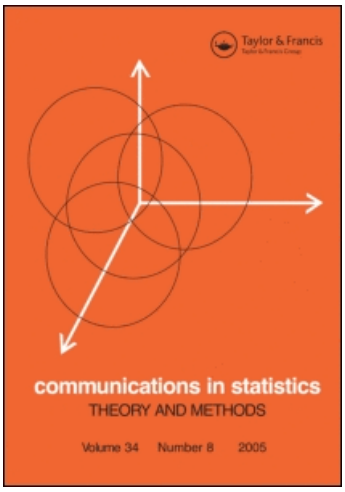

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Sequential Testing to Guarantee the Necessary Sample Size in Clinical Trials

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Sequential Testing to Guarantee the Necessary Sample Size in Clinical Trials

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This article addresses the sequential sampling issues related to attainment of a given number of subjects in a Poisson arrival process. The problem of guaranteeing the necessary sample size is formulated as that of open-ended hypothesis testing. To implement the procedure a one-sided stopping boundary must be specified. The formulas for the probabilities of general stopping time distribution are derived. For the linear boundary they are in the class of Lagrangian Poisson distributions. A locally optimal test is obtained.

Keywords Borel distribution; Clinical trials; Enrollment process; Lagrangian Poisson distribution; Locally optimal test; Poisson process.

Mathematics Subject Classification Primary 62P10; Secondary 60G40, 62L10.

1. Introduction and Summary

Adequate sample size planning for a clinical trial or a drug development trial is an integral part of the design required by the existing protocols. While formulas for the necessary sample size depend on the specific nature of the trial and on the scientific problem formulation (usually as hypothesis testing or confidence bounds in frequentist or Bayesian setting for continuous or discrete data), the number of subjects in a clinical study should always be large enough to provide reliable answers to the primary issue addressed by this trial. For economic and ethical reasons it is important not to overestimate this sample size.

Lenth (2001) reviewed the fundamental issues of sample-size planning and made several suggestions for applied statisticians how to interpret the existing formulas. A review of these formulas and guidelines for their use in clinical research can be found in Shuster (1990) and Chow et al. (2007), and in many other publications in specific areas of medical and biostatistical literature.

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The problem addressed in this article is different. If the necessary sample size N_0 for a trial is given, the issue is how to organize the interim analysis to make sure that this number is attained (or rather how to reach it with a given high probability). More specifically, if the current enrollment seems to be too low, at what time and how the decision about opening an additional center should be made?

Formulated this way, our problem becomes that of sequential analysis, and under the assumption of a Poisson enrollment process, the goal is to design the recruitment, so as to meet the target of N_0 subjects by a given time T_0. One may think of tracking a Poisson process and adding to it another process via opening new center(s) when the goal of N_0 subjects looks to be unattainable.

Although sequential estimation of a (homogeneous) Poisson process has been studied by several authors (El-Sayyad and Freeman, 1973; Shapiro and Wardrop, 1980; Vardi, 1979), this statistical problem has received little attention. We mention articles by Zacks (1991, 2005) who derived explicit formulas for the distribution of stopping times for this process which are defined by linear boundaries. The probabilities of the first crossing of a lower boundary by compound Poisson, gamma renewal or birth process in terms of pseudopolynomials were obtained by Picard and Lefevre (1996). Fedorov et al. (2005) gave approximations to the mean squared errors for estimators of treatment effect difference in multi-center clinical trials when the number of patients follows the Poisson distribution.

In Sec. 2, the problem of attaining the necessary sample size is formulated as that of finding a one-sided stopping boundary. The formulas for the distribution of stopping times are given in Sec. 3. Section 4 provides the form of a locally optimal testing procedure which turns out to have a degenerate, non sequential form and which minimizes a convex combination of Type I and Type II error probabilities. An example is given in Sec. 5.

2. Poisson Process Model and Open-Ended Testing

A natural model assumes that the patients arrive at the center according to a stationary Poisson process $N(t), 0 \le t \le T_0$, with the (unknown) rate λ. In reality this center consists of several clinics or hospitals. At the terminal instant T_0, it is desired to have more than N_0 subjects in the study. A sensible condition then is to have

$$P_\lambda(N(T_0) > N_0) \simeq 1 - \alpha,$$

for a small error probability α. Since the left-hand side of this formula is an increasing function of λ, one can define λ_0 as the solution to the equation,

$$P_{\lambda_0}(N(T_0) > N_0) = 1 - \alpha.$$

This condition means that the cumulative distribution function of a Poisson random variable with the parameter $\lambda_0 T_0$ evaluated at N_0 equals α. By using R language notation, we write:

$$\text{ppois}(N_0, \lambda_0 T_0) = \alpha.$$

In medical studies, both N_0 and T_0 (measured in days) can be fairly large numbers, so that according to the normal approximation to the Poisson distribution,

$$\lambda_0 T_0 + z_\alpha \sqrt{\lambda_0 T_0} \simeq N_0,$$

where z_α is the α-th percentile of the standard normal distribution, $\Phi(z_\alpha) = \alpha$. This fact suggests an approximate formula for λ_0,

$$\lambda_0 = \frac{N_0 - \sqrt{N_0} z_\alpha}{T_0}. \tag{1}$$

The suggested procedure is to test sequentially the null hypothesis $H_0 : \lambda \geq \lambda_0$ vs. one-sided alternative $H_1 : \lambda < \lambda_0$. The sampling process is continued until the instant at which H_0 is rejected, when additional center(s) must be opened, or until T_0. Thus, our procedure is an *open-ended* sequential scheme, which is known to have the power approaching one as $T_0 \to \infty$. These procedures were introduced by Robbins (1970) and their use in clinical trials was advocated by Berry and Ho (1988).

At time t, the null hypothesis is rejected if $N(t) \leq g(t)$ for a suitably chosen function $g(t)$ which determines the boundary of the stopping region. Let $g(t)$ be an arbitrary monotonically non decreasing (continuous from the right) function. The boundary defined by this function can be crossed only at the instants t_k, $k = 0, 1, \ldots,$ such that $g(t_k) = k$, $0 < t_0 \leq t_1 \leq \cdots$. When $g(t)$ is not strictly increasing, the usual definition, $t_k = \inf\{t : g(t) \geq k\}$, applies.

If g is strictly increasing, the stopping rule is

$$\tau_g = \min\{t_k : N(t_k) \leq g(t_k) = k\},$$

and one of our main goals is to recommend an appropriate function g.

3. Distribution of Stopping Time

The random variable τ_g has a discrete distribution whose probabilities $f_k = P_\lambda(\tau_g = t_k)$ can be determined in principle from the formulas for probability generating functions known in the queuing theory (e.g., Kemperman, 1961, pp. 99–105), although there are numerical difficulties with this approach. Zacks (1991, 2005) obtained explicit formulas for the distribution of stopping time τ_g defined by a linear function $g(t) = \lambda_0 t - b$, for some positive (integer) b, in which case the possible values are of the form $t_k = (b + k)/\lambda_0$, $k = 1, 2, \ldots$.

Assuming only that $t_0 < t_1 < \cdots$, we demonstrate the following representation of the probabilities f_k,

$$f_k = f_k(\lambda) = e^{-\lambda t_k} \frac{(\lambda t_k)^k}{k!} R_k(t_0, \ldots, t_k), \quad k = 0, 1, \ldots, \tag{2}$$

where the sequence R_k satisfies the formula

$$\sum_{k=0}^{n} \binom{n}{k} \left(\frac{t_k}{t_n}\right)^k \left(1 - \frac{t_k}{t_n}\right)^{n-k} R_k(t_0, \ldots, t_k) = 1. \tag{3}$$

One has $R_0(t_0) = 1$, $R_1(t_0, t_1) = t_0/t_1$, and R_n is an homogeneous function of degree zero, i.e.,

$$R_n(at_0, \ldots, at_n) = R_n(t_0, \ldots, t_n)$$

for all positive a. We put here $0^0 = 1$, so that the last term ($k = n$) in (3) is $R_n(t_0, \ldots, t_n)$.

To prove (3) notice that

$$f_n = P_\lambda(N(t_n) = n, N(t_k) > k, k = 0, 1, \ldots, n-1)$$

and by stationarity of the Poisson process and by its Markov property,

$$\begin{aligned} P_\lambda(N(t_n) = n | \tau_g \le t_n) &= \sum_{k=0}^{n} P_\lambda(N(t_n) = n | \tau_g = t_k) P_\lambda(\tau_g = t_k | \tau_g \le t_n) \\ &= \sum_{k=0}^{n} f_k \frac{P_\lambda(N(t_n - t_k) = n - k)}{P_\lambda(\tau_g \le t_n)}. \end{aligned}$$

It follows that

$$P_\lambda(N(t_n) = n) = \sum_{k=0}^{n} f_k P_\lambda(N(t_n - t_k) = n - k),$$

which establishes (2).

It is easy to see that $t_k^k R_k(t_0, \ldots, t_k) = Q_k(t_0, \ldots, t_{k-1})$ does not depend on t_k, and induction shows that (3) implies

$$t_n^n = \sum_{k=0}^{n} \binom{n}{k} (t_n - t_k)^{n-k} Q_k(t_0, \ldots, t_{k-1}).$$

Since t_n in this formula is an arbitrary positive number, by equating the coefficients at t_n^ℓ, $\ell = 0, 1, \ldots, n-1$, in both sides of this equation, we get

$$\sum_{k=0}^{n-\ell} \binom{n}{k} \binom{n-k}{\ell} (-1)^{n-k-\ell} t_k^{n-k-\ell} Q_k(t_0, \ldots, t_{k-1}) = 0.$$

When $\ell = 0$, it follows that

$$Q_n(t_0, \ldots, t_{n-1}) = \sum_{k=0}^{n-1} (-1)^{n-k-1} \binom{n}{k} t_k^{n-k} Q_k(t_0, \ldots, t_{k-1}). \tag{4}$$

One has $Q_0 = 1$, $Q_1(t_0) = t_0$, $Q_2(t_0, t_1) = 2t_0t_1 - t_0^2$, $Q_3(t_0, t_1, t_2) = t_0(6t_1t_2 - 3t_1^2 - 3t_0t_2 + t_0^2)$, and one can derive an explicit formula for Q_n as in Theorem 3.3, in Zacks (1991).

In particular, let for a fixed positive ρ, $t_k = \rho(k+1)$, $k = 0, 1, \ldots$, which corresponds to a linear function $g(t) = \rho^{-1}t - 1$. According to (4), the sequence $q_k = \rho^{-k} Q_k(t_0, \ldots, t_{k-1})$ satisfies the recurrence

$$q_n = \sum_{k=0}^{n-1} (-1)^{n-k-1} (k+1)^{n-k} \binom{n}{k} q_k.$$

This formula means that the n-th difference of the sequence q_k vanishes or that the values q_k are those of a polynomial in k of degree $n-1$; see Levy and Lessman (1992). Induction shows that $q_k = (k+1)^{k-1}$, $k = 1, 2, \ldots$. Thus, with $\mu = \rho\lambda$,

$$f_k = e^{-\mu(k+1)} \frac{\mu^k q_k}{k!} = e^{-\mu(k+1)} \frac{\mu^k (k+1)^{k-1}}{k!}, \quad k = 0, 1, \ldots. \tag{5}$$

These probabilities define the *Borel* distribution on non negative integers (see Johnson et al., 1992, p. 395.)

It is well known that for the Borel distribution probabilities

$$\sum_{k=0}^{\infty} f_k = 1,$$

if and only if $0 \le \mu \le 1$, so that if $\rho\lambda > 1$, $P(\tau_g = \infty) > 0$.

If $t_k = \rho(b+k)$, $k = 1, 2, \ldots$, corresponding to a general linear function $g(t) = \rho^{-1}t - b$, $b > 1$, then similarly to the above $Q_k(t_0, \ldots, t_{k-1}) = b\rho^k(k+b)^{k-1}$, $k = 1, 2, \ldots$. In this situation for $\mu = \rho\lambda$,

$$f_k = e^{-\mu(k+b)} \frac{b\mu^k (k+b)^{k-1}}{k!}, \quad k = 0, 1, \ldots, \tag{6}$$

determine a *Lagrangian Poisson distribution* (formula (9.248), p. 396 in Johnson et al., 1992). This is a proper probability distribution if and only if $0 \le \mu \le 1$, with finite mean only when $\mu < 1$.

We formulate now the main results of this section.

Theorem 3.1. *For the stopping rule τ_g such that $t_0 < t_1 < \cdots$, the probabilities $f_k = P(\tau_g = t_k)$, $k = 0, 1, \ldots$, satisfy the recurrent formula* (2). *They correspond to the Borel distribution* (5) *when the boundary is given by $g(t) = \rho^{-1}t - 1$, and to the Lagrangian Poisson distribution* (6) *when $g(t) = \rho^{-1}t - b$.*

Notice that formulas for the probabilities of first crossing of a lower boundary by Poisson (and more general) processes in terms of Abel–Gontcharoff polynomials are available (see Picard and Lefevre, 1996).

4. Locally Optimal Test

For pragmatic reasons we are interested in sequential procedures which terminate even earlier than at T_0. Namely, in many situations one can specify the last interim evaluation moment T_1, $T_1 \le T_0$, at which additional center(s) realistically can be activated. We define

$$\tau_g^* = \min\{t_k : t_k \le T_1, N(t_k) \le g(t_k)\},$$

and put $K = \lfloor g(T_1) \rfloor$, so that $g(T_K) = K$, $t_K \le T_1$. Then the probability to reject H_0 is $P_\lambda(\tau_g^* \le t_K)$.

The conditional probability of Type I error given that $\tau_g^* = t_K$ under $\lambda = \lambda_0$ is ppois$(K, \lambda_0 t_K)$. When linear interpolation is used, $K = \lfloor T_1 N_0 / T_0 \rfloor$, and by using (1), the approximate value of this probability is $\Phi\left(\sqrt{\frac{T_1}{T_0}} z_\alpha\right)$.

Let $\lambda = \lambda^*$ be a fixed value of the parameter. Here we derive a test of H_0 based on τ_g^* which is locally optimal at λ^*. This test is known to maximize the absolute value of the derivative of the power function at $\lambda = \lambda^*$. Since the sampling process is curtailed at T_1, one has

$$\beta(\lambda) = P_\lambda(\tau_g^* \le t_K) = \sum_{k=0}^{K} f_k(\lambda),$$

with $f_k(\lambda)$ defined by (2). Clearly,

$$\beta'(\lambda) = \sum_{k=0}^{K} f_k'(\lambda) = -\lambda^{-1} \sum_{k=0}^{K} (\lambda t_k - k) f_k(\lambda).$$

Let $s_k = \lambda^* t_k$, $k = 0, 1, \ldots, K$. Then our goal for a fixed K is to determine s's so as to maximize

$$\sum_{k=0}^{K} \frac{(s_k - k)e^{-s_k}}{k!} Q_k(s_0, \ldots, s_{k-1}). \tag{7}$$

It is immediate to see that for the optimal boundary $s_k > k$, and by differentiating, the best choice for s_K is seen to be $\hat{s}_K = K + 1$. We prove now that this formula holds for all k.

To find $\hat{s}_{K-1}$, notice that (4) implies that

$$\frac{\partial}{\partial s_{K-1}} Q_K(s_0, \ldots, s_{K-1}) = K Q_{K-1}(s_0, \ldots, s_{K-2}),$$

so that the partial derivative of (7) with regard to s_{K-1} is proportional to

$$(K - s_{K-1})e^{-s_{K-1}} + e^{-K-1}.$$

This derivative vanishes changing its sign from positive to negative only at $s_{K-1} = K + 1$.

Assuming now that $\hat{s}_j = K + 1$, $j = k + 1, \ldots, K$ and

$$\frac{\partial}{\partial s_j} Q_n(s_0, \ldots, s_j, K+1, \ldots, K+1)$$

$$= (n - j) \binom{n}{j} (K + 1 - s_j)^{n-j-1} Q_j(s_0, \ldots, s_{j-1}),$$

for $1 \le k < j < n \le K$, we show that $\hat{s}_k = K + 1$. According to the induction assumption for $n \ge k + 1$

$$\frac{\partial}{\partial s_k} Q_n(s_0, \ldots, s_k, K+1, \ldots, K+1)$$

$$= (-1)^{n-k-1}(n - k) \binom{n}{k} s_k^{n-k-1} Q_k(s_0, \ldots, s_{k-1})$$

$$+ \sum_{j=k+1}^{n-1} (-1)^{n-j-1} (K+1)^{n-j} \binom{n}{j} \frac{\partial}{\partial s_k} Q_j(s_0, \ldots, s_k, K+1, \ldots, K+1)$$

$$= \frac{Q_k(s_0, \ldots, s_{k-1})n!}{k!}\left[\frac{(-1)^{n-k-1}s_k^{n-k-1}}{(n-k-1)!} + \sum_{j=k+1}^{n-1}\frac{(K+1)^{n-j}(K+1-s_k)^{j-k-1}}{(n-j)!(j-k-1)!}\right]$$

$$= (n-k)\binom{n}{k}(K+1-s_k)^{n-k-1}Q_k(s_0, \ldots, s_{k-1}).$$

The partial derivative of (7) with regard to s_k is

$$\frac{(k+1-s_k)e^{-s_k}}{k!}Q_k(s_0, \ldots, s_{k-1})$$
$$+ e^{-K-1}\sum_{j=k+1}^{K}\frac{(K+1-j)}{j!}\frac{\partial}{\partial s_k}Q_j(s_0, \ldots, s_j, K+1, \ldots, K+1)$$
$$= \frac{Q_k(s_0, \ldots, s_{k-1})}{k!}\left[(k+1-s_k)e^{-s_k}\right.$$
$$\left. + e^{-K-1}\sum_{j=k+1}^{K}\frac{(K+1-j)(K+1-s-k)^{j-k-1}}{(j-k-1)!}\right],$$

and this derivative vanishes if and only if $s_k = K+1$.

It remains to show that $s_0 = K+1$. If $s_0 = u \le s_k = v, k = 1, 2, \ldots, n$, which correspond to the function $g(s) = -1, 0 \le s < u; = n, u \le s < v$, then $Q_k(s_0, \ldots, s_{k-1}) = v^k - (v-u)^k, k = 1, 2, \ldots, n$, which can be proven by using (4). Thus, $Q_k(s_0, K+1, \ldots, K+1) = (K+1)^k - (K+1-s_0)^k, k = 1, \ldots, K$, and (7) takes the form

$$s_0 e^{-s_0} + e^{-K-1}\sum_{k=1}^{K}\frac{(K+1-k)[(K+1)^k - (K+1-s_0)^k]}{k!}.$$

This function of s_0 is indeed maximized when $s_0 = K+1$.

Thus for a locally optimal at λ^* test, $t_k \equiv (K+1)/\lambda^*$, which corresponds to the boundary $g(t) = -1, 0 \le \lambda^* t < K+1; = K, \lambda^* t \ge K+1$. Since all t_k are equal, the formula (2) is not directly applicable, but the power function of this non sequential test can be easily evaluated:

$$\beta(\lambda) = P_\lambda(N(T_1) \le K) = \mathrm{ppois}\left(K, \frac{\lambda(K+1)}{\lambda^*}\right). \tag{8}$$

Here we assume that $T_1 = (K+1)/\lambda^*$. Observe that for large K, $\beta(\lambda^*) = \mathrm{ppois}(K, K+1) \simeq 0.5$, so that in practice λ^* must be taken from the alternative, $\lambda_0 \ge \lambda^*$.

For fixed $\lambda_1 < \lambda_0$, the test which maximizes $\beta(\lambda_1) + w[1 - \beta(\lambda_0)]$ for a given positive weight w has the same form. More precisely, the convex combination of the error probabilities of the first and of the second kind is minimized when $t_k \equiv [(K+1)\log(\lambda_0/\lambda_1) + \log w]/(\lambda_0 - \lambda_1), k = 0, 1, \ldots, K$.

Theorem 4.1. *For the locally optimal at λ^* test, $t_k \equiv (K+1)/\lambda^*$, corresponding to the boundary $g(t) = -1, 0 \le \lambda^* t < K+1; = K, \lambda^* t \ge K+1$. The power function of this procedure is given by* (8). *When $t_k \equiv [(K+1)\log(\lambda_0/\lambda_1) + \log w]/(\lambda_0 - \lambda_1)$, the corresponding test minimizes the weighted sum of the error probabilities of the first and the second kind errors, $w\beta(\lambda_0) + 1 - \beta(\lambda_1)$.*

In the next section, we compare the power of these tests to the power functions of sequential tests with linear boundaries.

5. An Example

Assume (as is the case in some cancer studies) that the desired number of subjects in a clinical trial is $N_0 = 500$ to be recruited during $T_0 = 548$ days and $T_1 = 340$ is the last interim analysis instant. If $\alpha = 0.05$, then $\lambda_0 = 0.98$.

Figure 1 depicts the graphs of the power function $\beta(\lambda)$ in (8) for $K = \lfloor T_1 N_0 / T_0 \rfloor = 310$, and $\lambda^* = (K+1)/T_1 = 0.92$. Also, when $\rho = 1/\lambda_0$ the power functions for linear boundary tests (5) and (6) for $b = 5$ and $b = 38$ are shown. Clearly, the power functions of (5) or (6) for $b = 5$ are too large leading to an unacceptable type I error probability. However, the test based on the Lagrangian Poisson distribution with $b = 38$ has a very reasonable power function which equals to 0.95 at $\lambda_1 = 0.82$ and to 0.07 at λ_0. Larger values of b result in smaller Type I error probability, but a smaller power at the alternative too.

If $\alpha = 0.01$, then $\lambda_0 = 1.01$ and $\text{ppois}(K, \lambda_0 T_1) = 0.04$. The choice $b = 33$ leads then to the power function equal to 0.95 at $\lambda_1 = 0.84$ and to the Type I error probability 0.05.

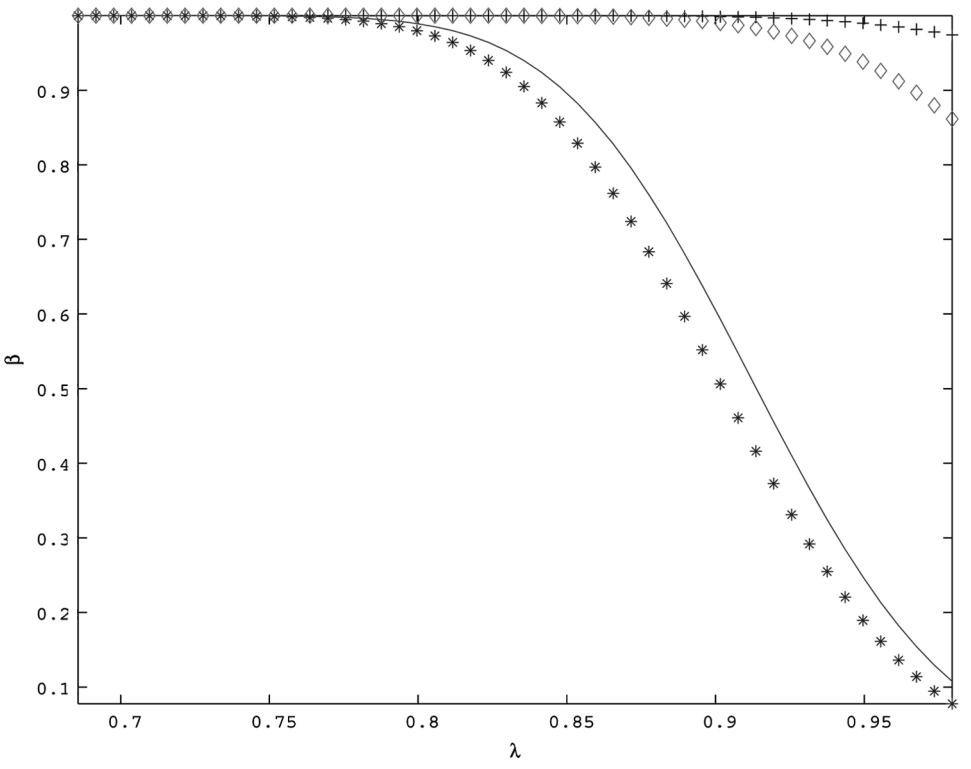

Figure 1. Plots of power functions (5) (line marked by +), (6) with $b = 5$ (line marked by $\diamond$), (8) for $\lambda^* = 0.92$ (continuous line), and (6) with $b = 38$ (line marked by $*$), when $\alpha = 0.05$, $N_0 = 500$, $T_0 = 548$.

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