

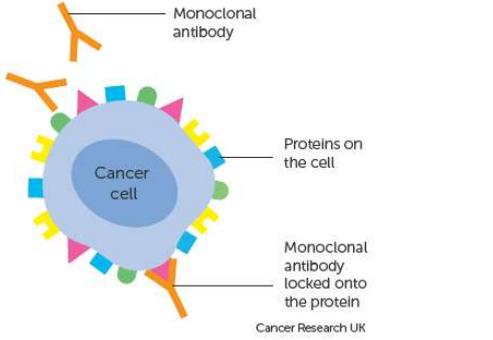
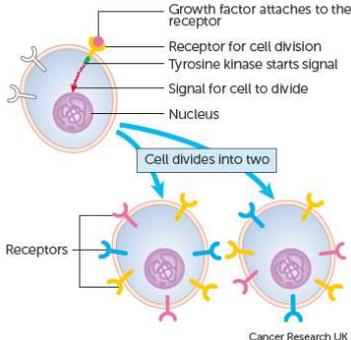
## Appendix 1: Example of a 2 page Study Aid

**Royal Marsden DDU Early Phase Clinical Trial Study Aid****Phase 1 Dose Expansion ICE-CAP (B1 prior IO, B2, B3 non resectable GBM)**

The complete trial participant information sheet (PIS) can be complex and this 2 page study aid is intended to help you understand your trial using simple jargon free language and clear diagrams. We have developed this summary based on feedback from patients to highlight information that you may find useful when making your decision to participate or not. Please use this study aid in conjunction with the online video educational modules we have provided you with.

**1. What is this trial testing?**

This trial is testing the combination of two anti-cancer drugs

<b>Atezolizumab (immune therapy)</b> an immunotherapy agent, approved for use in cancer care for the last four years, given as an injection through the veins (IV), designed to help your immune system recognise and slow down the growth of the cancer	<b>Ipatasertib (IPA)</b> A new/experimental oral targeted therapy drug, designed to target and reduce the activity of a overactive signal (Akt-PI3K) that drives cancer growth
 <p>Monoclonal antibody</p> <p>Cancer cell</p> <p>Proteins on the cell</p> <p>Monoclonal antibody locked onto the protein</p> <p>Cancer Research UK</p>	 <p>Growth factor attaches to the receptor</p> <p>Receptor for cell division</p> <p>Tyrosine kinase starts signal</p> <p>Signal for cell to divide</p> <p>Nucleus</p> <p>Cell divides into two</p> <p>Receptors</p> <p>Cancer Research UK</p>

**2. What type of clinical trial is this?**

This is a **Phase 1 dose expansion trial** and the main reason we are conducting it is to work out the side effect profile of this combination of drugs and whether they have any impact on cancer growth when used in humans. This combination has been through a dose finding stage where we worked out the safest dose to use. This trial will consist of procedures and treatments that are not standard for your type of and remember that these trials are designed primarily to understand these drugs to help future patients.

**3. Will it benefit me?**

We do not know. We allocate patients to a trial based on what has been observed in the lab (in glass dishes or animal models such as mice) or with patients who have tumours similar to you but this does not mean that you will necessarily benefit from this trial. It is possible that there will be no direct medical benefit from participating in this trial.

**4. What are the risks of participating in the trial?**

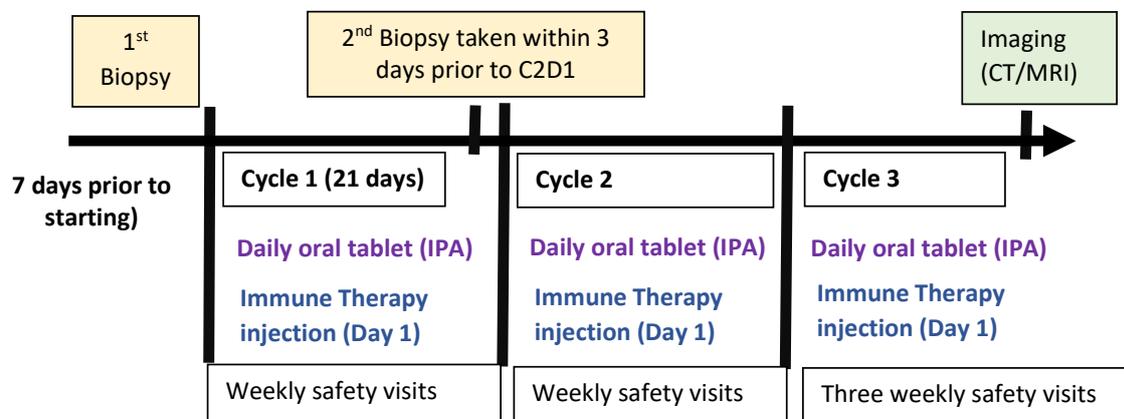
- We have an extensive understanding of the side effects of immunotherapy as it is a treatment that has been used in standard of care oncology for several years now. In the process of activating

your immune system, there can be autoimmune side effects and while these can be treated with steroids, sometimes these can be serious.

- Ipatasertib can cause high blood sugar and diarrhoea.
- For a full list of side effects please refer to page 8-10 of your trial information sheet.
- Given this is a new combination of drugs there may be unexpected side effects
- Risk to unborn children - if you are a woman and there is a chance you could be pregnant or a man and could father a child, you will need to adhere strictly to two forms of contraceptive measures during the study and for 6 months after the study -see pages 11 -12 of the trial PIS for more details.

##### 5. What will this trial require of me?

- Phase 1 trials are time intensive and we will demand more of your time in terms of visits and procedures than ordinary treatment given in the clinic.



##### 6. Do I have to go on this trial?

No - this is never the case, and there are always alternatives. For example, there is the option to focus on your quality of life— please discuss the risks and benefits of your various options with your doctors.

##### 7. Who do I call if I am sick?

During the week, please contact Oak ward via Royal Marsden Hospital switch or the Clinical Nurse Specialist you met in clinic. On the weekends, please call the Macmillan Hotline who will direct your call to one of the Drug Development Unit Consultants, one of whom is on call 24 hours a day, 7 days a week. Safety is our key priority, and you should never hesitate to call us.

##### 8. Will I be reimbursed for my travel?

Yes, please retain your fuel or public transport receipts for travel to and from the hospital and present them to the clerk on Oak ward. If you travel from afar, there may be capacity to reimburse staying near Sutton the night before.

##### 9. Can I go on holidays during the trial?

We ask you to not schedule any holidays for the first two cycles – this an experiment and there may be unpredictable side effects that can only be managed by our specialist expertise. Our primary concern is your safety and we are not able to provide care if you are overseas or not reachable. Depending on the progress of your disease and how you tolerate the treatment we can discuss holidays from the third cycle on.