

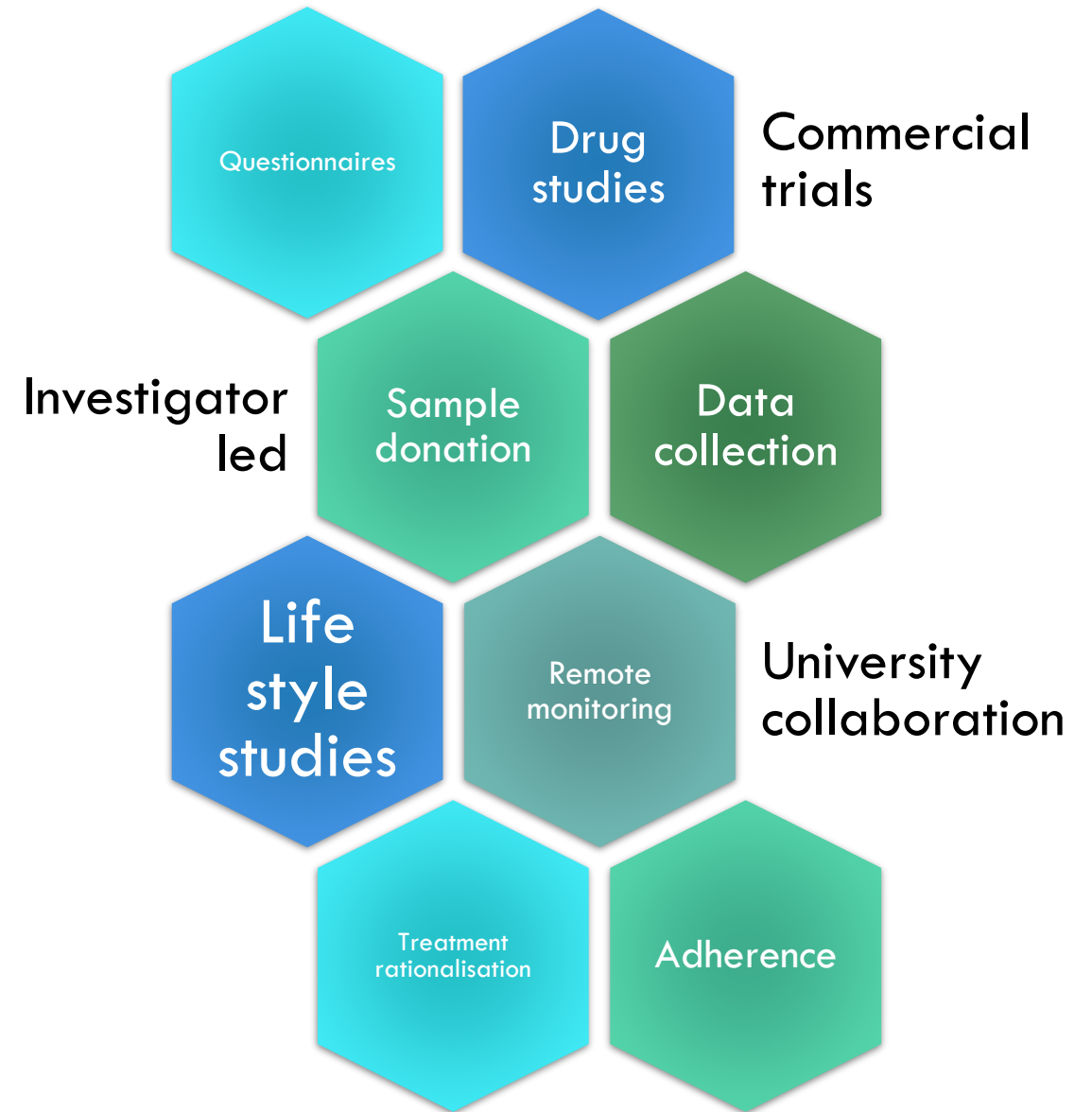


PATIENT FLOW THROUGH A RESEARCH STUDY



RESEARCH AT THE AWACFC

We host a wide variety of research at the All Wales Adult Cystic Fibrosis Centre, with the aim to be inclusive as possible and provide opportunities for all.



INFORMATION GIVING AND INFORMED CONSENT

- Your CF team may contact you or approach you in clinic to provide information about upcoming and open studies you may be eligible for
- Before any research starts you will be given the full information sheet (called a patient information sheet (PIS)) that outlines the full details, including risks and benefits of taking part. Feel free to discuss participation with family/friends as you wish
- The doctors and research nurses will discuss the study with you and give you an opportunity to ask questions before the study begins. But this does not mean that you cannot ask questions or discuss aspects of the study once it has started. The research nurses are here to support you throughout the research process so please let them know if you have any questions or concerns.
- Informed consent form (ICF) must be completed prior to any research activity taking place and the doctor/nurse will guide you through completing this.



CAN I CHANGE MY MIND ONCE I JOIN A RESEARCH STUDY?

YES

Taking part in research is completely voluntary and you are free to withdraw at any time

Changing your mind will not have any impact on your medical care and you won't be treated any differently.



ELIGIBILITY

- Each study has its own eligibility criteria that determines who can and can't take part (i.e. genotype, transplant status, significant comorbidities)
- Each study is different, so if you can't take part in one you may well be eligible for another
- Eligibility confirmed by doctors and the research team
- If you have any questions about which studies you might be eligible for please speak to the research team/doctors



SCREENING

- Once it has been established that you may qualify for a study you wish to take part in we schedule a screening visit (most drug studies have a screening visit, other types of studies may not)
- First formal visit of a research study
- Aim is to establish eligibility & clinical stability to enter the trial

- Typical screening visit procedures: Signing of ICF, demographics/background information, height/weight, physical examination, pregnancy test (if applicable), ECG, spirometry, vital signs, bloods (full panel serum chemistry, haematology, coagulation, genotype (if applicable), medication review, AE review.



RANDOMISATION / ENROLMENT

- Once eligibility confirmed, all screening tests are back and you are happy to continue can enrol and/or randomise
- This assigns the study treatment to you at random – we have no input into the decision and it is reached through a validated, computerised system.
- We can then scheduled for the first day of study drug dosing.
- It is important that you do not throw away empty medication packets/bottles as these are needed to confirm adherence.



STUDY VISITS

- Study visits range between studies, depending on the safety monitoring requirements set out by the protocol
- Typically they are every 2-4 weeks for later phase studies and much more intense for early phase and can even be consecutive study visit days involving inpatient stay.
- Usual activities for study visits include: confirming continuing consent, vital signs, ECG, spirometry, bloods, physical exam, study drug dosing/reconciliation, AE/meds review.
- Can be longer if PK sampling is required (repeat blood sampling over 6-12 hours post dose)



FINAL VISIT / ROLL OVER TO OPEN LABEL

- At the end of the study you will come in for a final visit and return all study provided equipment/medication
- If a study is being extended to open label then you may wish to continue on to the new protocol with no gap in treatment.
- Open label = we know you are definitely taking the active study drug
- Sometimes it can be difficult to come to the end of a study and suddenly have to stop a medication, but where possible we will minimise this impact and you will always be fully supported by your CF team.

