Great meeting at the 3rd Clinical Research and Clinical Trials Innovation Forum

Meeting Summary

Fantastic meeting last Thursday with the Clinical Trials Innovation Project. A big thank you to all the speakers. For those of you who could not attend, Dr. Baroutsou, EL.E.F.I. President of the BOD gave us valuable information on the Electronic Heath Record (EHR) progress: The recent developments with regards to digital health transformations in Greece and their impact on clinical trials were discussed. The EHR for Greek patients is limited in practice at Primary care for the moment, while EHR extension to Hospitalized patients is expected in the next 6 months. EHRs include the patient summary in the form of international standard EN17269 and will merge shortly with lab results, imaging data, biopsies plus hospital discharge information. Hospitals digitization and Health databases interoperability with EHR is work in progress that holds great potential for the future of digitizing clinical trials in Greece.

Ms. Vazeou, Sr. Manager at Amgen, gave an eye opening presentation on Central Monitoring. Drivers for change, of the traditional monitoring model, existed long before the COVID pandemic, but the pandemic crisis made the need for change more apparent. Protocols increased in number and complexity demanding more efficient monitoring approaches. Sponsors in the forefront of new monitoring approaches, confronted the crisis more efficiently. On-site, remote, central and virtual monitoring can be used in combination by sponsors to address study risks and increase efficiencies.

Remote SDV/R was not used extensively during the pandemic, due to lack of integrated technical solutions and thus uneven site adoption & regulatory requirements variability. Nevertheless, pandemic revealed that rSDV was possible in many countries, around half of them, in a varying percentage of sites with vast majority of them being oncology units. In the future, it is expected to see changes in SDV/R space. Extended use of Risk Based Monitoring and statistical monitoring analytics will make SDV/R more targeted. The use of e-Sources, e-Consent, IP barcoded tracking systems and interoperability between sites, vendors and sponsor systems will allow extensive and more holistic use of rSDV/R.

Finally, we mentioned that we have seen studies change drastically in the past year, with the use of technology, on all aspects and not only SDV. Hence we are making a call for your questions-interests to make sure we discuss all areas that affect clinical trials innovation and not just SDV.

In our next meeting in September 2021, we will have an in-depth discussion on HER and how we can address clinical research issues within the design.

Have a lovely summer and we hope to see you at our EL.E.F.I. Conference, 28-30 June 2021!


STATISTICAL REVIEW GUIDES & INFORMS ONSITE/OFFSITE MONITORING
Use analytics to identify unusual distribution of data earlier/near real time: trends, outliers, mis-contact, non-compliance
Identify higher risk sites to target additional monitoring
clinical trials day
MAY 20 - 2021
Remote Clinical Trials-Pandemic Adaptation & Resulted Evolution
Remote Monitoring- SDV/R
Vera Vazeou,
Clinical Research and Clinical Trials Innovation Forum
20-05-2021: Remote Clinical Trials
SDV –Part II
clinical trials day
MAY 20 - 2021
Confronted the Crisis More Efficiently
Virtual Monitoring
Central Monitoring
Remote/ Off-Site Monitoring
On-Site Monitoring
Site –study level review of risk indicators and trends- informs site monitor for targeted actions needed
Discuss Data entry, Discuss enrolment/retention, Check CRF for protocol compliance -completeness and discuss findings, Train site staff, FU on issue resolution, Perform site evaluation or close out
In person assessment of site quality via SDR/SDV, IP accountability/compliance, ICFs review etc.
Data Management Review
Medical Review
Safety Review
Statistical Review