Australian Government
Department of Health and Aged Care
Office of the Gene Technology Regulator

# Licence for dealings involving an intentional release of a GMO into the environment

**Licence number: DIR 208**

**Licence holder: Novotech Australia Pty Ltd**

**Clinical trial of a GM vaccinia virus for the treatment of solid tumours**

Issued: 11 March 2025

## Office of the Gene Technology Regulator

# *Final licence conditions*

## Section 1 Interpretations and Definitions

1. In this licence:

   (a) unless defined otherwise, words and phrases used in this licence have the same meaning as they do in the Act and the Regulations;

   (b) words denoting a gender include any other gender;

   (c) words in the singular include the plural and words in the plural include the singular;

   (d) words denoting persons include a partnership and a body whether corporate or otherwise;

   (e) references to any statute or other legislation (whether primary or subordinate) are a reference to a statute or other legislation of the Commonwealth of Australia as amended or replaced from time to time and equivalent provisions, if any, in corresponding State law, unless the contrary intention appears;

   (f) where any word or phrase is given a defined meaning, any other part of speech or other grammatical form in respect of that word has a corresponding meaning;

   (g) specific conditions prevail over general conditions to the extent of any inconsistency.

2. In this licence:

***'Act'*** means the *Gene Technology Act 2000* (Commonwealth) or the corresponding State Law under which this licence is issued.

***'Analytical facility'*** means a laboratory in Australia accredited to undertake testing of human diagnostic Samples, such as a medical testing laboratory accredited by the National Pathology Accreditation Advisory Council (NPAAC).

***'Clinical trial site'*** means a medical facility in Australia such as a clinical trial facility and associated Pharmacy, which are notified in writing to the Regulator for the purposes of conducting this clinical trial.

***'Contingency Plan'*** means a written plan detailing measures to be taken in the event of the unintentional release of the GMOs.

***'Decontaminate'*** (or ***'Decontamination'***) means, as the case requires, kill the GMOs by one or more of the following methods:

(a) chemical treatment;

(b) autoclaving;

(c) high-temperature incineration; or

(d) a method approved in writing by the Regulator.

*Note: 'As the case requires' has the effect that, depending on the circumstances, one or more of these techniques may not be appropriate.'*

***'Excluded persons'*** means:

(a) persons who display any evidence of an active infection or any immunosuppressive disorder, including HIV infection.

(b) women who are breastfeeding or who are pregnant; and women of childbearing potential (WOCBP) who are unwilling to use and document use of effective contraception for the duration of the study.

(c) persons who have recurrent or active skin disease, such as atopic dermatitis.

***'External service provider'*** means a person engaged by the licence holder solely in relation to transport, storage and/or disposal of the GMOs, or Sample analysis other than at a Clinical trial site, and who is not undertaking any dealings with the GMOs that are not for those purposes.

***'GM'*** means genetically modified.

**'*GMO'*** means the genetically modified organisms that are the subject of the dealings authorised by this licence.

***'OGTR'*** means the Office of the Gene Technology Regulator.

***'Personal information'*** has the same meaning as in the *Privacy Act 1988*. Personal information means information or an opinion about an identified individual, or an individual who is reasonably identifiable:

(a) whether the information or opinion is true or not; and

(b) whether the information or opinion is recorded in a material form or not.

***'Pharmacy'*** means a location within the Clinical trial site, where authorised staff store, prepare, and dispense medications in medical environment.

**'Regulations'** means the Gene Technology Regulations 2001 (Commonwealth) or the corresponding State Law under which this licence is issued.

***'Regulator'*** means the Gene Technology Regulator.

**'Sample'** means any biological material collected from an inoculated trial participant for analysis as part of the trial, and which may reasonably be expected to contain GMOs.

## Section 2 'General conditions and obligations

**Holder of licence**

3. The licence holder is Novotech (Australia) Pty Limited.

**Remaining an accredited organisation**

4. The licence holder must, at all times, remain an accredited organisation.

**Validity of licence**

5. This licence remains in force until it is suspended, cancelled or surrendered. No dealings with the GMO are authorised during any period of suspension, or after the licence has been cancelled or surrendered.

   *Note: Although this licence has no expiry date, the duration of preparation and administration of the GMOs is restricted in accordance with Condition 23.*

**Persons covered by this licence**

6. The persons covered by this licence are:

   (a) the licence holder, and any employees, agents (or External service providers engaged by the licence holder); and

   (b) the project supervisor(s); and

   (c) other persons who are, or have been, engaged or otherwise authorised by the licence holder or the project supervisor to conduct any of the dealings authorised by this licence.

7. To the extent that any activity by a trial participant may be considered to be a dealing with the GMO as described in **Attachment A** for purposes of the Act, that dealing is authorised by this licence.

8. The licence holder must keep a record of all persons covered by this licence, and must keep a record of the contact details of the project supervisor(s) for the licence.

*Note: Where External service providers are used, it is sufficient to record the company name and the position or job title of the person(s) conducting the dealing*

9. The licence holder must provide information related to the persons covered by the licence when requested to do so in writing by the Regulator and must provide the information within a time period stipulated by the Regulator.

**Description of GMOs covered**

10. The licence authorises specified dealings in respect of the GMOs identified and described in **Attachment A**.

*Note: Attachment A is not included in the draft licence as the GMO is described in this Risk Assessment and Risk Management Plan.*

**Dealings authorised by this licence**

11. The licence holder and persons covered by this licence may conduct the following dealings with the GMOs:

(a) import the GMO;

(b) conduct the following experiments with the GMO:

i) prepare the GMO for administration to trial participants;

ii) administer the GMO to trial participants by intravenous infusion;

iii) collect Samples from trial participants;

iv) analyse the Samples described in 11(b)iii);

(c) transport the GMO; and

(d) dispose of the GMO

and may possess, supply, use or store the GMO for the purposes of, or in the course of, any of these dealings.

12. Supply of the GMO for the purposes of dealings by a person or organisation not covered by this licence is only authorised by this licence if the Regulator provides prior written approval to the licence holder.

*Note: For approval to be granted, the receiving person or organisation must have an appropriate authorisation to conduct dealings with the GMOs.*

**Conditions imposed by the Act**

*Note: The Act mandates the following 3 conditions.*

**Informing people of licence conditions (section 63)**

13. The licence holder must inform any person covered by the licence, to whom a particular condition of the licence applies, of the following:

(a) the particular condition, including any variations of it; and

(b) the cancellation or suspension of the licence; and

(c) the surrender of the licence.

*Note: No particular condition of this licence applies to trial participants; therefore Condition 13 does not apply to trial participants.*

**Monitoring and audits (section 64*)***

14. If a person is authorised by this licence to deal with the GMO and a particular condition of this licence applies to the dealing by that person, the person must allow the Regulator, or a person authorised by the Regulator, to enter premises where the dealing is being undertaken, for the purposes of auditing or monitoring the dealing.

**Additional information to be given to the Regulator (section 65)**

15. The licence holder must immediately inform the Regulator, if they become aware of:

    (a) additional information about any risks to the health and safety of people, or to the environment, associated with the dealings authorised by the licence; or

    (b) any contraventions of the licence by a person covered by the licence; or

    (c) any unintended effects of the dealings authorised by the licence.

*Note 1: For the purposes of this condition:*
*(a) The licence holder is taken to have become aware of additional information if they were reckless as to whether such information existed; and*
*(b) The licence holder is taken to have become aware of contraventions, or unintended effects, if they were reckless as to whether such contraventions had occurred, or such unintended effects existed.*

*Note 2: Contraventions of the licence may occur through the action or inaction of a person.*

*Note 3: Additional information includes any changes at a Clinical trial site, which might increase the likelihood of unintentional exposure of people or release of the GMO into the environment.*

*Note 4: An example of informing immediately is contact made at the time of the incident via the OGTR free call phone number 1800 181 030.*

**Informing the Regulator of any material changes of circumstance**

16. The licence holder must immediately, by notice in writing, inform the Regulator of:

    (a) any relevant conviction of the licence holder occurring after the commencement of this licence;

    (b) any revocation or suspension after the commencement of this licence, of a licence or permit held by the licence holder under a law of the Commonwealth, a State or a foreign country, being a law relating to the health and safety of people or the environment;

    (c) any event or circumstances occurring after the commencement of this licence that would affect the capacity of the licence holder to meet the conditions in it.

17. The licence holder must provide information related to the licence holder's ongoing suitability to hold a licence when requested to do so in writing by the Regulator, and must provide the information within a time period stipulated by the Regulator.

**Further conditions with respect to informing persons covered by the licence**

18. If a particular condition, including any variation of it, applies to an External service provider covered by this licence, the licence holder must not permit that person to conduct any dealings unless the person has been informed of the condition, including any variation of it.

*Note: Information required under Condition 18 may be provided to External service providers who are engaged solely for storage and transport of the GMO through labelling of the outermost container of the GMOs in accordance with Condition 38(a).*

19. If a particular condition, including any variation of it, applies to a person with respect to any

dealing, other than to an External service provider, the licence holder must not permit a person covered by this licence to conduct that dealing unless:

(a) the licence holder has obtained from the person a signed and dated statement that the person:

i) has been informed by the licence holder of the condition and, when applicable, its variation; and

ii) has understood and agreed to be bound by the condition, or its variation; and

iii) has been trained in accordance with sub-condition 19(b) below; and

(b) the licence holder has trained that person in a manner which enables them to conduct the dealings in accordance with the conditions of this licence.

20. The licence holder must notify all persons covered by the licence, from whom Personal information relevant to the administration and/or enforcement of the licence is collected by the licence holder, that such Personal information may be disclosed to the Regulator.

21. The licence holder must ensure that a copy of the licence is readily available to all persons covered by the licence, other than External service providers, who are conducting dealings with the GMO.

*Note: The licence may be made available electronically.*

## Section 3 Limits and control measures

**Limits on clinical trials conducted under this licence**

22. The GMO may be administered to a maximum of 40 trial participants.

23. The preparation and administration of the GMO must be completed within 5 years from the date of issuing of the licence.

### Preparation and administration of the GMOs

24. Administration of the GMO to trial participants must not commence prior to approval by a Human Research Ethics Committee.

25. The following activities must occur within a Clinical trial site:

(a) preparation of the GMO for administration to trial participants; and

(b) administration of the GMO to trial participants.

*Note: Before any of these activities take place, the details of each Clinical trial site must have been notified to the Regulator in accordance with Condition 44(a).*

26. The licence holder must ensure all trial participants, from the time of GMO administration, are provided with a pustule management kit, including;

(a) disposable gloves, disposable waterproof dressing, press-sealed bags, alcohol swabs, gauze; and

(b) an unbreakable secondary container appropriate for transporting waste back to the Clinical trial site. The secondary container must be labelled to indicate the contact details for the Clinical trial site; that it contains GMOs; and that it must be destroyed by autoclaving, chemical treatment or high-temperature incineration.

*Note: Unbreakable means able to withstand all reasonably expected conditions of storage and transport such as: the forces, shocks and impacts expected during handling; or changes of temperature, humidity or air pressure.*

**Conditions relating to trial participants**

27. The licence holder must notify each trial participant, from whom Personal information relevant to the administration and/or enforcement of the licence is collected by the licence holder, that such Personal information may be disclosed to the Regulator.

28. The licence holder must ensure that exclusion criteria used in selecting trial participants include (though are not limited to) the following persons:

    (a) Excluded persons as defined in this licence;

    (b) those having received live poxvirus based treatments or vaccines 30 days prior to the first treatment with the GMO

29. Before inoculating any trial participant with the GMO, the licence holder must obtain written agreement from the trial participant that they will:

    (a) forgo any vaccination with live poxvirus based vaccines (as advised by licence holder), during treatment and for 30 days after last treatment with the GMO,

    (b) use barrier contraception for 60 days after each treatment with the GMO;

    (c) not donate blood, sperm, ova, tissues or organs during treatment and for 60 days after their last treatment with the GMO.

    (d) avoid direct physical contact with children under 12 months, of age and Excluded persons as defined in this licence, for at least 7 days after each treatment or any time lesions are present;

    (e) if seeking medical attention outside of the clinical trial, inform the medical practitioner of their participation in the trial.

*Note: Condition 29(b)* is intended to minimise physical contact with pustules and/or bodily fluids during sexual activity in addition to preventing conception.

30. The licence holder must instruct the clinical trial participants in hygiene measures intended to prevent transmission of the GMO during the clinical trial. The hygiene measures must include:

    (a) thorough hand washing with soap or hand disinfectant after contact with infusion site, pustules or dressings;

    (b) cleaning household surfaces potentially exposed to the GMO with disinfectants;

    (c) washing contaminated clothing and bedding with disinfectants;

    (d) instructions on the management of pustules or skin lesions, including:

        i) preventing the exposure of other people and animals to lesions, dressings or any potentially contaminated material; and

        ii) ensuring persons caring for lesions, wear disposable gloves and wash or disinfect their hands immediately afterwards; and

        iii) sealing used dressings and other materials used in caring for the lesion in a primary container (e.g. a press-sealed bag), placing these within a secondary container (e.g. a biohazard bin) provided by the licence holder, and storing the secondary container such that it is inaccessible to children and animals until it is returned to the Clinical trial site; and

iv) returning the secondary container referred to above, and its contents, to the Clinical trial site for disposal as clinical waste during the subsequent follow-up visit; and

v) inform the Clinical trial site as soon as reasonably possible if they suspect that exposure such as physical contact of a lesion, to another person or to an animal may have occurred.

**Conditions related to the conduct of the dealings**

31. Conditions that apply to dealings with GMOs do not apply to Samples collected from trial participants, or other materials or waste, that are reasonably expected not to contain the GMO. The licence holder must provide to the Regulator upon request, a written justification for this expectation.

32. The licence holder must ensure that dealings are only conducted in a manner which:

(a) does not compromise the health and safety of people; and

(b) minimises the exposure of persons conducting the dealings and the environment to the GMO, other than intended exposure of trial participants.

*Note: The licence holder may achieve this by only engaging or otherwise authorising persons to conduct dealings who are required to adhere to appropriate standards and guidelines. For example, standards developed by the National Pathology Accreditation Advisory Council for pathology practices, the Australian Guidelines for the Prevention and Control of Infection in Healthcare, Guidelines for Good Clinical Practice and the National Safety and Quality Health Service (NSQHS) Standards.*

33. The licence holder must ensure that procedures are in place to account for the GMO from import to destruction/export, and records must be made available to the Regulator on request.

**Work practices at Clinical trial sites**

34. For the purposes of Condition 3232, work practices and behaviours within a Clinical trial site must include, but are not limited to, the following:

(a) immunosuppressed persons must not prepare, handle or administer the GMO. In addition, these persons must not be engaged in the care of the trial participants for at least 7 days after each treatment or any time lesions are present;

(b) persons preparing and administering the GMOs must be;

i) suitably qualified and trained staff in conducting dealings with the GMOs;

ii) informed of the risks associated with the GMOs and procedures to follow in the event of exposure to the GMOs;

(c) persons preparing and administering the GMOs must wear personal protective equipment (PPE), including at least gowns, gloves, and eye protection;

(d) any broken skin (e.g. cuts, scratches, dermatitis) of persons conducting dealings not covered by PPE or clothing must be covered with a waterproof dressing;

(e) all work surfaces must be Decontaminated after they have been used for conducting dealings authorised by this licence;

(f) equipment used for dealings with the GMOs must be Decontaminated after use;

(g) the infusion site must be covered with an occlusive dressing following administration of the GMO.

**Transport, storage and disposal of the GMOs**

35. The licence holder must ensure that transport of the GMOs is conducted only for the purposes of, or in the course of, another dealing permitted by this licence, for supply in accordance with Condition 12, or for export.

36. For the purposes of import or export, and transport between the border and either a Storage facility or a Clinical trial site, the licence holder must ensure the GMO is packaged, labelled, stored and transported consistent with International Air Transport Association (IATA) shipping classification UN 3245/ UN 3373 [Category B].

37. Transport between a Storage facility and the clinical trial site can also be done consistent with IATA shipping classification UN/3245/3373 if the GMO is not repackaged at the Storage facility.

38. The licence holder must ensure that transport and storage of the GMO, unless conducted according to Condition 36 or 37, follows these sub-conditions:

    (a) GMOs must be contained within a sealed, unbreakable primary and secondary container(s), with the outer packaging labelled to indicate at least:

        i) that it contains GMOs; and

        ii) that it contains biohazardous material as designated by a biohazard label; and

        iii) the contact details for the licence holder; and

        iv) instructions to notify the licence holder in case of loss or spill of the GMOs; and

    (b) the external surface of the primary and secondary container must be Decontaminated prior to and after transport; and

    (c) procedures must be in place to ensure that GMOs can be accounted for and that a loss of GMOs during transport or storage or failure of delivery can be detected; and

    (d) access to the GMOs is restricted to authorised persons for whom Condition 18 or Condition 19 has been met (i.e. the GMOs are within a locked unit or an area which has restricted access). This includes situations where containers are left for collection in a holding area, or left unattended prior to Decontamination; and

    *Note: All stored GMOs remain the responsibility of the licence holder.*

    (e) if the GMO is being transported or stored with a coolant (e.g. dry ice, liquid nitrogen or any other coolant) which will release a gas, a mechanism to allow the escape of the gas must be included. If water ice is used as a coolant then the outer packaging should be constructed so as to prevent any leakage. All containers must be able to withstand the temperatures to which they will be subjected; and

    *Note: When transporting and storing with coolants, it is preferable for coolants to be used outside of the secondary container.*

    (f) a consolidated record of all GMOs being stored under this condition is maintained and made available to the Regulator upon request; and

    (g) for the purposes of transport entirely within a building, where the GMOs are accompanied by an authorised person for whom Condition 19 has been met, Conditions 38(a)iii), 38(a)iv) and 38(c) do not apply.

39. The licence holder must ensure that all GMOs and waste reasonably expected to contain the GMOs are Decontaminated:

    (a) prior to disposal, unless the method of disposal is also a method of Decontamination; and

(b) before or upon suspension, cancellation or surrender of the licence, unless covered by another authorisation under the Act, or exported; and

(c) by autoclaving, chemical treatment, high-temperature incineration or any other method approved in writing by the Regulator.

40. Where transport is conducted by External service providers for the purpose of destruction, the licence holder must ensure that the GMO, or waste reasonably expected to contain the GMO, enters the clinical waste stream for Decontamination via autoclaving or high-temperature incineration.

*Note: In the event of a spill during transport by an External service provider, compliance with relevant State or Territory legislation and regulations to manage clinical or biohazardous spills is sufficient.*

**Contingency plans**

41. The licence holder must ensure that any person (other than a trial participant) exposed to the GMOs is offered prompt medical treatment. The clinician must be provided with any relevant information about the GMO.

42. If there is a spill or an unintentional release of the GMOs at a Storage facility or Clinical trial site, the following measures must be implemented:

(a) the GMOs must be contained to prevent further dispersal; and

(b) persons cleaning up the GMO must wear appropriate PPE; and

(c) the exposed area must be Decontaminated with an appropriate chemical disinfectant effective against the GMOs, such as 10% bleach; or 70% ethanol

(d) any material used to clean up the spill or PPE worn during clean-up of the spill must be Decontaminated; and

(e) the licence holder must be notified as soon as reasonably practicable.

## Section 4 Reporting and Documentation

*Note: The following licence conditions are imposed to demonstrate compliance with other conditions and facilitate monitoring of compliance by staff of the OGTR. Notices and reports may be emailed to OGTR.M&C@health.gov.au. A summary of notification and reporting requirements is provided at **Attachment B**.*

43. The licence holder must notify the Regulator, in writing, of the name and address of each Storage facility before commencement of dealings at that location.

44. At least 14 days prior to first administering the GMO at each Clinical trial site, or a timeframe agreed to in writing by the Regulator, the licence holder must provide the Regulator with a Compliance Management Plan for that Clinical trial site, specifying:

(a) the name, address and description of the Clinical trial site, including any associated Pharmacies/storage areas/Analytical facilities;

(b) the role and contact details for key persons responsible for the management of the trial at the site;

(c) that the Institutional Biosafety Committee (IBC) associated with the site (if any) has been notified of the trial and have been consulted regarding site specific procedures;

(d) the proposed reporting structure for the trial at the site and how the reporting structure enables the licence holder to become aware of all reportable events including but not limited to Conditions 15, 16, 45 and 46;

(e) details of how the persons covered by the licence (for that type of dealing) will be informed of licence conditions applicable to them and how they will be trained to safely conduct the dealings;

(f) details of how compliance with Condition 30 will be achieved in relation to instructing clinical trial participants in hygiene measures intended to prevent transmission of the GMO;

(g) the person(s) or class of persons administering the GMO;

(h) where, within the site, the GMO is expected to be administered;

(i) the expected date of first administration;

(j) how compliance with Condition 32 will be achieved in relation to preparation of participant Samples for analysis subsequent to administering the GMO.

*Note: For the purpose of finding out whether the Act has been complied with, an OGTR inspector may, if entry is at a reasonable time, enter a facility occupied by the licence holder or a person covered by the licence and exercise monitoring powers.*

45. For each Clinical trial site, the licence holder must notify the Regulator, in writing, of the end of the clinical trial, no later than 30 days after:

(a) the final dose being administered; or

(b) the decision that no further participants will be treated at that site.

46. The licence holder must inform the Regulator as soon as reasonably possible:

(a) in the event of a trial participant experiencing a serious adverse event which may be related to the GMO;

(b) in the event of a loss or spill of the GMO;

(c) in the event of the exposure of a person other than a trial participant, or animals, to the GMO; and

(d) if a trial participant has not followed the procedures described in the instructions provided by the licence holder.

47. At least 14 days prior to first administering the GMO, the licence holder must provide to the Regulator a written methodology to reliably detect the GMO, or the presence of the genetic modifications described in this licence in a person.

48. Upon request from the Regulator, the licence holder must provide any signed records or documentation collected under a condition of this licence, within a time period stipulated by the Regulator.

# Attachment A

**DIR No: 208**

**Title:** Clinical trial of GM vaccinia virus for the treatment of solid tumours

**Organisation Details**

Postal address: Novotech (Australia) Pty Limited
Level 2, 15- 31 Pelham Street
Carlton
Victoria, 3053

Phone No: (+61 3) 9491 8560

**GMO Description**

**GMOs covered by this licence:**

*Vaccinia virus* genetically modified by introduction or deletion of only the genes or genetic elements listed in Table 1 below.

**Parent Organisms:**

Common Name: *Vaccinia virus*

Scientific Name: *Vaccinia virus*

**Modified traits:**

Categories: Human therapeutic

Description: The GMO, known as IDOV-Immune, is a live vaccinia virus treatment derived, modified to selectively replicate in cancerous cells and to enhance the human immune response to the target cancerous tumour cells. Modified genes are listed in Table 1.

**Table 1. Nucleic acid responsible for conferring the modified traits**

| **Genetic modifications** | |
|---|---|
| **Source, identity, nature of modification** | **Modified trait description** |
| Introduced genes: | Three separate genes related to immune function of human origin, which enhance anti-tumour immune responses. |
| Deleted genes: | The deletion of 3 VACV genes, which improves the efficacy and safety of the GMO. |

**Trial participants and route of administration of the GMOs**

Intravenous administration to adult humans with refractory solid tumours.

**Confidential commercial information (CCI)**

Details of the modifications made to the GMO were declared CCI under Section 185 of the *Gene Technology Act 2000*.

## Attachment B – Summary of reporting requirements*

| Prior to the commencement of the trial | Condition | Timeframe for reporting |
|---|---|---|
| The name and address of each Storage facility | 43 | Before commencement of dealings at that location |
| A written Compliance Management Plan for each Clinical trial site:<br>(e) the name, address and description of the Clinical trial site, including any associated Pharmacies/storage areas/Analytical facilities;<br>(f) the role and contact details for key persons responsible for the management of the trial at the site;<br>(g) that the Institutional Biosafety Committee (IBC) associated with the site (if any) has been notified of the trial and have been consulted regarding site specific procedures;<br>(h) the proposed reporting structure for the trial at the site and how the reporting structure enables the licence holder to become aware of all reportable events including but not limited to Conditions 15, 16, 45 and 46;<br>(i) details of how the persons covered by the licence (for that type of dealing) will be informed of licence conditions applicable to them and how they will be trained to safely conduct the dealings;<br>(j) details of how compliance with Condition 30 will be achieved in relation to instructing clinical trial participants in hygiene measures intended to prevent transmission of the GMO. the person(s) or class of persons administering the GMO;<br>(k) where, within the site, the GMO is expected to be administered;<br>(l) the expected date of first administration;<br>(m) how compliance with Condition 32 will be achieved in relation to preparation of participant Samples for analysis subsequent to administering the GMO. | 44 | At least 14 days prior to the first administration of the GMO at each Clinical trial site, or a timeframe agreed to in writing by the Regulator |
| For each Clinical trial site, the licence holder must notify the Regulator, in writing, of the end of the clinical trial, no later than 30 days after:<br>(n) the final dose being administered; or<br>(o) the decision that no further participants will be treated at that site. | 45 | 30 days after final dose or discontinuation of participation |

| | | |
|---|---|---|
| The licence holder must inform the Regulator as soon as reasonably possible:<br>(p) in the event of a trial participant experiencing a serious adverse event which may be related to the GMO;<br>(q) in the event of a loss or spill of the GMO;<br>(r) in the event of the exposure of a person other than a trial participant, or animals, to the GMO; and<br>(s) if a trial participant has not followed the procedures described in the instructions provided by the licence holder. | 46 | Immediately |
| At least 14 days prior to first administering the GMO, the licence holder must provide to the Regulator a written methodology to reliably detect the GMO, or the presence of the genetic modifications described in this licence in a person. | 47 | 14 days prior to first treatment |
| Upon request from the Regulator, the licence holder must provide any signed records or documentation collected under a condition of this licence, within a time period stipulated by the Regulator. | 48 | Upon request |
| **Information to be provided at any time during the clinical trial** | **Condition** | **Timeframe for reporting** |
| Any additional information related to the health and safety of people and the environment associated with the dealings covered by the licence, or any unintended effects of the dealings authorised by the licence | 15(a), (c) | Immediately |
| Information related to any contravention of the licence by a person covered by the licence | 15(b) | Immediately |
| Any relevant conviction of the licence holder | 16(a) | Immediately |
| Any revocation or suspension of a licence or permit held by the licence holder under a law of the Commonwealth, a State or a foreign country | 16(b) | Immediately |
| Any event or circumstances that would impact the licence holder capacity to meet the licence conditions | 16(c) | Immediately |