LETTER TO EDITOR

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Clinical Research and Clinical Trial Coding: A New Perspective

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Coding is an instrument which helps in bringing uniformity to the complete practice. Medical coding is compulsory mandate in many parts of the world, mainly USA and Canada. Medical coding is in itself a very professional aspect of medical practice. It helps in bringing harmonization to the practice and helps to remove the fault reporting in medical profession. Clinical trials are an important part of drug research which is often amalgamated with the medical practice. Regions other than America are becoming hot spots with respect to clinical research and clinical trial perspective. Though certain areas under clinical trials and clinical research, coding is compulsory but it is somehow restricted to clinical data management especially in the region of "Data Review and Discrepancy Management". The present letter especially focuses on bringing coding to complete clinical research and clinical trial perspective, hence bringing in clearer harmonization in clinical trials and clinical research thus restricting the fraud claims by the investigators and sponsors to bring false products in the market through false FDA approvals.

Clinical Research and Clinical Trials are important part of drug discovery process. It is only through clinical trials and research's that exclusive report of the trial product on its safety and efficacy in human subjects is known. Clinical research (CR) and clinical trials (CT) adds to the medical knowledge as well as disease knowledge. Thus, it holds a very important and crucial role in disease eradication and treatment goals. As already known CT and CR are conducted in different phases signifying the importance of knowledge as well as information generation to the investigators and sponsors as a whole. Phases like Phase I, Phase IIa, Phase IIb, Phase III and Phase IV, focus on different perspective of trial product in ranges from healthy volunteers to diseased volunteers. Each of the phases give prime focus on, Bioavailability, Bioequivalence, Dose proportionality, Metabolism, Pharmacodynamics, Pharmacokinetics, Drug disease interactions, Drug-drug interactions, Efficacy at various doses, Patient safety, Risk-benefit information and Epidemiological data. [1] Likewise Medical coding which focuses on coding every facet of medical practice from diagnosing to treatments such as interventions like surgery, Clinical research and clinical trial coding shall also be focused dearly.

Recent trends in Clinical research industry have seen drastic changes in the penetration towards other demographics such as in Asian continents. India is becoming a central hub for clinical trials and clinical research. Many claims of outcomes from CR and CT have been rejected by FDA highlighting the fraud claims of the investigational product. Bringing in coding in these demographics in the region of clinical research is the best possible way to curb this menace. Often clinical research which involves human volunteers are in need of medical interventions. Thus, coding can play crucial role in the present area. Harmonization in the clinical research practice would boost the authenticity of trials conducted in this part of the region. Moreover use of coding dictionaries such as MedDRA and WHO-DDE would be enhanced completely.

Clinical research and Clinical trial coding is the future of this industry to save it from getting perished due to illegal and fraud practices. Now is the trend of Electronic Health Records. Inculcating coding into these practices would bring in clear picture of the trials that are in actually conducted. This would also help in bringing better picture of results which we get from conducting trials. Transparency is the issue in clinical research which after implementing coding practices can boost the serviceability of the clinical trial practice as a whole.

Complete utilization of MedDRA (Medical Dictionary for Regulatory Activities) would result in if holistic coding approach is carried out in clinical research industry. MedDRA has wide range of applicability as it has documentated medical terms generated during all phases of clinical trails. In addition it has coding instruments for therapeutic indications such as signs, symptoms, diseases, diagnoses, modification in functions. [2]

An amalgamation of medical coding and clinical trial coding would help in claiming original claims and would regularize the practice in complete clinical research industry. Hence, I totally recommend drafting of Clinical research and clinical trial coding.

REFERENCES

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