TrACER Intervention Statement

The NCCN recommends using G-CSF in the first cycle of high FN risk chemotherapy, and against using G-CSF in the first cycle of low FN risk chemotherapy. This directly translates to inclusion of standing G-CSF orders for high risk FN chemotherapy and exclusion of standing G-CSF orders for low FN risk chemotherapy.

For intermediate FN risk chemotherapy, however, the NCCN doesn't recommend for or against G-CSF, but suggests that providers *consider* giving G-CSF based on individual patient factors. It is unclear exactly how this recommendation can be translated to G-CSF standing orders. Currently, G-CSF standing orders for intermediate FN risk regimens are largely based on provider preference or other heuristics, and vary from hospital to hospital.

TrACER is intended to test which type of G-CSF standing order default setting is preferable by randomizing some hospitals to **include** G-CSF standing orders (Intervention Arm 3) and some to **exclude** G-CSF standing orders (Intervention Arm 4) in intermediate FN risk regimens (including appropriate G-CSF default settings for high and low FN risk regimens as well). TrACER will then collect information from these hospitals and eligible patients such as patient outcomes, G-CSF prescribing rates, and how often providers overrode the default G-CSF prescriptions, among others. Comparing data between intervention arms will reveal which standing order defaults – if any – produce the highest operational efficiency and best clinical outcomes.

	NCCN	Ideal G-CSF Standing Order	TrACER Assigned G-CSF	Affected
FN Risk	Recommendation	Default	Standing Order Defaults	Intervention Arm(s)
High	Use G-CSF	Include	Include	Both 3 & 4
Intermediate	Consider G-CSF	Unknown	Include	3
			Exclude	4
Low	Do not use G-CSF	Exclude	Exclude	Both 3 & 4

Tracer is therefore not a drug trial, but a <u>system trial</u>. It is not intended to test G-CSF itself, but the operational and clinical effects of including or excluding G-CSF standing orders in prescriptions of certain types of chemotherapy. Providers should still follow NCCN guidelines and *consider* whether G-CSF is appropriate based on individual patient characteristics, and act accordingly by adding or removing G-CSF from prescription set. Each addition or removal of G-CSF is therefore not a protocol violation, but a data point that will be used to determine the appropriateness of the G-CSF default setting.

The TrACER study is in no way endorsing the inclusion or exclusion of G-CSF in a chemotherapy order for any particular patient. It is still the duty of the provider to consider the necessity of G-CSF for each and every patient and act in a way that is consistent with both guidelines and the patient's needs.