

## Guaranty of DRiFOs®

**DRiFOs®** is a user-friendly online system launched by Luminary Medical K.K. in 2015 for licensed users to search the most updated adverse drug events reported to the Pharmaceuticals and Medical Devices Agency (PMDA) in Japan. **DRiFOs®** uses the Japanese Adverse Drug Event Report database (JADER), which is an open-access database provided by the PMDA from 2012.<sup>1)</sup>

**DRiFOs®** also adopts the data definition of the JADER, such as MedDRA/J<sup>2)</sup> for medical terminology.

Statistical indices, known as quantitative signal detection methods, are calculated by the following formula.<sup>3)</sup>

	Event	All Other events
Medicinal Product	<b>A</b>	<b>B</b>
All Other medicinal products	<b>C</b>	<b>D</b>

Proportional Reporting Ratio (PRR):  $AI(A+B)/C/(C+D)= A(C+D)/C(A+B)$

95% confidence interval for PRR:

Reporting Odds Ratio (ROR):  $(A/B)/(C/D) = AD/CD$

95% Confidence interval for ROR:  $95\%CI = e^{\ln(ROR) \pm 1.96 \sqrt{\frac{1}{a} + \frac{1}{b} + \frac{1}{c} + \frac{1}{d}}}$

Luminary Medical K.K. guarantees the above.

Date: September 18, 2017

Signature:



(Katsuhiko Niga / CEO of Luminary Medical K.K.)

- 1) Pharmaceuticals and Medical Devices Agency. JADER.  
<https://www.pmda.go.jp/safety/info-services/drugs/adr-info/suspected-adr/0006.html>
- 2) Pharmaceutical and Medical Device Regulatory Science Society of Japan.  
*MedDRA/J*. <https://www.pmrj.jp/jmo/php/indexj.php>
- 3) Working Group VIII of Council for International Organizations of Medical Sciences (CIOMS). *Practical Aspects of Signal Detection in Pharmacovigilance*. 2010. P51-52.