



## Allan K. Johansen's Audit Experience from July 1997: Regions/Countries, Audit Types and Therapeutic Areas

### Western Europe:

Austria (1)	Denmark (5)	Finland (2)
France (2)	Germany (4)	Italy (1)
The Netherlands (3)	Norway (1)	Spain (2)
Sweden (3)	United Kingdom (3)	<i>Total W. Europe:</i> 27

### Central & Eastern Europe:

Czech Republic (1)	Croatia (1)	Hungary (1)
Poland (2)	Russia (2)	<i>Total CEE:</i> 7

### Africa:

Ethiopia (3)	Senegal (1)	South Africa (9)
Uganda (2)		<i>Total Africa:</i> 15

### Asia-Pacific:

Australia (55)	Bangladesh (5)	China (25)
India (7)	Japan (1)	Malaysia (1)
New Zealand (9)	The Philippines (4)	SAR Hong Kong (7)
Singapore (4)	South Korea (6)	Thailand (16)
Taiwan (10)		<i>Total A-P:</i> 150

### The Americas:

Argentina (5)	Canada (3)	Mexico (3)
USA (17)		<i>Total NA &amp; LA:</i> 28

<b>Types of audits</b>	<b>Number of audits</b>
<i>Investigator Site*</i> audits Phase II-IV - including visits to local lab(s), imaging dept., pharmacy, local Ethics Committee, as well as local company affiliate or CRO office, some in combination with company Affiliate Clinical Management System or CRO in-process audits (*incl. 'For cause': 2, Pre-Regulatory Inspection Visits: 8)	Lead: 101 Co-auditor: 59 Total*: <b>160</b>
<i>Service Providers</i> (CRO/AROs, IRB) - pre-contract (qualification) / in-process audits	11 / 16
<i>CPU / Phase I Unit</i> - pre-contract (qualification) / in-process audits	13 / 16
<i>Pharmacovigilance</i> audits (at local company Sponsor Affiliates offices)	7
<i>Sponsor Clinical Management System</i> audits / Gap Analysis	7 / 2
<i>Laboratory</i> audits (incl. hospital labs functioning as central labs for clinical trials) – pre-contract (qualification) / in-process	1 / 3
<i>Documents: Clinical Study Report (CSR)</i> audits	2
<i>(Due Diligence)</i>	2)
<i>(Hosting of FDA foreign invest. site inspections</i> (China/HK & Thailand)	2)

### **Therapeutic Areas** covered in audits / QA projects:

CNS (Huntington, Alzheimer), Endocrinology (Diabetes - IDD & NIDD, Obesity), Emergency Medicine, Graft Rejection (liver & kidney), Infectious Diseases (HBV, HCV, HIV, Human African Trypanosomiasis, Malaria, visceral Leishmaniasis, and pulmonary TB)  
*(continued over)*



**a<sup>3</sup> GCP consulting**

**Therapeutic Areas – continued:**

Oncology (e.g. breast, gastric, melanoma, pancreas, prostate and pulmonary).

Other: Neutropenia, Osteoporosis, Rheumatoid Arthritis, Thalassemia and Vaccines (e.g. Influenza and Ross River), plus Medical Devices (pain management)

[As of Dec. 2015]