Scope of the deliberate release authorization of GMO in the framework of the clinical trial
(Status 6.August 2015)

For an investigation medicinal product (IMP) consisting of, or containing, genetically modified organisms (GMO), the authorization of the clinical trial includes the authorization of the deliberate release of the GMO in the framework of the clinical trial (acc. to § 9 (4) GCP-V). Until recently, the scope of this deliberate release authorization was limited to the actual administration of the GMO to the study subjects.

Now, on the basis of a close temporal and spatial relationship with the actual administration of an IMP to the study subjects, additional activities may henceforth be covered by the release authorization of the GMO.

These activities include:

- Short-term storage of the IMP and any materials, samples and waste that may contain the GMO
- In-house transportation of the IMP and any materials, samples and waste that may contain the GMO
- Reconstitution and preparation of the IMP for administration, provided that no manufacturing license in accordance with § 13 AMG is required
- Administration of the IMP to the study subjects
- Return transport of potentially contaminated materials and waste form the study subject to the study site
- Decontamination and disposal of potentially contaminated materials and waste
- Diagnostic laboratory testing

As a consequence the Paul-Ehrlich-Institut does no longer request the applicant to provide proof of notification/approval in accordance with the Genetic Engineering Act (§ 8 (1) or (2) GenTG) for these activities.

The external transport and the manufacture of the IMP, however, are not covered by the release authorization of the GMO. Furthermore, activities with subject samples that may allow replication of the GMO (e.g. biodistribution and shedding analyses) are also not covered by the release authorization (irrespective of the chosen method of analysis).

To allow evaluation whether the above mentioned activities are suitable to be integrated into the release authorization, the Paul-Ehrlich-Institut is requesting to also include the following information in the ERA documentation of a clinical trial application:

1) Specific information on the duration and location of storage, and any safety measures applied to ensure proper storage of the IMP and any materials that may contain the GMO (contaminated materials and waste, subject samples) at the study site
2) Information on safety measures for in-house transportation of the IMP and any materials that may contain the GMO (contaminated materials and waste, subject samples)