

Clinical Trial Diversity Planning for Sponsors: What to Know About FDA's Recent Draft Guidance



On April 13, 2022, the U.S. Food and Drug Administration (“FDA”) issued a [draft guidance](#) providing specific recommendations to the industry on how to improve diversity in clinical trials. The FDA’s focus on increasing racial and ethnic diversity in clinical trials is not new, with the agency issuing several guidances since 2016 on this topic.^{[1](#)} However, the recent draft guidance sets out new expectations for sponsors conducting clinical trials intended to support marketing authorization of drugs, biologics, and medical devices.

Read the [client alert](#) by FDA Senior Associate [Elizabeth Mulkey](#) and Partner [Alexander Varond](#).

The Unified Patent Court is (Finally) Coming to Europe and Bringing Some Pretty Fundamental Changes with It



Seven years after the Member States of the EU signed the Agreement on a Unified Patent Court (“UPCA”), the Unitary Patent (“UP”) and the Unified Patent Court (“UPC”) are likely to commence during the second half of 2022. This promises to bring significant changes to patent protections across Europe, potentially making it easier to both assert *and invalidate* a patent in 24 Member States. Importantly, if current European Patent (“EP”) holders wish to opt out of the UP in favor of the existing EP regimen, it will require that they take affirmative steps to do so.

Read the [client alert](#).

European Life Sciences Deal Trends



In Europe, life sciences deals increased over the last few years with a strong acceleration in 2021. As a result, the market wonders whether this is just a pick or rather a steady trend which will impact our market in the future as well. Analyzing the reasons of such growth and comparing it with more mature markets such as the U.S. comfort us in thinking that it is just the beginning for continental Europe.

The U.S. life sciences market has been very strong over the past decades and is seen as very mature. The level of venture investments, which are now very much standardized, licensing, M&A and IPOs is very high, both in volume and in number.

For the last ten years or so, the life sciences UK market attracted U.S. investors and an increasing number of growth funds. After a first step of development through venture investments, such companies are now ready for licensing, M&A and IPOs. This is also the trend that we anticipate for the European market even if each country or region still has its own specificities (in particular UK, Germany, France and the Nordic Countries).

Read the [client alert](#).