ERRATUM

Erratum to:
A fresh look at analytical methods for vaccines

Timothy Schofield

This erratum contains corrections to the article: Schofield T. A fresh look at analytical methods for vaccines. Vaccine Insights 2022; 1(5), 247–258.

In the version of this article initially published, there were several typographical errors. The correction is listed in full below. The corrections were made to the HTML and PDF versions of this article as of May 21, 2024; the amended article may be accessed here.

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In the section SPECIFICATIONS & THEIR ROLE IN THE VACCINE ANALYTICAL METHOD LIFECYCLE (paragraph 2, pp 248–249), the original article read:

• A definition of satisfactory patient outcome (e.g., equal to 95% efficacy) is translated to a limit on a vaccine biomarker (correlate of protection);

• The correlate of protection is used in vaccine clinical studies to define a limit on a critical quality attribute (a specification limit);

• The specification limit is used to define limits on critical process parameters (a design space).

The corrected article reads:

• A definition of satisfactory patient outcome (e.g., \( P_{\text{limit}} \) equal to 95% efficacy) is translated to a limit on a vaccine biomarker (correlate of protection; \( z_{\text{limit}} \)).
• The correlate of protection is used in vaccine clinical studies to define a limit on a critical quality attribute (a specification limit; $y_{lim}^i$);

• The specification limit is used to define limits on critical process parameters (a design space; $x_{lim}^i$).

In the same section (paragraph 4, p. 249), the original article read:

Thus, limits in Figure 1 (e.g., or Design Space) are derived from the appropriately budgeted portions of the specification range.

The corrected article reads:

Thus, limits in Figure 1 (e.g., $x_{lim}^i$ or design space) are derived from the appropriately budgeted portions of the specification range.

In the sub-section Method control (paragraph 2, p. 252), the original article read:

In this depiction the specification limit (or the analytical budget,) is used to define the ATP, where $v$ and $w$ represent performance parameters such as accuracy and precision. The relationship between a critical method parameter ($u$) and performance parameters can be used to derive a method parameter limit ($v_{lim}$ in red), while the relationship between a suitability parameter ($s$) and the performance parameters can be used to derive a system suitability limit ($s_{lim}$ in green).

The corrected article reads:

In this depiction the specification limit (or the analytical budget, $y_{lim}^i$) is used to define the ATP ($v_{lim}^i$, $w_{lim}^i$), where $v$ and $w$ represent performance parameters such as accuracy and precision. The relationship between a critical method parameter ($u$) and performance parameters can be used to derive a method parameter limit ($u_{lim}$, in red), while the relationship between a suitability parameter ($s$) and the performance parameters can be used to derive a system suitability limit ($s_{lim}$, in green).

In the same sub-section (paragraph 4, p. 252), the original article read:

System suitability parameters provide additional control. Like critical parameter parameters, these can be established through a model between performance characteristics...

The corrected article reads:

System suitability parameters provide additional control. Like critical method parameters, these can be established through a model between performance characteristics...
In the sub-section **Some statistical opportunities** (paragraph 2, p. 254), the original article read:

\[ U_{RV} = t_{\alpha, n-1} \left( \frac{\sigma}{\sqrt{n}} \right) \]. The factor is a statistical constant associated with a probability equal to \( \alpha \) and with \( n - 1 \) degrees of freedom.

The corrected article reads:

\[ U_{RV} = t_{\alpha, n-1} \left( \frac{\sigma}{\sqrt{n}} \right) \]. The factor \( t_{\alpha, n-1} \) is a statistical constant associated with a probability equal to \( \alpha \) and with \( n - 1 \) degrees of freedom.