have been corrected by applying the 0.96 HR adjustment to both PFS and OS. <p>The impact of this is to increase the ICER of HCX vs EOX from £60,469 to £66,982 (Table 30) and £64,766 to £71,637 (Table 31). These changes have been made to the amended report.</p>
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Issue 2 Market Research

Description of problem	Description of proposed amendment	Justification for amendment	ERG Response
In section 3.3 it is stated that the "manufacturer conducted" the market research involving sampling 112 patient records. This is not correct as Roche did	Amend the relevant sections in the ERG report which imply that this market research was conducted by Roche to reflect the fact that Roche purchased this data from Synovate, who had conducted this research independently	It is factually inaccurate to say that Roche conducted this research.	The ERG acknowledges this statement as factually inaccurate. The ERG has amended the report so that it is clear that this research was

<p>not commission this research. Synovate, a market research company, independently perform surveillance of the use of interventions in the UK. Roche purchased this data but were not involved in specifying how or from where it was sampled.</p>	<p>from Roche.</p>		<p>conducted by Synovate and the data purchased by Roche.</p>
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Issue 3 Inaccurate percentages quoted on page 19

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<p>On page 19 of the ERG report it states: “The proportion of HER2 positivity in the ToGA trial screening population varies with tumour histology (intestinal 34%, diffuse 6%, mixed 20%)”</p> <p>The percentage quoted for each histological subtype are incorrect based on Bang 2009 as referenced.</p>	<p>Based on the findings from ToGA screening programme, the HER2 positivity rates for the different histological subtypes are as follows:</p> <ul style="list-style-type: none"> a. intestinal 32.2% b. diffuse 6.1% c. mixed 20.4% 	<p>The figures stated are inaccurate.</p>	<p>The ERG accepts this. The ERG has amended the report to show the correct figures.</p>

Issue 4 Typo Table 17

Description of problem	Description of proposed amendment	Justification for amendment	ERG Response
<p>In Table 7 page 49 TA19 is referred to this should be TA91</p>	<p>Amend from TA19 to TA91</p>	<p>The TA stated has been misquoted from Roche’s submission</p>	<p>The ERG accepts this. The ERG has amended the report to show the correct reference.</p>