

ABCD (Diabetes Care) Ltd Audit Lead Role Description

Role Title: Clinical lead, ABCD audits of new diabetes therapies and devices.Reports to: Chair of ABCD CommitteePurpose of the role: To manage the ABCD Audit Programme.

Outline of the work

- As new diabetes medications and technologies are launched or are likely to be launched, the clinical lead should approach the companies concerned and explain the ABCD audit programme of new diabetes therapies and devices.
- Explain the difference between the real-world data which ABCD collects and the RCTs which gathered the evidence which brought the treatments to market.
- Explain that when the new treatments go into real clinical use that it is often a completely different set of patients who receive the treatment than in the clinical trials and it is important to find out what happens in this real-world situation.
- Show them the enormous amount of learning that has been achieved historically: <u>https://abcd.care/all-abcd-audit-publications</u> For a diabetes medication audit point them to <u>https://abcd.care/abcd-nationwide-liraglutide-audit-publications</u> as an example of what can belearned. For a new diabetes technology audit point them to <u>https://abcd.care/abcd-nationwide-freestyle-libre-audit-publications</u> as an example of what can be learned.
- Explain that the audits are independent and that the company can have no say in or control over the audit whatsoever though they can make suggestions though we explain that ABCD is not in any way bound to take their suggestions.
- Negotiate with the company for funds to support the audit. Each company is different; one finds oneself negotiating with different departments depending on with department the company in question thinks is most appropriate.
- Make application according to need of the Company in question often filling in long documents.Create an audit objectives document this will sometimes become part of the contract.
- Ensure the funding is enough to cover the cost of audits clinical lead, research fellows, audit administrator, online tool creation, ABCD overheads.
- Agree timescales for the audit establishment, data collection and reporting and timescales forpayments to ABCD.
- As the contract emerges check with great care and edit as needed the contract writer often does not have the understanding of the ABCD audits programme and the clinical lead who should adjust accordingly.
- Once the contract is signed develop the audit questionnaires first visit data entry form and follow-up visit data entry form. Be extremely wary of making the questionnaires too lengthy – decide carefully what data is most informative to collect.
- In parallel undertake contracting process with Harvey Walsh for development of a new audit tool.
- Supervise the development of the new tool explaining carefully ensuring that their software engineers understand exactly what the tool needs drop down choices, yes/no etc. Most audits are nationwide, and the tools are developed on the NHS network. If the audit is worldwide, then the tool is developed on a different server outside of the NHS network. In some cases (eg FreeStyle Libre) the tool was developed on both servers so that Northern Ireland, which is outside of the NHS network, could partake.
- Once developed, test the not yet live tool carefully with mock patient data to find as many of theinevitable bugs as possible. Once apparently debugged, test further with real patient data searching for any further bug s The audit tool needs to allow the user to download and analyse their data. This section needs to have a download of "Basic



Output" and another of "Sophisticated Output" the latter being to makedata download and analysis easy for those with limited experience with data analysis.

- Develop an admin logon to the tool for downloading national data in anonymised form. This tool should also allow us to know who the audit contributors are, and what audit sites and centres they are from and to know how many patients they have entered so that we can develop a list of all contributors and of the biggest contributors. Test the admin tool. In parallel develop the webpage for the audit ready for go-live
- Once the tool is debugged, make it live, including the real patient data that was entered duringtesting.
- Develop a webpage to apply to join the audit.
- Develop a webpage with Harvey Walsh to log on to the audit.
- Develop a standard email for the audits data administrator to send to all applicants with their logininformation.
- Once the audit is ready, make all aspects of it live, announce it on the ABCD website and ensure the ABCD membership is alerted by specific email or through the ABCD member update email.
- Use appropriate networks to spread the word and encourage participation.
- Explain that all contributors are listed in all papers and presentations from the audit and the biggestcontributors are invited to be co-authors.
- Supervise the audits administrator in the day to day running of the audits.
- Deal with and respond to the multiple emails that are continually coming in regarding the multipleaudits.
- As abstract deadlines approach (eg ABCD, DUK, ATTD, ADA, EASD) consider which audits might be analysed for possible abstract submission.
- Create the abstracts, identify the co-authors, decide who will be presenting author etc observe therules for the meeting concerned re how many first author papers for the same author are allowed.
- Share the abstract with the co-authors setting deadlines for their responses.
- As particular audits mature sufficiently convert meeting abstracts into papers. Choose whichjournals most appropriate for the findings.
- Consider what audit analyses might be appropriate for the next issue of BJD and write papers accordingly.
- Appoint and then supervise the ABCD audits research fellow(s) in their support for all of the above.Write reports for the main ABCD committee meetings.
- Present the ABCD audits programme at the main ABCD meetings and encourage participation by members.

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