



A+ Science Newsletter, August 2017

*"In the midst of movement and chaos, keep stillness inside of you."*

Deepak Chopra

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We are back after a short break in July. We hope your summer has allowed you some well needed vacation time to reflect, recharge and enjoy the beautiful weather with friends and family. Good quality time off is what really catapult things and gives a renewed sense of enthusiasm and energy to make great things happen.

In this month's newsletter, we have a message from our Pharmacovigilance Team.

EMA will launch a new EudraVigilance system with enhanced functionalities for reporting and analyzing of suspected adverse reactions. A successful result has been announced from the independent EudraVigilance audit and a favorable recommendation from the PRAC, thus confirming that the EMA is on track, and the new EudraVigilance system is expected to be released 22 November 2017.

Our Pharmacovigilance Department is happy to announce that our safety database is compliant and prepared to ensure full compatibility for the new E2B (R3) format, built on the ISO ICSR standard. MAHs can submit individual case safety reports in E2B (R2) format, however, any receipt of ICSRs from EudraVigilance will be in E2B (R3) format only. This requires a compliant and updated database. A contingency plan is also developed to ensure a validated conversion tool is available for use to make sure readability of the files immediately if required.

A+ Science offers support in understanding how the new regulations impact your business and we are available to assist throughout the transition period.

The aim of pharmacovigilance is the safer and more effective use of medicines for everyone. It involves all activities that relate to noticing, assessing, understanding, managing and preventing adverse effects of medicines.

The pharmacovigilance team at A+ Science can offer you complete solutions.



Nordic Life Science Days 2017  
12-14 September, Malmömassan

Do not forget to stop by booth E04 in the main hall to meet representatives from A+ Science!

If you wish to book a meeting with any of our representatives, email us at [info@a-plusscience.com](mailto:info@a-plusscience.com)



A+ Science will be attending several events. If you will be participating and wish to meet us there, please send an email to [info@a-plusscience.com](mailto:info@a-plusscience.com)

Nationell konferens om kliniska studier, 7–8 September, Stockholm  
NLSDays 2017, 12-14 September, Malmö - Medicon Valley  
Park Annual 2017, 27 September, Sahlgrenska Science Park, Gothenburg  
BIO-Europe 2017, 6-8 November, Berlin  
Läkemedelskongressen, 7 November, Stockholm

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