CASE STUDY – EFTISARC-NEO

Unlock the Power of Clinical Data: Automating Data Entry with CliniNote

Learn how CliniNote transformed gathering Real World Data
for life changing clinical trials in oncology

Highlights:

THE PROBLEM

Manual data entry for clinical trials based on unstructured notes was time-consuming and often burdened with discrepancies

THE APPROACH

CliniNote implemented a new method to structure data while medical notes are being prepared and enter it to the eCRF semi-automatically.

THE IMPACT

The study team has so far saved the equivalent of 246 hours of it's budget for (manual) data entry and reduced the number of discrepancy notes almost 7 times when CliniNote solution was used by clinicians to collect and to enter data.

Introduction and context

***Customer**: PIB-NIO - Poland's biggest oncological research institute*
Employing over 400 medical doctors and helping 400 000 patients per year
Focus on treating oncological diseases with using state-of-the-art methods.

Project: Phase II single-arm single-stage clinical trial evaluating new therapeutic option including immunomodulation in soft tissue sarcomas. Systemic treatment lasts for 9 weeks (study week 1-9). Radiation therapy lasts for 5 weeks (5 days per week) in weeks 2-6. Surgery takes place 5-6 weeks after completion of radiation therapy (week 11-12). Patients are followed up regularly for a period of 24 months.

Clinical oncologists from PIB-NIO in Warsaw, Poland were **facing the challenge** – how to find the time to provide Evidence-Based Care to their patients and be the part of clinical trials?

How to gather, analyse and use medical data to find corelations? **What is the most effective way to fill in eCRFs and ensure the data's quality**?

Doctors were overloaded with administrative work and **found it difficult** to work with complex eCRFs. Medical professionals wanted to take part in more clinical trials to improve their patient care, **but it was impossible while doing it the old way**. Spending hundreds of hours on frustrating administrative tasks to copy data from medical notes to eCRF, manually extracting data from unstructured, often chaotic text, could no longer be accepted.

PIB-NIO **needed a solution** that saved time and promised reliable data structurization and conversion. **Something had to change**, so they turned to CliniNote.

The method

CliniNote worked with doctors to get to know their everyday challenges, which made it possible to **create tailor-made solutions**. CliniNote Assistant, a user-friendly browser extension, was efficiently introduced on hospital computers. The process took only a few minutes, which was highly appreciated by employees overloaded with work.

CliniNote analysed medical notes from the hospital and **identified key points from core data** sets. For clinical trial purposes, templates were created to ensure structurization of the note **to make it a mirror of the eCRF's framework**. With just a few clicks such templates are now inserted into the Hospital Information System and require minimal work from medical professionals filling them in, providing clear, interchangeable **high quality source materia**l for eCRF.

Doctors engaged in the project claim that using CliniNote did not take any more time than creating a medical note from scratch using their old method. That is a perfect example how **easy and user-friendly** the integration process is. We also observed the process of finding source data in past medical notes and matching it to parameters from eCRF. Finally, we calculated possible savings.

The results

The hospital staff noticed the benefits of CliniNote right away, especially how easy the implementation was and how much changed for their everyday challenges since CliniNote's incorporation.

CliniNote significantly improved the data collection process in the EFTISARC-NEO clinical study conducted in the Soft Tissue/Bone Sarcoma and Melanoma Department of PIB-NIO. The usefulness of the tool was very positively assessed by the doctors and the Head of the Clinic where the described clinical trial is being run.

Key points

Here's what the client got by switching to CliniNote solutions:

- **A 41% reduction in time needed just to fill in eCRFs with data in clinical trials on the examined data sample**
- **246 hours of data manager's work already saved using CliniNote, easily convertible into cash savings in a study budget**

- **7x reduction in the number of discrepancy notes for data entered with CliniNote compared to this entered manually!**

Hospital staff confirms that ever since switching to CliniNote solutions, taking part in clinical trials is **no longer such an administrative, frustrating burden**. Now, with CliniNote templates and semi-automatic algorithms, all stages of gathering medical data are **easier and faster**. With templates, documenting the visits **takes no more time** than classic, unstructured notes preparation and **no core information is omitted** in patient notes. All key parameters are measured and documented. The source material is better than ever – the **number of discrepancy notes dropped significantly,** gifting clinical oncologists more time for what they do the best – taking care of their patients.

CliniNote proved itself to be a solution helping in structurisation of data with proven time-and cost-effectiveness for medical research institutes.

"With CliniNote, the process of entering data into eCRF is much faster and more efficient, as we do not have to enter data manually. Automation eliminates the risk of delays, which are common in non-commercial studies. We plan to use CliniNote in subsequent projects for which we apply to the Medical Research Agency, because we see real benefits in streamlining research documentation."

Katarzyna Kozak, MD, PhD
Maria Sklodowska-Curie National Research Institute of Oncology Warsaw Poland
Soft Tissue/Bone Sarcoma and Melanoma Department

Ready to follow PIB-NIO's footsteps on the road to Real World Data? Contact us and see how CliniNote can make your problems in clinical trials go away.