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FDA Posts First List of Surrogate Endpoints

By Bill Myers

The FDA has published the first-ever list of surrogate endpoints, giving sponsors the first concrete suggestions for the kinds of laboratory measures or physical signs that might help develop drugs even when clinically meaningful data proves elusive.

The list, required by the 21st Century Cures Act, covers a range of diseases, from asthma to osteoporosis and offers different endpoints for adults and children.

It includes surrogate endpoints that some sponsors have already used in previous NDA and BLA trials as well as those deemed potentially useful in previous guidances.

The FDA stresses that sponsors still need to clear plans with CDER or CBER before starting trials because the proposed surrogates will only be accepted on a "case-by-case" basis.

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—Sofija Jovic, business transformation adviser, WCG Clinical

The long-awaited list represents a positive step forward for sponsors, says Sofija Jovic, business transformation adviser at WCG Clinical.

"The whole question of how we de-risk drug development has a lot to do with how drug companies perceive or try to define what it is the FDA wants them to do," she says.

The law is designed to help get effective drugs to market more quickly even when trials don't necessarily net clinically significant data.

At the least, the FDA list will help researchers narrow the number of variables they're looking for in a trial, Jovic says. This, in turn, may help ease the burden on trial participants. The reason: Sponsors can check the long list of surrogate goals to see if they can streamline or cut out any planned trial tests.

"That's sort of the unspoken issue in recruiting patients and bringing them into the process," Jovic says. "The protocols are often written with the FDA ... not the patient in mind."

The list has to be refreshed every six months. Jovic says she expects that future editions may well bring the FDA "closer to that gray area" where drug development can be risky and the questions may get tougher, including, for example, whether sponsors will be allowed to consider quality of life issues.

Read the FDA's list here: www.fdanews.com/07-25-18-SurrogateEndpoint.pdf.