

Trastuzumab duration questionnaire

Name: _____

Hospital: _____

This questionnaire is designed to survey clinician's opinions on trastuzumab treatment in the HER2 positive early breast cancer setting, and more specifically the comparison between 12 months and 6 months duration of trastuzumab treatment. Its aim is to capture what clinicians consider both the effectiveness and toxicity profile of the two treatment durations.

Disease-Free Survival at 4 years

The PERSEPHONE trial assumed that patients receiving 12 months of trastuzumab would have a 4-year DFS of 85%. If this is proved accurate,

(a) ... what 4-year DFS rate would you expect patients receiving 6 months trastuzumab to have?

(Please tick one box in column (a) to answer this part of the question)

(b) ... what is the lowest 4-year DFS rate for 6 months trastuzumab patients that you would be comfortable with in order to change your practice to prescribing 6 months instead of the current standard of 12 months trastuzumab?

(Please tick one box in column (b) to answer this part of the question)

4-year DFS rate for 6 months trastuzumab patients	(a)	(b)
85%		
84%		
83%		
82%		
81%		
80%		
79%		
78%		
77%		
76%		
75%		
Other		

If 'Other' ticked above, please specify (a) _____

(b) _____

Disease-Free Survival in different subsets of patients

At the present time, in your opinion, in terms of disease-free-survival, is 6 months trastuzumab an inferior treatment, an equivalent treatment or a superior treatment when compared to 12 months trastuzumab in the following subsets of patients?

(Please tick one box in each row)

	<u>Inferior</u>	<u>Equivalent</u>	<u>Superior</u>
ER Positive patients	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER Negative patients	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Patients receiving anthracycline-based CT (no taxane)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Patients receiving taxane-based CT (no anthracyclines)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Patients receiving taxane + anthracycline CT	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Patients receiving CT with no taxane or anthracycline	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Patients receiving concurrent trastuzumab and CT	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Patients receiving sequential trastuzumab (i.e. after all CT)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Are there alternative/additional subsets of patients for whom you consider 6 months trastuzumab treatment to be either an inferior treatment, an equivalent treatment or a superior treatment, in terms of disease-free-survival, when compared to 12 months trastuzumab?

If so, please specify below.

(Please tick one box in each row)

	<u>Inferior</u>	<u>Equivalent</u>	<u>Superior</u>
_____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
_____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
_____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
_____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Cardiotoxicity

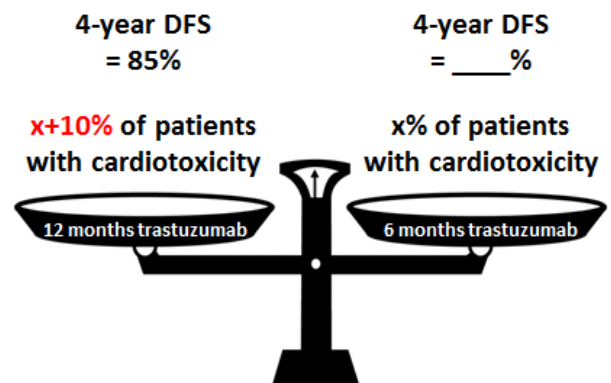
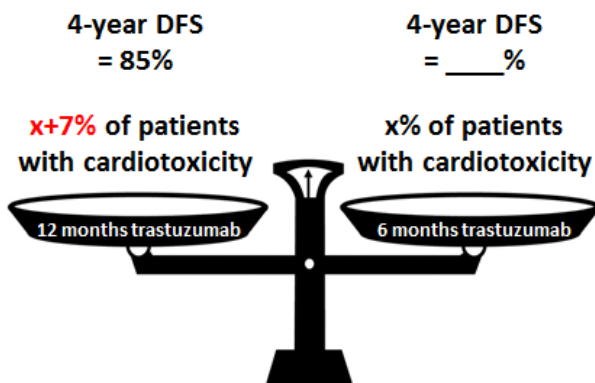
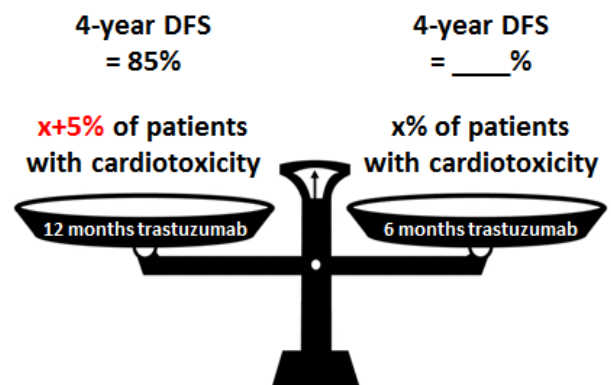
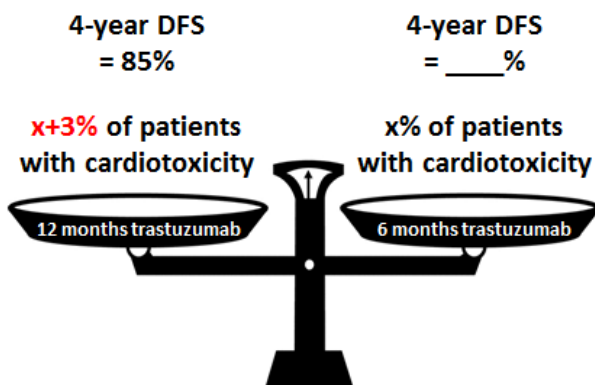
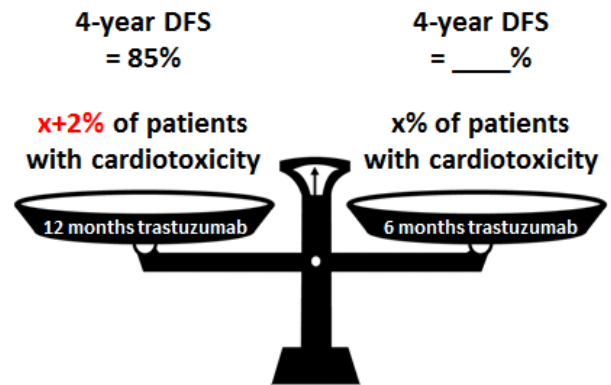
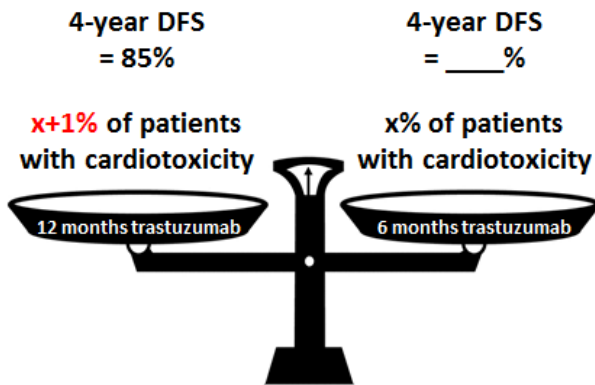
In your opinion, what % of patients would, during their trastuzumab treatment, ...	12 months trastuzumab	6 months trastuzumab
... suffer clinically relevant congestive heart failure [†] (CHF)?	_____%	_____%
... report an LVEF <50% <u>or</u> an ECHO/MUGA classed as 'abnormal' by a cardiologist?	_____%	_____%

[†] Clinically relevant CHF = symptoms of cardiac disease, or signs of congestive heart failure or receive medication for cardiac disease

Trade-off of Disease-Free Survival and Cardiotoxicity

We're now going to consider what decrease in DFS might be deemed as acceptable to avoid various **hypothetical increased levels** of cardiotoxicity (defined as LVEF <50% or an ECHO/MUGA classed as 'abnormal' by a cardiologist).

Assuming 12 month trastuzumab gives a 4-year DFS of 85%, how low a 4-year DFS would you accept as a trade-off to avoid the following **hypothetical absolute increases** in cardiotoxicity rates?



Please use the section below should you wish to add any comments

Thank you very much for taking time to consider the questions and complete this questionnaire.

Please return this questionnaire to Shrushma Loi, PERSEPHONE Trial Co-ordinator.

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OR

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