Turkey – At the Crossroads of Asia and Europe

To a lot of Europeans, Turkey is — let's face it — tucked away past the Balkans, out on the eastern edge. It's a great place to go on holiday, has lovely beaches and some interesting archaeology, and then there's that song about Istanbul (not Constantinople) that remains a pop culture fixture. But if that's all that comes to mind when you think about Turkey, then you really are missing the point.

The country was a founding member of the UN and belongs to NATO, the OECD and the Council of Europe. It is one of the G20 economies, is an associate member of the EU, and is fully part of the EU Customs Union. The first application to join the EU as a full member was made in 1999 and ongoing negotiations started in 2005.

As a bridge between Europe and the Middle East and Asia, Turkey occupies a unique position, with a population of around 75 million, nearly three-quarters of whom live in towns and cities. Most are considered to be ethnically Turkish, but there are also people of Armenian, Greek and Jewish origins, with minority ethnic groupings of Abkhazians, Albanians, Arabs, Assyrians, Bosniaks, Circassians, Georgians, Hamshenis, Laz, Crimean Tatars, Bulgarians, Pomaks and Roma.[1]

From a pharmaceutical R&D perspective, this wide diversity offers a great opportunity for data spread within a clinical trial — all while dealing with one administration, the Turkish Medicines and Medical Devices Agency (TMMDA). The Turkish regulations are completely in line with EC Directives (EC 2001/20 and EC 2005/28), so adding the country to a trial running within EU countries should not require significant additional work, following ethics approval.

To date, over 1500 trials have taken place in Turkey.[2] The Middle East and North Africa region as a whole accounts for only around 1 % of the distribution of clinical trials, so this low density of trials offers significant opportunities for growth.

What Does the Trial Environment Look Like?

Turkey has a highly-centralised healthcare system and many world-class healthcare facilities, following a significant reform programme introduced in 2003. In 2012, there were 129,772 physicians treating an average of 583 patients each.[3] Doctors are interested in participating in clinical trials, and speak good English. Turkey is considered to have a unique patient base, especially for studies in hepatitis, and genetic diseases.

The Clinical Trials Department of the TMMDA reviews clinical trials in Turkey. Its staff numbers have grown exponentially in recent years. Under the Clinical Trials Department, there are a phase evaluation unit, bioequivalence/bioavailability evaluation unit, and a post-marketing surveillance evaluation unit. The department has a programme working to standardise ethics approvals and improve on time from submission to approval. The goal is to reach targets of 30-day approvals for ethics and 30-day approvals for the Turkish Ministry of Health, which monitors the timing taken by ethics committees and has taken more of a performance-based approach.

YEAR	PHASE I	PHASE II	PHASE III	PHASE IV	BA/BE*	PMS**
1997	0	2	66	48	2	0
1998	0	2	61	50	0	0
1999	0	5	59	59	0	0
2000	0	4	66	52	4	0
2001	0	5	61	92	16	0
2002	2	10	71	103	13	0
2003	0	10	81	89	33	0
2004	0	18	74	136	80	7
2005	0	10	66	135	143	21
2006	0	17	71	198	109	36
2007	0	16	105	214	92	45
2008	3	17	114	177	96	42
2009	5	28	113	147	81	78
2010	4	23	102	178	97	50
2011	4	18	71	51	109	31
2012	0	32	123	93	105	38

*BA/BE: Bioavailability/Bioequivalence.
**PMS: Observational studies with drugs .

Numbers of clinical trials from 1997-2012 [4]