

CHANGE CONTROL NOTIFICATION FORM

Date of notification: 24 Sept 2026

Step 1- Change description
Requesters <i>Charles River France RMS</i> <i>Charles River Germany RMS</i> <i>Charles River Italy RMS</i> <i>Charles River UK RMS</i>
Change ref: Updates to the International Genetic Standardization (IGS) Program for Outbred Rodent Stocks
Describe Current Status & Proposed Change We would like to inform you of upcoming changes to our International Genetic Standardization (IGS) breeding program for the outbred Crl:CD1(ICR) mouse and Crl:WI(Han), Crl:WI, and Crl:CD(SD) rat stocks , which will be implemented in September 2026 and will affect animals commercialized from Q1 2027 onwards . The main differences to the programme are as follows. Until now, animals added to the foundation colony (also known as backward migration) were rederived by Caesarean section and maintained at SOPF/VAF Elite health status in isolators of our foundation colonies. The high level of biosecurity provided by isolator housing, combined with rigorous health monitoring, ensured that forward migrations did not introduce adventitious agents into barrier-maintained colonies. While highly effective, this approach requires the ongoing maintenance of permanent foundation colonies, resulting in unavoidable animal surplus and significant operational complexity. To support the 3Rs and enhance both the sustainability and efficiency of the program, we have decided to transition from permanent foundation colonies to a strategy based on cryopreserved embryo banks, which eliminates the need for Caesarean rederivation procedures, long-term isolator maintenance, and extensive health monitoring of foundation colonies, while significantly reducing surplus animal generation. <i>Here are the updates to the IGS program CRL is making:</i> Cryopreserved embryo banks will be established by GEMS Embryology Lab in Wilmington, USA and GEMS Embryology Lab in Lyon, France using animals planned for backward migration sourced from North American and European colonies, respectively. To avoid genetic bottlenecks and maintain adequate genetic diversity, embryo banks will be created at a scale sufficient to support a complete forward migration cycle.

In addition, several modifications are being introduced to adapt the program to this updated methodology while maintaining the genetic integrity and quality of the models including:

- Increasing the interval between forward migrations from 3 years to 5 years
- Reducing the proportion of male breeders replaced during forward migration from 25% to 15%
- Adding embryo-derived females, in addition to males, in forward migration activities to minimize animal wastage.

Should you have any questions regarding these changes or their implementation, please do not hesitate to contact Dr Kevin Dhondt or Dr Aleksandar Popovic.

Reason for the change & Business Justification:

To support the 3Rs and enhance both the sustainability and efficiency of the program

Impact Assessment on product and service quality:

Based on decades of experience and extensive genetic monitoring, we are confident that the revised IGS program will continue to deliver the highest standards of genetic quality, while providing additional benefits, including:

- Maintenance of expected heterozygosity levels
- Preservation of genetic consistency among global colonies
- Continued provision of animals with a high health status
- A reduction in surplus animals bred and not used in research in line with the 3Rs

In summary, these changes are not expected to affect the genetic characteristics, health status, research performance, or reproducibility of the commercialized animals and are designed to maintain the high level of global standardization associated with the IGS program.

We appreciate your continued support and collaboration as we implement these improvements.

Is this Change permanent? YES NO

Documentation provided

<https://www.criver.com/products-services/research-models-services/international-genetic-standardization-igs-program?region=3671>

Prepared by Kevin Dhondt, EU Director of Veterinary Professional Services – 10th September 2026



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