3. Usability of data structures corresponding to those of the Clinical Data Interchange Standards Consortium (CDISC), who have defined the standard data format to be used in clinical trials.

The use of EDC is important in carrying out clinical trials effectively. However, in many cases, EDC cannot be introduced because of the above-mentioned factors. Accordingly, we have created EDC freeware to overcome these concerns.

Method: In the proposed system, we provide software that utilizes computer-aided design (CAD). This makes it easy to construct a suitable data input interface by arranging various components on the screen. Furthermore, to enable the use of touch-panel input devices such as iPads or tablet PCs, the resolution and other aspects of the input screen can be adjusted. The tables and database variables of the system conform to the standard domain and variables of CDISC.

Results: This system was first used on a server in the local server in 2012, and is currently employed on a cloud server to enable multicenter studies. The system has mainly been used to collect case data with respect to Phase 1 trials and the early development of equipment. Five studies and 86 cases have been registered so far. In clinical trials using an endoscope, an iPad was used to input data. Data collection was generally performed by CDISC Clinical Data Acquisition Standards Harmonization (CDASH) and the Study Data Tabulation Model (SDTM). The proposed system has been available to the public as freeware since 2014.

Conclusion: In the institute, the adoption of IT in clinical trials has been promoted through the introduction of this system. We can now conduct trials, including multicenter studies, more easily. Operating as freeware, this system has the clear advantage of low introduction costs compared with other commercial EDC systems. A number of free-of-charge EDC systems already exist, such as OpenClinica and REDCap. The point that distinguishes our EDC system is its adoption of Case Report Form design methods via CAD software, which provides excellent usability. Moreover, the proposed system is compatible with the standard domains in CDISC CDASH and SDTM, and so input data can be output in CDISC format without further processing. In future, we will consider adding new functions, such as a connection to Healthcare Information Systems. Therefore, this system is expected to prove useful in investigator-initiated trials and so on. The above points suggest that the widespread use of the proposed system in academia will lead to effective, low-cost clinical trial

No conflict of interest.

816   POSTER
Novel benchmark database of digitized and calibrated cervical cells for Artificial Intelligence based screening of cervical cancer

R. Gupta[1], A. Sarwar[2], V. Sharma[3], J. Suri[4], M. Ali[5]. [1]Sri Guru Ram Das Institute of Medical Sciences and Research, 9781709615, AMRITSAR, India; [2]Deptt. of Computer Science & IT University of Jammu India, Computer Science & IT, jammu India, India; [3]Department of Computer Science & IT University of Jammu, Department of Computer Science & IT, Jammu, India; [4]Govt. Medical College Jammu India, Pathology, Jmamu, India; [5]University of Jammu, Computer science & IT, jammu, India

Background: The primary objective of this research work is to develop a novel benchmark database of digitized and calibrated, cervical cells obtained from slides of Papanicolaou smear test. This database can serve as a potential tool for designing, developing, training, testing and validating various Artificial intelligence based systems for prognosis of cervical cancer by characterization and classification of Papanicolaou smear images.we have also presented a artificial intelligence based novel hybrid ensemble technique for efficient screening of cervical cancer by automated analysis of Papanicolaou smear images.

Material and Methods: The database prepared in this work consists of data of about 200 clinical cases, arranged in 7000 tuples; each tuple containing 40 attributes,corresponding to the features of cytoplasm and nucleus.The slides of pap-smear test were obtained from three medical institutions in northern India viz Government Medical College, Jammu, Acharaya Shree Chandra College of Medical Science and Hospital, Jammu & Nijjer Pathology Laboratory, Amritsar.The slides were observed and analyzed under microscope (NIKON Nikon Eclipse E400 DS-F12) with a digital camera, and an attached computer. For extraction features an open source software, CellProfiler was used developed by BROAD institute and MIT. Authors have also presented a novel hybrid ensemble technique for the predictive performance by coalescing the classifying potential of multiple learning algorithms.

Results: The screening of these Pap smear images can be regarded as classification into normal and abnormal cells i.e. two-class problem and also as an elaborated classification into different respective stages according to the 2001-Bethseda system of classification. Among all the algorithms implemented, the hybrid ensemble approach outperformed with

ROC Area of 0.998 for 2-class problem and about 0.996 for Multiclass problem.

Practical implications of the study: The Novel Digital Database and Novel Ensemble Technique proposed in this work can be combined together to device a hardware tool which could facilitate easy and convenient mass level screening of cervical cancer.The tool could be devised in such a way as it would be usable not only to the medical doctors but also to the trained medical technicians, for preliminary screening which would be subjected to further diagnostic subroutines, if required. This way the novel database and the novel hybrid ensemble technique would potentially help in mitigating not only the mortality due to cervical cancer but also would help in reducing the financial burden on individual nations and the world as a whole.

No conflict of interest.

817   POSTER
PROACT: A new way of engaging and empowering patients that fundamentally changes our understanding of tolerability impacts in early clinical development

A. Hughes[1], D. Landers[2], T. Arkenau[3], B. O'Connor[4], J. Royle[5]. [1]Manchester Cancer Research Centre and AstraZeneca, Experimental Cancer Medicine Team at The Christie NHS Foundation Trust, Manchester, United Kingdom; [2]AstraZeneca, Early Clinical Development, Macclesfield, United Kingdom; [3]Sarah Cannon Research Institute, Harley Street, London, United Kingdom; [4]PatientPharma, CEO, Dublin, Ireland; [5]AstraZeneca, Patient Safety, Macclesfield, United Kingdom

Background: In developing a new medication, excellence in both clinical delivery and the understanding of the patient tolerability are required to deliver optimal treatment. However, in early clinical studies it is difficult for patients to contribute directly to the understanding of a new compound. Patient Reported Opinions about Clinical Tolerability (PROACT) provides a new, simple and innovative way in which patients can collaborate.

A pilot was conducted involving patients in AstraZeneca (AZ) studies, at the Sarah Cannon Research Institute (SCRI) UK, to investigate patient uptake of PROACT and to characterise information captured by the PROACT system.

Material and Methods: Patients enrolled were required to have their own mobile device and consent to taking part. Patients used PROACT to upload video messages that become instantly available to their clinical team. The team can reply to the patient within PROACT. After a delay, the patient's video is analysed and personally-identifiable information is removed. The information is then made available to the sponsor in an analytics module for decision-making.

Results: 16 people were informed of the PROACT pilot. Of these 16, 8 people had a smart device and consented to take part. Use of PROACT varied and all messages volunteered by patients were relevant and informative for drug development. Topics disclosed included tolerability impacts, study design, and drug formulation. Alignment with the clinical study data provided a richer understanding of tolerability, impact on patients, why this was, and the consequences of treatment. The results of the analysis enabled the sponsor to begin to answer questions such as 'which aspects of study treatment or conduct are most impactful?', and 'how are patients self-managing their care?'. This information can then be shared to support patients and enhance their experience.

Conclusions: This is a first step towards a new way of engaging and empowering patients that fundamentally changes the communication paradigm within an ongoing clinical trial. As previous studies have shown, engaged patients who have the skills, ability and willingness to help manage their own health have better health outcomes at lower cost to the health system.

Conflict of interest: Ownership: Bartley O'Connor is CEO of Patient-Pharma who have build the IT platform.

818   POSTER
Comparative proteomic and glycobiologic analysis of fibrosarcoma and fibroblast cell line secretomes

O. Meral[1], H. Uysal[1]. [1]Ankara University Faculty of Veterinary Medicine, Department of Biochemistry, Ankara, Turkey

Background: The secretome analysis, comprises the proteins released by cancer cells or tissues, serves useful tools for the discovery of novel biomarkers. Comparative glycobiologic and proteomic analysis of cancer and normal cell line secretomes provides for a better understanding of the molecular mechanism of cancer development and is essential for developing more efective strategies for new biomarker or drug discovery. The present study aimed to evaluate the difference of protein expressions