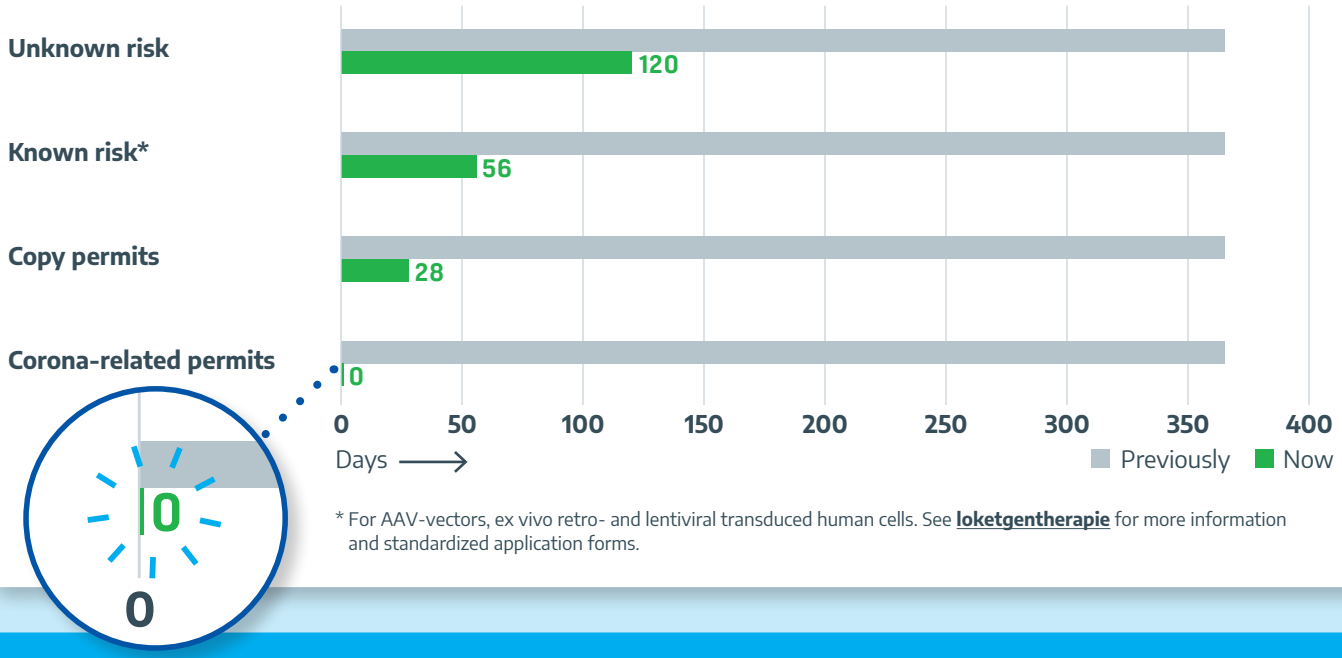
WELCOMING CELL AND GENE THERAPIES IN THE NETHERLANDS

REALIZING THE FASTEST, CLEAREST AND SIMPLEST PROCEDURES FOR CLINICAL TRIALS AND APPLICATIONS

Progress in science and medicine has given rise to Advanced Therapy Medicinal Products (ATMPs), such as cell and gene therapies. To make the most of these innovations for patients and the Dutch research climate, HollandBIO wants the Netherlands to join the international frontrunners in this field. In line with countries like Belgium and the UK, we want permits for medical GMOs to be handed out within 60 days at decreased administrative requirements. That's why together with all stakeholders and our government we critically reviewed the permit application process. As a result, the Dutch **GMO Decree** was amended accordingly.

Timelines to obtain a medical GMO permit



* For AAV-vectors, ex vivo retro- and lentiviral transduced human cells. See **loketgentherapie** for more information and standardized application forms.

Work in progress

Together, we'll keep improving the GMO permit application process. That's why it's important to timely flag challenges encountered in the application process with HollandBIO and Bureau GGO. Right now, focus lies on designing permits with a broader scope, regularly assessing the risks of new medical GMO platforms to allow for standardized and faster procedures, and joining European Interplay agreements, like those on indication extensions.

The Netherlands welcomes cell and gene therapies: they are important for patients, for our research climate and for innovation.

More information? Contact HollandBIO at info@hollandbio.nl or +31 070 833 13 33