KS/GCP-20151001

TRAINING COURSE

THIS IS TO CERTIFY THAT:

HAS PARTICIPATED IN

Good Clinical Practice for Investigators – Paediatric trials
Identification no. in SACCME: 15100928

COVERING FOLLOWING TOPICS

ICH and GCP overview, The Principles of ICH E6, ICH E6 article 4 (Investigator qualification and agreement, Adequate Resource, Medical care of Trial Subjects, Communication with IEC, Compliance with Protocol, Investigational Product, Randomization Procedures and Unblinding, Inform Consent of Trial Subjects, Inform Consent of Trial Subjects – paediatric clinical trials, Records and Reports, ALCOA, Safety Reporting, Premature Termination or Suspension of Trial, Final Report)

19.10.2015

Mgr. Katarína Kováčová

Credits for attendance: 5

KOVAC SERVICES S.R.O.

The credits are acknowledgments according the regulation of Ministry of Health 366/2005 as amended by the act, and according the agreement between Slovak Accreditation Council for Continuing Medical Education (SACCME) and European Accreditation council for Continuing Medical Education (EACCME).
This ICH E6 GCP Investigator Site Training meets the Minimum Criteria for ICH GCP Investigator Site Personnel Training identified by TransCelerate BioPharma as necessary to enable mutual recognition of GCP training among trial sponsors.