



## The ABCD Nationwide Empagliflozin Audit - Objectives

Using modern technologies on the NHS N3 computer network to facilitate easy gathering of anonymised data, ABCD is setting up a nationwide audit of empagliflozin (Jardiance) in real clinical use in the UK. The aim will be to ascertain whether the experience in real clinical use matches the data from phase 3 clinical trials. Clinicians using empagliflozin will be invited to submit the data that they routinely collect as they monitor the progress of their patients (HbA1c, weight, side effects etc) to the nationwide audit. An IT tool has been developed on the NHS computer network, N3, to make this process as easy and user friendly as possible. It will also facilitate easy analysis of locally collected data by the local clinicians. ABCD hopes to gain insight into both the safety and efficacy of empagliflozin. ABCD hopes that the data from the nationwide audit will inform future practice and guidelines.

From the data submitted in the audit ABCD hopes it might be able to quantify and analyse in detail:

- How much **HbA1c reduction** occurs with empagliflozin in real clinical use. Is this reduction durable over time in the real world?
- How much **weight loss** occurs with empagliflozin in real clinical use. Is weight loss durable over time?
- What is the impact on **blood pressure** with empagliflozin in real clinical use.
- What is the real world experience of **progression to insulin treatment** in patients treated with empagliflozin? Is this delayed?
- What is the impact on **lipids** of empagliflozin in real clinical use.
- What is the impact on alanine aminotransferase (ALT) of empagliflozin – through weight loss and impact on lipids might empagliflozin improve non-alcoholic fatty liver disease (**NAFLD**).
- Who are the patients **who respond** especially well to empagliflozin in real clinical use – does it relate to initial HbA1c, weight, body mass index, duration of diabetes, initial age or sex, or particular other medications being used etc. Is it possible to predict the patients who are more likely to respond to empagliflozin.
- Similarly, who are the patients **who don't respond** to empagliflozin?
- What are the **side effects**? They seem to be relatively minor and tolerable in the clinical trials but is that also the case in real practice? Are there any important side effects that have not yet been identified?

- If there are **safety issues** with empagliflozin which may come out in due course, we hope to get some forewarning of these now through pooling the national experience.
- To what extent does empagliflozin allow avoidance of insulin and continuation in their jobs for **professional drivers**, or regaining of their jobs for such workers who have lost them through insulin?
- What is the size of the problem of **hypoglycaemia** with empagliflozin and insulin, or empagliflozin and sulphonylureas. Is there a problem of worsening hyperglycaemia if insulin is reduced and empagliflozin started? Are there guidelines that can be deduced from the nationwide experience with regard to how to add empagliflozin to insulin and how to add empagliflozin to sulphonylureas without inducing hypoglycaemia or hyperglycaemia.
- What percentage of patients **cannot tolerate empagliflozin** in real clinical use?
- Is the clinical **efficacy of empagliflozin sustained** in real clinical use? Does the weight loss continue with time or does it plateau off?
- Are there important differences with regard to **dose of empagliflozin** used – 10mg versus 25mg. What are the characteristics of the patients given the two doses. How great is the difference in efficacy in real clinical use?
- What percentage of patients progress from the 10mg dose to the 25mg dose? What is the **effect of increasing to 25mg on HbA1c, weight, BP** etc?
- Through comparison with data from the ABCD nationwide dapagliflozin and canagliflozin audits, are there **any noteworthy differences of between the three SGLT2 inhibitors**?
- Through combining the data obtained in the three audits is there more power to demonstrate **important class effects** earlier – such as durability of effect on HbA1c and weight in real clinical use?