

**How to establish milestones in your LSDF grant**

The following is meant as a guide to negotiating and finalizing your milestones and timeline with LSDF program staff. Milestones serve as unambiguous indicators of progress and are used to satisfy Washington state requirements that grants are paid on a reimbursement basis against agreed-upon work. Generally, milestones measure concrete, discrete outcomes such as a deliverable. There needs to be a sufficient number of milestones so progress is not measured against a broad indicator spanning a considerable period and to make reimbursement logical, but not so many that they become trivial or burdensome to manage.

**Grant milestones must include both scientific and business tasks, even if all or some of the business tasks are funded through non-LSDF sources.**

Milestones are reported on in quarterly grant progress reports by the principal investigator, and are cited on reimbursement requests submitted as frequently as monthly. Milestones do not have to be completed for payment to be made, but progress towards milestone completion must be clear and definite.

**Failure to meet milestones can result in renegotiation of the milestones to more realistically predict progress; acceleration of effort to catch up; and, when particularly critical milestones are missed and/or the work will not be completed as originally proposed, termination of the grant.**

The following are hypothetical examples using a one-year grant term. The “acceptable” format is not a required template. The **bolded milestones** are mandatory milestones.

*Unacceptable:*

- Year 1:            synthesize inhibitor
- hire two new members for our group
- buy new hypervariator
- initiate recruitment efforts for clinical study

*Acceptable:*

<b>Milestone #</b>	<b>Milestone</b>	<b>Completion Date<sup>1</sup></b>	<b>Criterion/Deliverable</b>
1	Recruit staff for clinical study	Start date	Post job descriptions and ads for study coordinator and research nurse. Study coordinator requires PhD and five years relevant experience; research nurse must be RN with 10 years relevant experience.
2	Request FDA approval for clinical study	Start date	IND/IDE application submitted to FDA
3	Obtain FDA approval for clinical study	Month 2	FDA approval of IND/IDE application received. Go/no-go point, i.e., if FDA

<sup>1</sup> All dates refer to the indicated number of months following the Effective Date of the LSDF grant agreement. Dates are converted to calendar dates following execution of the grant agreement.

			approval is denied or significantly delayed, project stops for LSDF review.
4	Hire staff for clinical study	Month 2	One study coordinator and one research nurse hired.
5	Request institutional approval for animal/human subjects studies	Month 2	Animal/human subjects protocol(s) submitted to IACUC/IRB at ABC University
6	Receive institutional approval for animal/human subjects studies	Month 3	ABC University IACUC/IRB protocol approval letter received. Go/no-go point, i.e., if IACUC/ IRB approval is denied or significantly delayed, project stops for LSDF review.
7	Synthesize inhibitor against protein XYZ3	Month 3	Produce 100 mg of inhibitor using grantee's validated GMP synthesis protocols. Go/no-go point, i.e., if inhibitor yield significantly lower, project stops for LSDF review.
<b>8</b>	<b>First quarterly update meeting</b>	<b>Month 3</b>	<b>In-person meeting between project team and LSDF staff</b>
9	Distribute information on first-in-human clinical study of an XYZ3 inhibitor for treatment of early-stage breast cancer	Month 4	In-person visits and consultations by study coordinator and research nurse (including presentation of study goals, procedures, and inclusion criteria) completed with 10 oncologists in the statewide ABC Hospital and Clinic Network.
10	Freedom-to-operate analysis	Month 4	Commercial partner, Company X, performs FTO as cost-sharing with the project
11	Identify patients for the study of XYZ3 inhibitor for breast cancer	Month 6	15 eligible patients consented and enrolled from the 100 ABC oncologists contacted. Go/no-go point, i.e., if recruitment is fewer than five patients, project stops for LSDF review.
<b>12</b>	<b>Collaboration agreements executed</b>	<b>Month 6</b>	<b>Collaboration agreements specifying intellectual property rights and disposition signed among grantee, co-applicants, service providers, and collaborators.</b>
<b>13</b>	<b>Semi-annual progress report</b>	<b>Month 6</b>	<b>Progress report submitted through LSDF website.</b>
<b>14</b>	<b>Second quarterly update meeting</b>	<b>Month 6</b>	<b>In-person meeting between project team and LSDF staff.</b>
15	Order new hypervariator	Month 6	Purchase agreement signed.
16	Management committee meeting	Month 6	Co-investigators and at least one additional co-I lab member meet for four hours.

17	Complete dose-escalation study with 15 patients	Month 8	Administer three doses of XYZ3 inhibitor to five patients each and monitor for toxicity as detailed in the FDA- and IRB-approved protocol. Go/no-go point, i.e., if significant toxicity is observed, project stops for LSDF review.
18	Install new hypervariator	Month 9	Receive hypervariator, install in B2-243.
19	Company funding	Month 9	Commercialization partner or grantee organization completes two meetings with angel investment groups.
<b>20</b>	<b>Third quarterly meeting</b>	<b>Month 9</b>	<b>In-person meeting between project team and LSDF staff</b>
<b>21</b>	<b>Develop method for submission of post-award progress reports</b>	<b>(one month before end of grant term)</b>	<b>Agree on the schedule and mechanism for post-award progress reports with LSDF program staff</b>
22	Analyze data from dose-escalation study	Month 12	Select optimal dose(s) for follow-on studies based on toxicity profile.
23	Apply for follow-on funding to continue work after LSDF grant term ends	Month 12	One NIH SBIR proposal submitted.
<b>24</b>	<b>Semi-annual progress report</b>	<b>Month 12</b>	<b>Progress report submitted through LSDF website.</b>
<b>25</b>	<b>Meeting with technology transfer</b>	<b>Month 12</b>	<b>In-person meeting with technology transfer office staff; LSDF program staff person participates. Also represents fourth quarterly update meeting.</b>