MINISTRY OF HEALTH
SINGAPORE

Consultation on Clinical Genetic and Genomic Services (CGGS) under the Healthcare Services Act (HCSA)

Health Regulation Group
Ministry of Health
January 2024

Aim and Agenda

Aim of consult: Seek inputs and feedback from licensees/providers for Clinical Genetic and Genomic Services (CGGS) requirements

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1	**Introduction to HCSA**	Slide 3
2	**Overview of Clinical Genetic and Genomic Services (CGGS)**	Slides 4 – 7
3	**CGGS Licence Conditions (LCs) and Guidelines**	
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Introduction to HCSA

- With effect from 18 Dec 2023, **the Healthcare Services Act (HCSA) has been fully implemented** and has replaced the Private Hospitals and Medical Clinics Act (PHMCA).

- All licensable premises under the PHMCA have been **fully transited to 16 Licensable Healthcare Services (LHSes)** under the HCSA.

- For each LHS, broad regulatory requirements are set out in Regulations[1], with specific technical requirements prescribed in Licence Conditions (LCs).
  - Regulations and LCs will be complemented with guidance which carry illustrations of good practices to help licensees interpret and meet the requirements in the Regulations and LCs.

- Under each LHS, there are also Specified Services (SSes) which fall within the scope of a LHS but **will require MOH's approval prior to commencement**.

- More information on HCSA can be found on the HCSA website.

[1] Some Regulations (e.g., General Regulations, Fees Regulations and Advertisement Regulations) apply to all licensees while others only apply to specific LHSes.

Introduction and Definition of CGGS

- With effect from **1 Apr 2024**, additional regulatory requirements will be promulgated for the provision of Clinical Genetic and Genomic Services (CGGS) under the HCSA.

**** Please note that the regulation of CGGS which was originally slated to start from 1 Apr 2024, has been postponed to 1 Sep 2024.**

CGGS is defined as a medical practice that provides **screening, diagnosis, management, risk assessment, education and counselling services** to an individual and/or his/her family member(s) with, or who is/are at risk of, conditions that have a genetic basis.

- As CGGS falls within the scope of several LHSes, it will be regulated under the following:

1) Outpatient Medical Service (OMS), Acute Hospital Service (AHS) and Community Hospital Service (CHS)
   - Involves the **offering and/or ordering** of genetic tests; and the provision of **counselling[1] or genetic counselling[2]**.

2) Clinical Laboratory Service (CLS)
   - Involves the **testing of human specimens** for the primary purpose of detecting a germline variant(s) or somatic variant(s), genotype(s), phenotype(s) or karyotype(s), with the exception of those performed in embryos[3].

[1] ***Counselling*** *is the process of helping a patient to understand and manage his or her health.*
[2] ***Genetic counselling*** *is the process of helping a patient to understand or adapt to the medical, psychological and genetic contributions of a disease or condition to allow for informed decisions to be made with regard to the disease or condition, or the risk of having one.*
[3] *Pre-implantation Genetic Testing for Monogenic or Single Gene Defects (PGT-M), and Pre-implantation Genetic Testing for Chromosomal Structural Rearrangements (PGT-SR) services are regulated as specified services under HCSA. The licence conditions for Pre-implantation Genetic Testing would apply to the service.*

3 Levels of CGGS

Level 1*	▪ Pre-test counselling, consent taking, ordering, testing, follow-up management (i.e., interpretation and disclosure of genetic test results) and post-test counselling of the following: ▪ Standard genetic test that detects abnormalities in chromosome structure, protein function, and DNA sequence and carries similar risks (and requires similar consent) as other medical tests. ▪ Comprises biochemical genetic tests; or haemoglobin electrophoresis for detecting haemoglobinopathies; or genetic testing of variant/change(s) important in tissue typing for transplant; or for blood typing and blood product transfusion (see **Annex B-I** for examples); or tests in **Annex B-II**.
Level 2*	▪ Pre-test counselling, consent taking, ordering, testing, follow-up management (i.e., interpretation and disclosure of genetic test results) and post-test counselling of the following: ▪ Tests for somatic variant/change(s) but may potentially reveal germline variant/change(s) that will require further confirmatory tests; or ▪ Tests involving germline variant/change(s) and have **no** risk of identifying a hereditary syndrome or pharmacogenetic tests[1] except tests in **Annex B-II** (see **Annex B-III** for examples).
Level 3*	▪ Pre-test genetic counselling, consent taking, ordering, testing, follow-up management (i.e., interpretation and disclosure of genetic test results) and post-test genetic counselling of the following: ▪ Tests for germline variant/change(s) that may impact future generations/offspring; or ▪ Tests identifying or investigating germline variant/change(s) and have risks of identifying a hereditary cancer syndrome; or ▪ Tests identifying a germline variant/change that is actionable, other than informing drug selection or dosing (see **Annex B-IV** for examples).

Increasing

1) Impact of the tests to the patient and family;

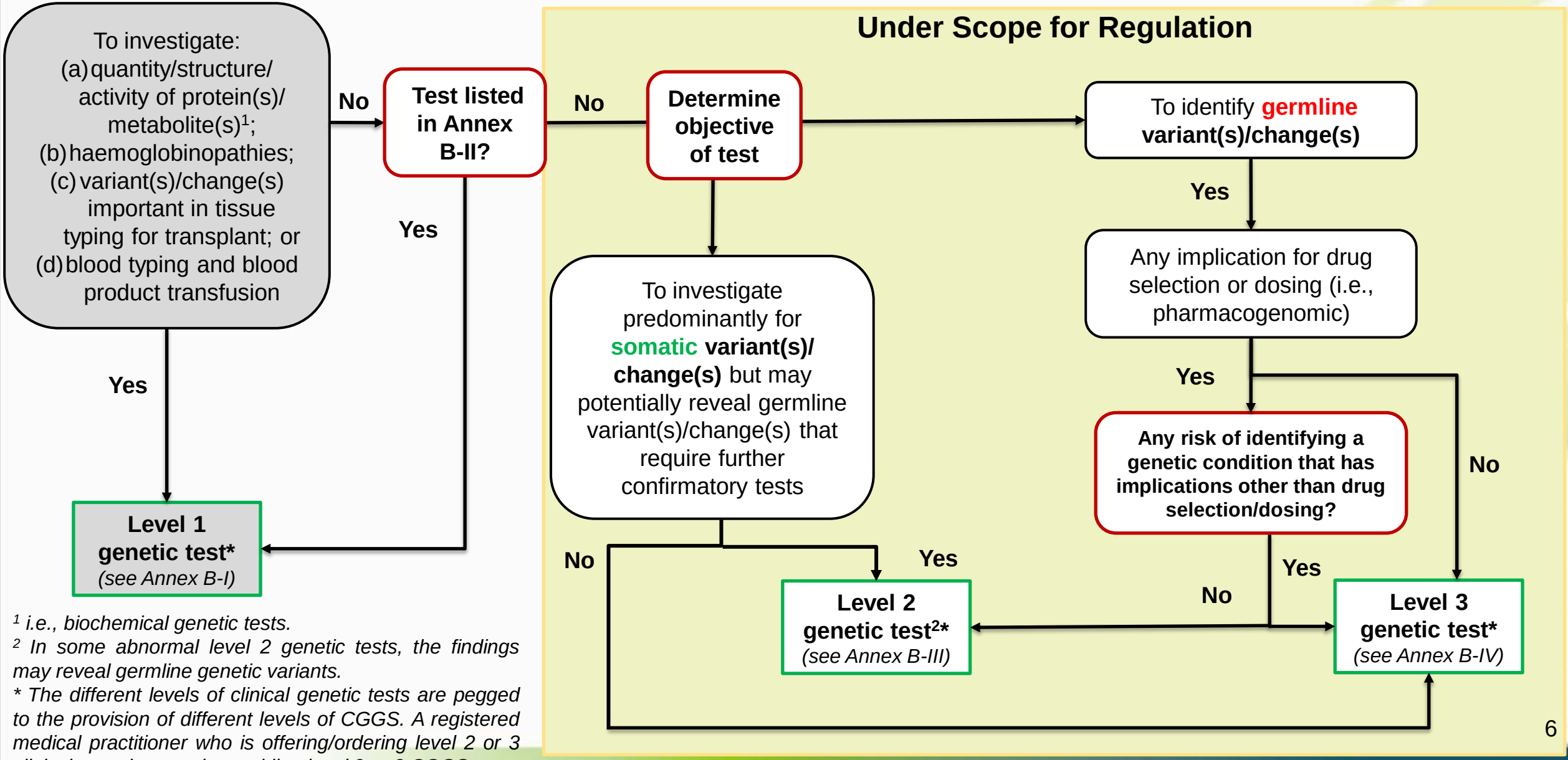
2) Risk of inappropriate ordering of genetic tests; and

3) Predisposition to wrong interpretation of test results.

[1] *Level 2 pharmacogenetic tests are those that test for **germline variants** and the ordering and/or interpretation of test results would require additional specialised expertise whereas level 1 tests are those that are more routinely used.*

** The different levels of clinical genetic tests are pegged to the provision of different levels of CGGS. A registered medical practitioner who is offering/ordering level 2 or 3 clinical genetic tests, is providing level 2 or 3 CGGS.*

Decision Matrix to Differentiate 3 Levels of Clinical Genetic Tests under CGGS



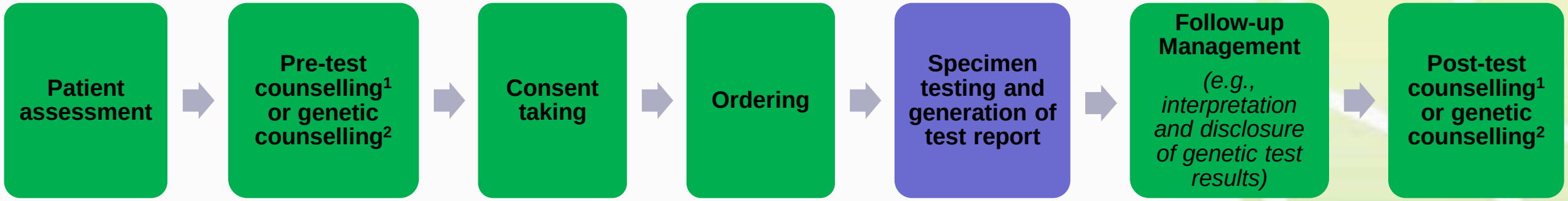
[1] *i.e., biochemical genetic tests.*

[2] *In some abnormal level 2 genetic tests, the findings may reveal germline genetic variants.*

** The different levels of clinical genetic tests are pegged to the provision of different levels of CGGS. A registered medical practitioner who is offering/ordering level 2 or 3 clinical genetic tests, is providing level 2 or 3 CGGS.*

Overview on the Processes for the Provision of CGGS

The diagram below shows the key steps in the provision of CGGS.



Legend:
- Clinical Genetic and Genomic Services (CGGS)
- Clinical Laboratory Genetic/Genomic Testing (LGT) Services

[1] ***Counselling*** *is mandatory for the provision of level 2 CGGS*
[2] ***Genetic counselling*** *is mandatory for the provision of level 3 CGGS.*

1. Regulation of CGGS for OMS, AHS and CHS Licensees

Regulation of CGGS for OMS

- Licensees are required to comply with all regulatory requirements applicable to OMS set out in the Act, Regulations and Licence Conditions (LCs)[1].

- Provision of **level 1 CGGS <u>does not</u> require MOH's approval** prior to commencement of service.
  - Processes for the provision of level 1 CGGS would be similar to other investigations done under OMS.

- Provision of **levels 2 or 3 CGGS <u>will require</u> MOH's approval** prior to commencement of service.
  - Licensees providing or intending to provide level 2 or 3 CGGS will need to apply to provide CGGS as a Specified Service (SS).
  - Regulatory requirements for the provision of levels 2 and 3 CGGS will be prescribed in the CGGS LCs.

- Under OMS, CGGS can be provided via the following modes of service delivery (MOSDs):

	Permanent Premises	Temporary Premises	Conveyances	Remote
CGGS	✓	✓	✓	-*

** Levels 2 and 3 CGGS should only be provided remotely alongside other allowable MOSDs (i.e., permanent premises, temporary premises or conveyance) and will not be offered as a standalone remote MOSD. Licensees will be approved to provide CGGS remotely as part of the approval for other MOSDs.*

[1] *Non-compliance may result in regulatory sanctions such as suspension of licence or amendment of licence conditions.*

Regulation of CGGS for AHS and CHS

- Licensees are required to comply with all regulatory requirements applicable to AHS or CHS set out in the Act, Regulations and LCs[1,2].

- Provision of **level 1 CGGS <u>does not</u> require MOH's approval** prior to commencement of service.
  - Processes for the provision of level 1 CGGS would be similar to other investigations done under AHS and CHS.

- Provision of **levels 2 or 3 CGGS also <u>does not</u> require MOH's approval** prior to commencement.
  - This is because AHS and CHS licensees are required to appoint Quality Assurance Committees (QACs) and put in place credentialing frameworks to govern the clinical services provided.
  - Regulatory requirements for levels 2 and 3 CGGS will be prescribed in the CGGS LCs for licensees to comply with.

- Under AHS and CHS, the only applicable mode of service delivery for CGGS will be permanent premises.

[1] *Non-compliance may result in regulatory sanctions such as suspension of licence or amendment of licence conditions.*
[2] *More details on whether the level of medical capability (LMC) for acute hospitals takes into account the new CGGS regulatory regime will be shared at a later date.*

Overview of Requirements for the Provision of Level 2 or 3 CGGS

CGGS Processes	Level 2	Level 3
Counselling a patient about a genetic test	• **Pre-test counselling** is **mandatory** for all level 2 genetic tests. • **Pre-test genetic counselling** is not mandatory but can be offered to the patient if there is a reasonable chance of a level 2 genetic test revealing a germline variant/change that has wider implications than drug dosing/selection. • **Pre-test genetic counselling** (where provided) shall be conducted and documented by a registered medical practitioner with the relevant qualifications/training and working experience** **OR** a Genetic Counsellor with the relevant qualifications/training and working experience^	• **Pre-test genetic counselling** is **mandatory** for all level 3 genetic tests. • **Pre-test genetic counselling** shall be conducted and documented by a registered medical practitioner with the relevant qualifications/training and working experience** **OR** a Genetic Counsellor with the relevant qualifications/training and working experience^
Consent Taking	• Written or verbal consent shall be obtained from the patient in accordance with HCSA Gen Regs Sec 36(2). *Sec 36(2), Gen Regs, HCSA: A licensee must establish and implement an appropriate system for obtaining the consent of a patient for any medical procedure that is carried out, or to be carried out, in the provision of the licensable healthcare service, and maintaining a proper record of the consent obtained.*	• Written consent shall be obtained from the patient and documented by a registered medical practitioner with the relevant qualifications/training and working experience* **OR** delegated to a team member who shall be under the supervision of a registered medical practitioner with the relevant qualifications/training and working experience*.
Ordering a genetic test	• Shall be ordered by a registered medical practitioner with the relevant qualifications/training and working experience* (called 'ordering doctor').	
Interpreting a genetic test result	• Interpretation of genetic test results shall be done by the ordering doctor **OR** a registered medical practitioner with the relevant qualifications/training and working experience*.	
Returning result to patient	• Disclosure of genetic test results shall be done by the ordering doctor **OR** a registered medical practitioner with the relevant qualifications/training and working experience* **OR** delegated to a team member who shall be under the supervision of a registered medical practitioner with the relevant qualifications/training and working experience*.	
	• It is **mandatory to offer** the patient **post-test counselling.** If a patient declines post-test counselling, this shall be documented. • **Post-test genetic counselling** **is not mandatory but highly recommended** for any abnormal level 2 genetic test that has implications other than drug dosing and/or if the individual is found to be at risk of having a germline genetic variant. • **Post-test genetic counselling** (where provided) shall be conducted and documented by a registered medical practitioner with the relevant qualifications/training and working experience** **OR** a Genetic Counsellor with the relevant qualifications/training and working experience^.	• It is **mandatory to offer** the patient **post-test genetic counselling.** If a patient declines post-test genetic counselling, this shall be documented. • **Post-test genetic counselling** (where provided) shall be conducted and documented by a registered medical practitioner with the relevant qualifications/training and working experience** **OR** a Genetic Counsellor with the relevant qualifications/training and working experience^

** See Slides 12-13 for the relevant qualifications/training and working experience ** See Slides 14-15 for the relevant qualifications/training and working experience*
^ See Slide 16 for the relevant qualifications/training and working experience

1. Personnel Requirements: Registered Medical Practitioner Providing CGGS

- Licensees shall ensure that specific aspects of CGGS including: (i) ordering levels 2 and/or 3 clinical genetic tests; (ii) interpretation of genetic test results; and (iii) medical consultation and follow-up management, are provided by a registered medical practitioner who meets the following requirements:

	Qualifications/Training*
a)	Has relevant qualifications or training in **clinical genetics**; **OR**
b)	Has relevant qualifications or training in **managing a disease/condition**; **OR**
c)	Has (a) or (b) but does not meet (e) or (f); will need to work under **direct supervision** of (a) + (e) or (b) + (e).

	Working Experience*
e)	Has accumulated **≥ 2 years of post-qualification relevant working experience** (within 3-year period) in clinical genetics or working with the genetics of that particular disease/condition

'Direct supervision' *requires that the supervising medical practitioner (i.e., supervisor): (a) signs off on case notes; (b) has oversight of the work done by the supervisee; and (c) remains accessible and available for case discussion with the supervisee.*

The supervisor must be employed, engaged or credentialed by the same licensee.

** See **Annexes C-I and II** for relevant qualifications, training and working experience*

1. Personnel Requirements: Registered Medical Practitioner Providing CGGS

- For registered medical practitioners who do not have the relevant qualifications or training but have accumulated **≥ 4 years of post-qualification relevant working experience** i.e.,

	Qualifications/Training
d)	NA i.e., Does not meet (a) or (b) but has (f)

	Working Experience*
f)	Has accumulated **≥ 4 years of post-qualification relevant working experience** (within a 6-year period) in clinical genetics or working with the genetics of that particular disease/ condition

They are given a 5-year sunrise period until 1 Apr 2029 to obtain the required qualification or training as stipulated in (a) or (b).

** See **Annexes C-I and II** for relevant working experience*

**** Please note that the regulation of CGGS which was originally slated to start from 1 Apr 2024, has been postponed to 1 Sep 2024. This applies for the sunrise period which will be until 1 Sep 2029.**

2. Personnel Requirements: Registered Medical Practitioner Providing Genetic Counselling

- Licensees shall ensure that genetic counselling for **level 3 CGGS** is provided by a registered medical practitioner who meets the following requirements:

	Qualifications/Training*
a)	Has relevant qualifications or training in **genetic counselling for that particular disease/condition**; **OR**
b)	Has relevant qualifications or training in **clinical genetics**; **OR**
c)	Has (a) or (b) but does not meet (e) or (f); will need to work under **direct supervision** of (a) + (e) or (b) + (e) or genetic counsellor who meets stipulated criteria.

	Working Experience*
e)	Has accumulated **≥ 2 years of post-qualification relevant working experience** (within 3-year period) in clinical genetic counselling for that particular disease/condition or clinical genetics

'Direct supervision' *requires that the supervising medical practitioner/genetic counsellor (i.e., supervisor): (a) signs off on case notes; (b) has oversight of the work done by the supervisee; and (c) remains accessible and available for case discussion with the supervisee.*

The supervisor must be employed, engaged or credentialed by the same licensee.

** See **Annexes C-I, II and III** for relevant qualifications, training and working experience*

2. Personnel Requirements: Registered Medical Practitioner Providing Genetic Counselling

- For registered medical practitioners who do not have the relevant qualifications or training but have accumulated **≥ 4 years of post-qualification relevant working experience** i.e.,

	Qualifications/Training
d)	NA i.e., Does not meet (a) or (b) but has (f)

	Working Experience*
f)	Has accumulated **≥ 4 years of post-qualification relevant working experience** (within a 6-year period) in clinical genetic counselling for that particular disease/condition or clinical genetics

They are given a 5-year sunrise period until 1 Apr 2029 to obtain the required qualification or training as stipulated in (a) or (b).

** See **Annexes C-I, II and III** for relevant working experience*

**** Please note that the regulation of CGGS which was originally slated to start from 1 Apr 2024, has been postponed to 1 Sep 2024. This applies for the sunrise period which will be until 1 Sep 2029.**

3. Personnel Requirements: Non-Medical Practitioner Providing Genetic Counselling*

- If genetic counselling for **level 3 CGGS** is provided by a non-medical practitioner, Licensees must ensure that the non-medical practitioner meets the following requirements:

	Qualifications/Training**
a)	Has a recognised degree/certification in genetic counselling, which is supported or recognised by credible bodies listed in **Annex C-III**; **OR**
b)	Has (a) but does not meet (c); will need to work under **direct supervision** of (a) + (c) (i.e., a genetic counsellor who meets stipulated criteria) or registered medical practitioner who meets stipulated criteria

	Working Experience**
c)	Has accumulated **≥ 2 years of post-qualification relevant working experience** (within 3-year period) in clinical genetic counselling

'Direct supervision' *requires that the supervising medical practitioner/genetic counsellor (i.e., supervisor): (a) signs off on case notes; (b) has oversight of the work done by the supervisee; and (c) remains accessible and available for case discussion with the supervisee.*

The supervisor must be employed, engaged or credentialed by the same licensee.

** Genetic counselling may be outsourced to appropriately trained personnel (who meets the requirements set out in the CGGS LCs). However, the licensee and the ordering doctor remain responsible for the patient's safety and welfare.*

*** See **Annex C-III** for relevant qualifications, training and working experience*

Application of CGGS Specified Service under OMS via HALP

- New licensees intending to provide CGGS are to submit a new licence application for the OMS from **2 Feb 2024** and apply for the provision of CGGS as a SS in HALP.*

- Existing OMS licensees providing CGGS are to apply for the provision of CGGS as a SS in HALP from **2 Feb 2024.***

**** Please note that the regulation of CGGS which was originally slated to start from 1 Apr 2024, has been postponed to 1 Sep 2024.**

This applies for the application of CGGS via the HALP system for OMS licensees (initial commencement date is deferred from 2 Feb 2024 to a later date until further notice).

** New or existing licensees who fail to apply for the provision of CGGS as a SS before commencement of the service will be penalised under Section 9A of HCSA (imprisonment or fine).*

Application of CGGS SS under OMS

Step 1: Application via HALP (go.gov.sg/halp)

- Submit a Request for Change (RFC) application in HALP
- Select **CGGS SS**

Step 2: Personnel Requirements

- Fill in the specific qualification/training and/or working experience that you or the personnel working in your clinic would have
- (Please refer to Slides 12-16 and Annexes C-I to III for the personnel requirements and acceptable qualifications/ training)

Step 3: Submission of Supporting Documents

Examples:

- Certificate(s) of relevant qualification, certification/ examination (e.g., certification in clinical genetics)
- Certificate of training course completion or attendance (e.g., completion of clinical genetics workshop)
- Letter certified or signed by supervisor/work organisation/ institution (e.g., proof of working experience, direct supervision)
- Log book (supervised, signed off, with stipulated minimal number of cases i.e., 20 within the last 2 years)

Step 4: Approval from MOH

- Await approval from MOH via email notification (i.e., approx. 2 months processing time) before commencing the service

Licence Fee Structure

- CGGS is considered a simple SS and would be subject to the simple SS fee structure for OMS licensees:

Single SS	Bundled SS
$900	$1,700 for two SSes $2,500 for three or more SSes

- For example:
  - OMS providing Blood Transfusion Service + CGGS -> $1,700 for bundle of two SSes.
  - OMS providing Blood Transfusion Service + Endoscopy Service + CGGS -> $2,500 for bundle of three SSes.

2. Regulation of LGT Services under CGGS for CLS Licensees

Regulation of LGT Services under CGGS for CLS

- Licensees are required to comply with all regulatory requirements applicable to CLS set out in the Act, Regulations and Licence Conditions (LCs)[1,2].

- Provision of **level 1 LGT services does <u>not</u> require licensees to <u>notify</u> MOH** prior to commencement of service, and is already regulated under the current requirements applicable to clinical laboratory services.

- Provision of **levels 2 and/or 3 LGT services will require licensees to <u>notify</u> MOH** prior to commencement of service.
  - Licensees are to ensure that they have complied with the LGT LCs prior to starting these services.
  - Regulatory requirements for levels 2 and 3 LGT services will be prescribed in the LGT LCs.

- Licensees shall ensure that its CLS is accredited by a laboratory accreditation body approved by MOH (refer to **<u>Annex C-VI</u>**) before it can provide **level 3 LGT services**.

- Under CLS, LGT services may be provided via the following modes of service delivery (MOSDs) subject to approval:

	Permanent Premises	Temporary Premises	Conveyances	Remote
LGT services	According to allowable MOSDs for each applicable lab discipline			**NA**

[1] Non-compliance may result in regulatory sanctions such as suspension of licence or amendment of licence conditions.

*[2] The onus is on the ordering doctor and licensee of the clinic/institution, and **NOT** the clinical laboratory, to ensure that the CGGS components (e.g., genetic counselling/counselling and consent taking) are conducted in accordance with the CGGS LCs requirements.*

Key Personnel Providing LGT services*

LGT
**Personnel overseeing the conduct of LGT services and processes
Trained Personnel
***Additional Personnel

* These LGT personnel are addition to key appointment holders (i.e., CGO, Section Leader) in CLS Regulations under HCSA.
** Personnel overseeing the conduct of LGT services and processes will oversee the work of Trained Personnel and Additional Personnel.
*** Additional Personnel shall work under the supervision of either the Personnel overseeing conduct of LGT services, or the Trained Personnel.

1. Personnel Requirements – Personnel Overseeing the Conduct of LGT Services and Processes

- Licensees shall appoint a personnel to oversee the conduct of LGT services and processes, including genetic test result analyses, generation of genetic test report findings, and signing off the genetic test reports.

	Qualification/Training*
a)	A registered **medical practitioner** who has relevant qualifications or training[1]; **OR**
b)	A **doctoral scientist** who has relevant qualifications or training[1]; **OR**
c)	A person with a **degree in medicine** who has relevant qualifications or training[1]; **OR**
d)	A person with a **Master's degree**[1]

	Working Experience*
e)	Has accumulated **≥ 5 years of post-qualification relevant working experience**[1] (within 7-year period) in a clinical laboratory service*
f)	Has accumulated **≥ 10 years of post-qualification relevant working experience**[1] (within 12-year period) in a clinical laboratory service*

* Personnel must currently be in active practice, or had only in the recent 3 years ceased active practice.

[1] Relevant qualifications/training and working experience in molecular genetics, biochemical genetics, or cytogenetics.

** See **Annex C-IV** for relevant qualifications, training and working experience*

2. Personnel Requirements – Trained Personnel

- Licensees shall employ or engage at least one personnel to be involved in the provision of LGT services who meets the following requirements (known as "**Trained Personnel**"):

	Qualification/Training*
a)	At least a **diploma or basic degree in medical laboratory technology**; **OR**
b)	A **basic degree in a relevant science subject**[1]

	Working Experience*
c)	Has accumulated **≥ 3 years of post-qualification relevant working experience**[2] (within 5-year period) in a clinical laboratory service*

* Personnel must currently be in active practice, or had only in the recent 3 years ceased active practice.

- For personnel who **do not** have 3 years of post-qualification relevant working experience, he/she shall work under the close supervision of the personnel overseeing the conduct of LGT services or a trained personnel.

[1] Relevant science subject such as Biomedical Science, Biochemistry, Genetics, Microbiology, Molecular Cell Biology, Engineering, Chemistry, or Nutrition.

[2] Working experience in molecular genetics, biochemical genetics, or cytogenetics.

** See **Annex C-IV** for relevant qualifications, training and working experience*

Quality Management System and Post-Analytical Procedures

Quality Management System (QMS)	
Existing HCSA regulations	Licensees must establish and implement a QMS for quality assessment and assurance of the CLS, in accordance with requirements set out in CLSRS Regulation Section 11.
New requirements in LGT LCs	In addition to this, the QMS shall minimally cover the following aspect of the provision of LGT services: 1. objectives and scope of the LGT services 2. list of all LGT services provided

Post-analytical Procedures	
Existing HCSA regulations	CLSRS Reg 37 states that Test Report must state all Incidental Findings (IF) that are potentially clinically significant and abnormal findings; and bring to the attention of the requestor.
New requirements in LGT LCs	In addition, Licensees shall establish and implement a Standard Operating Procedure (SOP) on the return of IF and/or Secondary Findings (SF) to the requesting healthcare institutions, overseas healthcare facilities and/or medical practitioners.* In developing the SOP, proper consideration shall be given to factors such as the predictive value, actionability of the IF and/or SF and the availability of patient's consent.

** LGT services can only be ordered by a requestor who is a registered medical practitioner, i.e., CLS licensees can only accept orders from a registered medical practitioner for the purpose of LGT services.*

Notification of LGT services via HALP and Licence Fees

- Please note that currently, system enhancements are underway for the notification process, and expected to be completed by 1 Apr 2024. When the system changes are completed, CLS licensees providing LGT services do not have to seek prior approval, but must submit a notification to MOH through the HALP system. Further details on the process will be shared with licensees at a later date.

- Provision of LGT services by CLS licensees will not incur additional licence fees (i.e., no additional fees are charged for LGT services besides CLS fees).

**** Please note that the regulation of CGGS which was originally slated to start from 1 Apr 2024, has been postponed to 1 Sep 2024.**

This applies for the notification of LGT via the HALP system for CLS licensees (i.e., initial commencement date is deferred from 1 Apr 2024 to a later date until further notice).

Notification of LGT services

The notification function is currently built under the “CGGS SS” tab, and the following illustrates the notification process for CLS LHS licensee. We will share the updated process for submitting the notification when the system enhancements are ready by Apr 2024.

Step 1: Submission of a Request for Change and Notification via HALP (go.gov.sg/halp)

- Submit a Request For Change (RFC) application in HALP
- Select **CGGS SS***
- Indicate whether **LGT services** are being provided and if so, the **levels of genetic tests conducted** (e.g., levels 2 and 3)

Step 2: Personnel Requirements

- Fill in the specific qualification/training and/or working experience that you or the personnel working in your clinical laboratory would have
- If your clinical laboratory is providing L3 genetic testing, fill in the laboratory accreditation body your CLS is accredited by
- (Please refer to Slides 22-24 and Annex C-IV for the personnel requirements and examples of the relevant qualifications/training)

Step 3: Submission of Supporting Documents

Examples:

- Certificate(s) of relevant qualification (e.g., PhD/MSc in Biomedical Science)
- Records e.g., results review, reports signed off, External Quality Assessment review, approval of new tests/methods, evidence of consultation with regard to testing/results interpretation
- Letter signed by work organisation showing work experience within a CLS
- Records of training, competency assessment and continuing education

- For application of new CLS licence, applicants should submit their application via HALP no later than two months before intended commencement date.
- For existing licensees (i.e., applied for relevant LHS licence previously), you may submit a RFC via HALP. Existing licensees may continue to provide LGT services as long as they have notified MOH.

3. Guidelines for the Provision of CGGS

CGGS Guidelines

- The CGGS Guidelines (adapted from the Standards) aims to provide guidance to licensees on the minimum standards required for the provision of CGGS and serves as good practice to meet the requirements in the LCs.

For all licensees	
1.	Definition and tiering of the three levels of CGGS
2.	Guidelines relating to the provision of level 1 CGGS • Personnel requirements • Counselling, consent and disclosure of test results
3.	Guidelines relating to the provision of LGT services • Pre-analytical / analytical / post-analytical procedures
4.	Guidelines relating to documentation / record keeping • Consent for level 3 clinical genetic tests, pre-test / post-test genetic counselling, clinical laboratory service records, genetic test reports, sample and information requirements to conduct the genetic test, training of clinical laboratory personnel
5.	Confidentiality of genetic test results and/or genetic information of patients
6.	Outsourcing of LGT services to foreign (overseas) clinical laboratories

Timeline

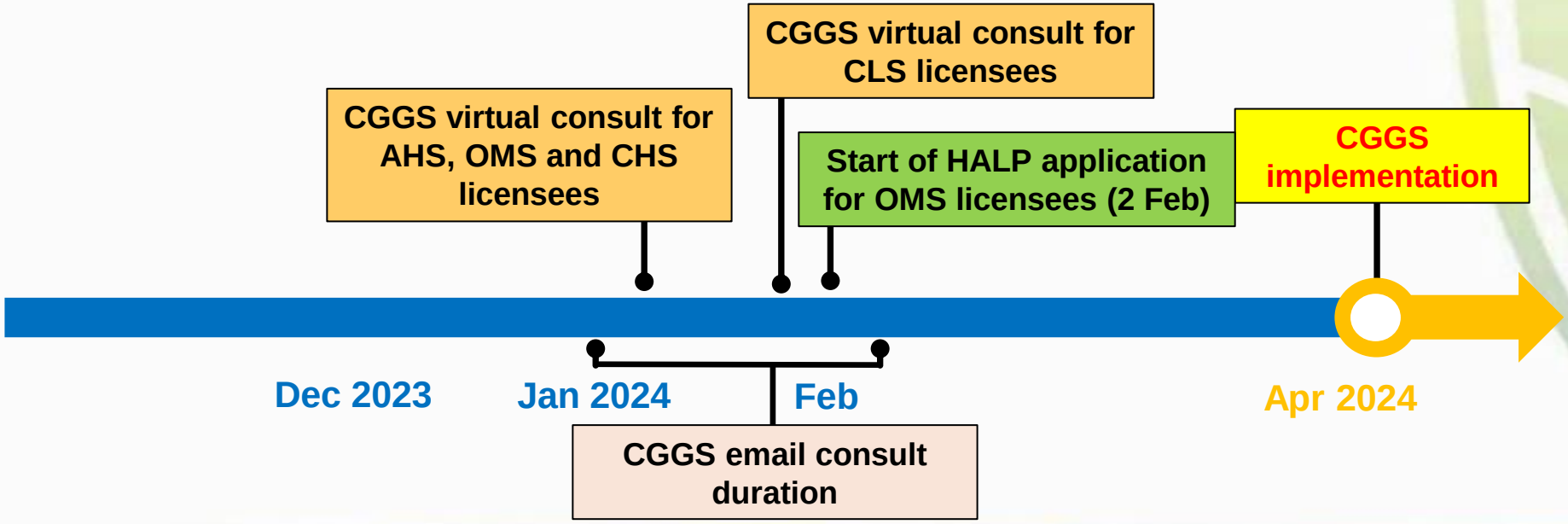
- The CGGS stakeholder consultations will take place from 5 Jan to 9 Feb 2024.
  - Email consultation from 5 Jan to 9 Feb 2024.
  - Virtual consultations on 8 and 26 Jan 2024.

- The CGGS and LGT LCs will be imposed from 1 Apr 2024.

**** Please note that the regulation of CGGS which was originally slated to start from 1 Apr 2024, has been postponed to 1 Sep 2024.**

This applies for the application of CGGS via the HALP system for OMS licensees (initial commencement date is deferred from 2 Feb 2024 to a later date until further notice) and notification of LGT via the HALP system for CLS licensees (i.e., initial commencement date is deferred from 1 Apr 2024 to a later date until further notice).

- Licensees are reminded to comply with the existing Standards and to apply via HALP for the provision of CGGS as a SS (for OMS licensees) and CLS licensees are to notify MOH via HALP.



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The End

Thank you

MINISTRY OF HEALTH
SINGAPORE

Annexes

Annex A-I: CGGS LCs Definitions

- *"Counselling" is the process of helping a patient to understand and manage the patient's health, which may take place in a medical consultation with a patient before and after a level 1 genetic test or level 2 genetic test is performed.*

- *"Direct supervision" requires that the supervising medical practitioner/genetic counsellor (i.e, supervisor): (a) signs off on case notes; (b) has oversight of the work done by the supervisee; and (c) remains accessible and available for case discussion with the supervisee.*

  The supervisor must be employed, engaged or credentialed by the same licensee.

- *"Genetic counselling" is the process of helping a patient to understand and/or adapt to the medical, psychological and genetic contributions of a disease or condition so as to allow for informed decisions to be made with regard to the disease or medical condition or the risk of having a disease or medical condition. this may take place before and after a level 2 genetic test or level 3 genetic test is performed.*

- *"Genetic Testing" or "Genetic Test" means the analysis of an individual's human chromosomes, DNA, RNA, genes and/or gene product such as proteins and/or metabolites with the purpose of detecting a germline or somatic variant(s) that can be indicative of a heritable or non-heritable change(s)/condition(s).*

Annex A-II: LGT LCs Definitions

- *"Genetic Testing" or "Genetic Test" means the analysis of an individual's human chromosomes, DNA, RNA, genes and/or gene product such as proteins and/or metabolites with the purpose of detecting a germline variant(s) or somatic variant(s) that can be indicative of a heritable or non-heritable change(s)/condition(s).*

- *"Germline Variant" means an alteration in DNA present within the germ cells (sperm or egg) that can be passed on to the next generation.*

- *"Incidental Findings" means non-intended findings that arise and are outside the original purpose for which the test or procedure was conducted. This is distinct from "secondary findings", which are not the primary target or goal in conducting the test or procedure but nonetheless intended to be sought.*

- *"Laboratory-developed test" ("LDT") means a medical device in the form of an in vitro assay or test for clinical diagnostic use that is:*

  (a) manufactured based on basic scientific principles; or

  (b) developed or manufactured based on reputable scientific sources,

  but excludes a medical device that is modified or adapted from an in vitro assay or test manufactured or supplied by another person (as defined under the Health Products (Medical Device) Regulations 2010);

Annex A-II: LGT LCs Definitions (cont'd)

- *"Secondary Findings" means additional findings which are intended to be sought but are not the primary target or goal in conducting the test or procedure, as determined by the practitioner. This is distinct from "incidental findings", which are findings that are not intended.*

- *"Somatic Variant" means an alteration in DNA in any cells of the body except germ cells (sperm or egg) and cannot be transmitted to the next generation.*

Annex B-I: Examples of Level 1 Clinical Genetic Tests

The list below is non-exhaustive and for reference purpose only.

Level 1	• Examples of biochemical genetic tests;
	  ○ Tests involving the analysis of the quantity of protein/metabolite e.g., amino acids, organic acids, carnitine and acylcarnitines, acylglycines, glycosaminoglycans, glycoproteins, cerebrospinal fluid (CSF) neurotransmitters;
	  ○ Tests involving the analysis of the structure of protein/metabolite e.g., determination of transthyretin (TTR) protein structure in plasma using mass spectrometry (test for transthyretin-associated familial amyloidosis); and
	  ○ Tests involving the analysis of protein activity e.g., enzymes such as galactose-1-phosphate uridyl transferase (GALT) enzyme activity (test for galactosemia), biotinidase enzyme activity (test for biotinidase deficiency (BIOT)), α-glucosidase enzyme activity (test for Pompe disease (glycogen storage disease type II)).
	• Haemoglobin electrophoresis for detecting haemoglobinopathies;
	• Tissue typing for transplant;
	• Blood typing; work up for transfusion reactions;
	• Electrocardiogram (ECG) (e.g., to detect prolonged QT interval); and
	• Any other test(s) set out in Annex B-II.

Annex B-II: List of Level 1 Clinical Genetic Tests[1,2,3]

Clinical recommendations regarding drug interactions and toxicity should be included for test reports of level 1 clinical genetic tests listed below.

Gene(s)/Variant(s) being screened for	Examples of drugs affected by gene(s)/variant(s) being tested for	Examples of indications for which gene(s)/variant(s) are tested
VKORC1, CYP4F2 and CYP2C9	Warfarin	Thromboembolic/excessive clotting disorder Anticoagulation
TPMT, NUDT15	Thiopurines (azathioprine, mercaptopurine and thioguanine)	Autoimmune disorder Inflammatory disorder Cancer
UGT1A1	Irinotecan	Cancer
*HLA-B*5701*	Abacavir	HIV
*HLA-B*5801*	Allopurinol	Gout, hyperuricemia
*HLA-B*1502*	Carbamazepine, phenytoin	Epilepsy
HLA-B27	Sulphasalazine	Juvenile Arthritis (ERA)/autoimmune disorder/allergy
*HLA-DQ2**		Risk of celiac disease
*HLA-DQ8** **Mainly predicts autoimmune disorder primarily due to ingestion of gluten*		Risk of celiac disease
CYP3A5	Tacrolimus	Need for immunosuppression e.g., post-transplant

[1] The list of genetic tests was recommended by the Genetic Testing Advisory Committee for classification as Level 1 clinical genetic tests.
[2] Clinical Pharmacogenetics Implementation Consortium (CPIC) Guidelines (2020). Retrieved from https://cpicpgx.org/guidelines/.
[3] Dutch Pharmacogenetics Working Group (DPWG) Guidelines (2020). Retrieved from https://www.knmp.nl/patientenzorg/medicatiebewaking/farmacogenetica/pharmacogenetics-1.

Annex B-II: List of Level 1 Clinical Genetic Tests (cont'd)

Gene(s)/Variant(s) being screened for	Examples of drugs affected by gene(s)/variant(s) being screened for	Examples of indications for which gene(s)/variant(s) are tested
CYP2C19	Citalopram, Escitalopram	Major depressive and anxiety disorders
	Clopidogrel	Coronary heart disease
	Voriconazole	Invasive fungal infections
CYP2C19 and CYP2D6	Amitriptyline	Major depressive disorders
CYP2D6	Fluvoxamine, Paroxetine, Nortriptyline	Major depressive and anxiety disorders
	Codeine, Tramadol, Oxycodone	Pain management
	Ondansetron, Tropisetron	Suppression of nausea and vomiting
	Tamoxifen	Cancer
*CYP2C9, HLA-B*1502*	Phenytoin	Epilepsy
ABCG2	Rosuvastatin	Lipid lowering
SLCO1B1	Simvastatin, Rosuvastatin	Lipid lowering
*Actionable PGx Genotyping Panel (CYP3A5, CYP2C9, CYP2C19, CYP2D6, CYP4F2, NUDT15, TPMT, VKORC1, SLCO1B1, HLA-B*1502, HLA-B*5701, HLA-B*5801)*	Multiple	Pre-emptive genotyping that provides an assessment for genes with strong drug gene associations
DPYD	5-fluorouracil chemotherapy	Cancer

Annex B-III: Examples of Level 2 Clinical Genetic Tests

The list below is non-exhaustive and for reference purpose only.

Level 2	• Epidermal Growth Factor Receptor (EGFR) variant testing in lung cancer tissue for the sole purpose of predicting sensitivity or resistance to targeted therapy in lung cancer; • KRAS variant testing in colorectal cancer tissue for the sole purpose of predicting sensitivity or resistance to targeted therapy in colorectal cancer; • Fluorescent-in-situ hybridisation of tumour/cancer tissue for gene amplification of gene variants/changes for the sole purpose of predicting sensitivity or resistance to targeted therapy in colorectal cancer; • NGS based gene panel for somatic gene variants/changes in tumour/cancer tissue for the sole purpose of predicting sensitivity or resistance to targeted therapy e.g., Acute Myeloid Leukemia gene panel; • Tumour microsatellite instability (MSI) tests, tumour next-generation sequencing (NGS) tests and tumour immunohistochemical (IHC) tests for mismatch repair (MMR) proteins that may potentially reveal germline variants/changes but where further tests would be needed for the diagnosis and/or confirmation of the germline variant/change/condition e.g., testing for TP53 variants in ovarian cancer tissue; and • Breast cancer gene expression profiling tests e.g., Oncotype and Prosigna.

Annex B-IV: Examples of Level 3 Clinical Genetic Tests

The list below is non-exhaustive and for reference purpose only.

Level 3	• Tumour NGS tests that predominantly investigate variants/changes that are invariably/almost certainly germline, and where these variants/changes have risks of identifying a hereditary cancer syndrome (i.e., a single gene disorder predisposing to cancer) e.g., testing for BRCA1 variants in breast or ovarian cancer tissue; • Prenatal QF-PCR Aneuploidy; • Non-invasive Prenatal Screening (NIPT); • NGS based NIPT; • MS-PCR for Prader Willi syndrome, Fragile X syndrome; • Karyotyping (prenatal, postnatal) for constitutional/germline abnormalities; • Chromosomal microarray analysis (prenatal, postnatal) for constitutional/germline abnormalities; • Uniparental disomy (UPD) analysis; • Gene sequence analysis for a germline variant(s)/change(s); • Gene deletion/duplication analysis for a germline variant(s)/changes(s); • Fluorescent-in-situ hybridisation for constitutional/germline abnormalities; • NGS based gene panels for constitutional/germline abnormalities e.g., identification of gene variants/changes associated with Hypertrophic Cardiomyopathy (HCM); • Whole exome sequencing (WES) for germline genetic variants/changes; • Whole genome sequencing (WGS) for germline genetic variants/changes; • ApoE for Alzheimer's disease prediction; and • Polygenic risk score analyses.

Annex C-I: Relevant Qualifications, Training and Working Experience for Personnel Providing CGGS

The list below is exhaustive.

Requirement	**(1) Clinical genetics**
Qualifications and/or training	Relevant qualifications and/or training in clinical genetics include courses on genetics- related topics such as genetic counselling and non-invasive prenatal testing (NIPT). It also includes satisfactory completion of online modules, and satisfactory attendance at genetics related seminars and workshops. a) Examples of relevant qualifications in clinical genetics: Certification in clinical genetics by any of the following certifying bodies: (i) American Board of Medical Genetics and Genomics (ii) Joint Royal Colleges of Physicians Training Board (United Kingdom) (iii) Royal Australasian College of Physicians (Australia and New Zealand) (iv) Canadian College of Medical Geneticists (v) European Union of Medical Specialists. b) Examples of relevant training in clinical genetics: (i) Trained under a person who has one of the qualifications/certifications listed in (a) above; (ii) Trained at one of the sites approved by any of the certifying bodies listed in (a) above; or (iii) Completed short-term workshops such as 'Genomic Education for Medical Professionals' (a quarterly workshop held locally), and 'Executive Certificate Program in Clinical Genomics' (5-day didactic teaching programme; held in partnership with Duke NUS Centre for Lifelong learning). Such short-term workshops can be counted towards the duration of training but should not be counted as sufficient in meeting the requirement.[1] The list of accreditation/certification bodies and sites approved by abovementioned certifying bodies is provided in **Annex C-II**.

[1] MOH will not define the acceptable range of duration for short-term courses and will also not maintain a list of acceptable short-term courses. Licensees will be responsible for factoring in short-term courses into the total training duration (i.e., MOH will however, assess whether the personnel has had received accredited training or attended training courses provided by any of the accreditation/certification bodies in the table in **Annex C-II**).

Annex C-I: Relevant Qualifications, Training and Working Experience for Personnel Providing CGGS (cont'd)

Requirement	**(1) Clinical genetics**
Working experience	Examples of relevant working experience in clinical genetics[2]: a) Clinical experience/training at a recognised/accredited site; or b) Clinical experience/training under a person who is accredited; or c) Clinical experience/training under a person who meets the relevant qualification, and working/training experience in clinical genetics
Supporting documents	Examples of appropriate supporting documents to show working experience in clinical genetics (any of the following): a) Log book (supervised, signed off, with stipulated minimal number of cases i.e., 20 within the last 2 years) b) Successful completion of recognised qualifications/certification/ examination c) Certificate of attendance (for training) d) Letter certified or signed by supervisor/work organisation/institution[3]

[2] Working experience in genetics research cannot be counted as having working experience in clinical genetics.

[3] Minimum components required in the letter include: (i) name of individual; (ii) number of years of working experience (for cumulative working experience, also include the duration which spans the cumulative working experience); (iii) summary of individual's scope of work; (iv) location/address of the organisation which the individual had acquired working experience; (v) name and qualifications of individual's supervisor (for individuals who do not meet the specific qualification requirements and are under direct supervision of an individual who has met the requirements); and (vi) certification of true copy by supervisor/organisation.

Annex C-I: Relevant Qualifications, Training and Working Experience for Personnel Providing CGGS (cont'd)

Requirement	**(2) Managing a disease/condition**
Qualifications and/or training	For management of disease/condition belonging to a relevant specialty, the individual should have: a) specialist/fellowship qualifications/training in the relevant specialty; or b) show written/documented record that their training exposed them to management of the condition from that specialty.
Working experience	<u>Examples of relevant experience in working with the genetics of that particular disease or condition:</u> a) Clinical experience/training at a recognised/accredited site; or b) Clinical experience/training under a person who is accredited; or c) Clinical experience/training under a person who meets the relevant qualification, or working/training experience in the area of genetics of that particular disease/condition
Supporting documents	<u>Examples of appropriate supporting documents to prove that personnel has experience in working with the genetics of that particular disease or condition (any of the following):</u> a) Log book (supervised, signed off, with stipulated minimal number of cases i.e., 20 within the last 2 years) b) Successful completion of recognised qualifications/certification/ examination c) Certificate of attendance (for training) d) Letter certified or signed by supervisor/work organisation/institution[3]

Annex C-II: Relevant Qualifications and Accredited Training Sites for Clinical Genetics

The list below is exhaustive.

Country/ Continent	Accreditation/ Certification Body	Relevant Qualifications and Training	Accredited Sites for Advanced Training in Clinical Genetics
United States of America	American Board of Medical Genetics and Genomics (ABMGG)	• Completed Accreditation Council for Graduate Medical Education (ACGME)-accredited specialised training in medical genetics and genomics • Attained the fellow of American Board of Medical Genetics and Genomics (ABMGG)	Training sites must be accredited by the Accreditation Council for Graduate Medical Education (ACGME) Examples: a) Yale University – Clinical Genetics and Genomics Residency Training Program b) Stanford University – Division of Medical Genetics c) University of Michigan
United Kingdom	Joint Royal Colleges of Physicians Training Board (JRCPTB)	• Completed specialised training in clinical genetics through the Specialised Advisory Committee (SAC) in JRCPTB	Training sites are accredited by the General Medical Council Examples: a) St Mary's Hospital b) Nottingham University Hospitals NHS Trust - City Campus c) Royal Liverpool University Hospital d) Newcastle University e) The Walton Centre NHS Foundation Trust f) NHS Nightingale Hospital London g) Great Ormond Street Hospital Central London Site
Australia	Royal Australasian College of Physicians (RACP)	• Completed specialised training in clinical genetics through the Specialist Advisory Committee (SAC) in Clinical Genetics of the RACP • Attained the Fellow of Royal College Australasian of Physicians (FRACP) qualification	a) New South Wales: (i) Hunter Genetics Unit (ii) Liverpool Hospital (iii) Royal Prince Alfred Hospital (iv) Royal North Shore Hospital (v) St Vincents Hospital – Clinical Genomics (vi) Sydney Children's Hospital (vii) Prince of Wales Hospital (Cancer Genetics) (viii) The Children's Hospital at Westmead – Clinical Services; Metabolic Services (ix) Westmead Hospital – Adult Clinical Services; Adult Metabolic Services

Annex C-II: Relevant Qualifications and Accredited Training Sites for Clinical Genetics (cont'd)

Country/ Continent	Accreditation/ Certification Body	Relevant Qualifications and Training	Accredited Sites for Advanced Training in Clinical Genetics
Australia (cont'd)	Royal Australasian College of Physicians (RACP)	• Completed specialised training in clinical genetics through the Specialist Advisory Committee (SAC) in Clinical Genetics of the RACP • Attained the Fellow of Royal College Australasian of Physicians (FRACP) qualification	b) Queensland: (i) Genetic Health Queensland (ii) Queensland Children's Hospital – Queensland Lifespan Metabolic Medicine Service; Mater Misericordiae Health Services Brisbane c) Western Australia: (i) Genetic Services of Western Australia d) Victoria: (i) Victorian Clinical Genetics Services – Clinical Unit (ii) Royal Children's Hospital – Department of Metabolic Medicine (iii) Royal Melbourne Hospital (iv) Austin Health (v) Monash Health e) South Australia: (i) South Australian Metabolic Service (ii) Royal Adelaide Hospital (iii) Women's and Children's Hospital (South Australian Clinical Genetics Service) – Clinical Services
New Zealand	Royal Australasian College of Physicians (RACP)		b) Auckland: (i) Auckland City Hospital – Northern Hub (ii) Starship Paediatric Metabolic Unit b) Wellington: (i) Wellington Hospital – Central Hub b) Christchurch: (i) Women's and Children's Hospital in Christchurch – South Island Hub

Annex C-II: Relevant Qualifications and Accredited Training Sites for Clinical Genetics (cont'd)

Country/ Continent	Accreditation/ Certification Body	Relevant Qualifications and Training	Accredited Sites for Advanced Training in Clinical Genetics
Canada	Canadian College of Medical Geneticists (CCMG)	• Completed specialised training in clinical genetics through CCMG training program • Completed specialised training and fellowship accredited by the American Board of Medical Genetics and Genomics (ABMGG)	a) University of Calgary b) McGill University c) McMaster University d) Université de Montréal, Hôpital Ste-Justine e) University of Alberta/Alberta Precision Labs North f) University of British Columbia g) University of Manitoba h) University of Ottawa i) University of Toronto – Hospital for Sick Children
Europe	European Union of Medical Specialists (UEMS)	• Completed specialised training in clinical genetics and attained the European Certificate in Medical Genetics and Genomics (ECMGG)	Not applicable

Annex C-III: Relevant Qualifications, Training and Working Experience for Personnel Providing Genetic Counselling Services

The list below is exhaustive.

Requirement	Personnel providing Genetic Counselling Services
Qualifications	a) Recognised genetic counselling degrees or certifications include: i. A programme recognised by any of the accreditation bodies below, leading to the following degrees: a. Graduate diploma in genetic counselling (before 2008) b. Master of Genetic Counselling c. Master of Science in Genomic Counselling d. Master of Science in Genetic and Genomic Counselling e. Genetic counselling certification from any of the following certification bodies: 1. American Board of Genetic Counselling (USA) 2. Genetic Counsellor Registration Board (UK) 3. Canadian Board of Genetic Counselling (CA) 4. Health Professions Council of South Africa (SA) 5. European Board of Medical Genetics (EU) 6. Certification Committee, Human Genetics Society of Australasia (AU/NZ) b) The recognised genetic counselling degrees/certifications listed in (a) above must be supported or recognised by credible bodies, namely: i. Accreditation Council for Genetic Counselling (USA) ii. Accreditation Committee for Genetic Counselling, Human Genetics Society of Australasia (Australia) iii. Genetic Counsellor Registration Board (UK) iv. European Board of Medical Genetics (EU) v. Health Professions Council of South Africa vi. Canadian Board of Genetic Counselling

Annex C-III: Relevant Qualifications, Training and Working Experience for Personnel Providing Genetic Counselling Services (cont'd)

Requirement	Personnel providing Genetic Counselling Services
Working experience	a) Relevant working experience in clinical genetic counselling include: i. Clinical experience/training in genetic counselling at a recognised/accredited site (for clinical genetics or in the genetics of that particular disease/condition) ii. Clinical experience/training in genetic counselling under a person who is accredited (for clinical genetics or in the genetics of that particular disease/condition) iii. Clinical experience/training in genetic counselling under a person who meets the relevant qualification, or working/training experience in clinical genetics or in the area of genetics of that particular disease/condition b) Relevant working experience in clinical genetic counselling for that particular disease or condition include: i. Clinical experience/training in genetic counselling at a recognised/accredited site (for clinical genetics or in the genetics of that particular disease/condition) ii. Clinical experience/training in genetic counselling under a person who is accredited (for clinical genetics or in the genetics of that particular disease/condition) iii. Clinical experience/training in genetic counselling under a person who meets the relevant qualification, or working/training experience in clinical genetics or in the area of genetics of that particular disease/condition

Annex C-IV: Examples of Relevant Qualifications, Training and Working Experience for Personnel Providing LGT services

The list below is non-exhaustive and for reference purpose only.

Requirement	**(1) Personnel overseeing the conduct of LGT services and processes**
Qualifications or training	Examples of Relevant qualifications in molecular genetics, biochemical genetics or cytogenetics for medical practitioners, doctoral scientists and persons with Master's degree i. PhD/MSc in Biomedical Science/Biochemistry/Genetics/ Microbiology/Molecular Cell Biology ii. Certification from American Board of Medical Genetics and Genomics (ABMGG) iii. Clinical Genetic Molecular Biologist Scientist (CGMBS) Certification Examples of Relevant training in molecular genetics, biochemical genetics or cytogenetics for medical practitioners, doctoral scientists and persons with Master's degree i. Job training within clinical laboratory; or ii. Certified courses; or iii. Attachment in another clinical laboratory (e.g., attachment under the Health Manpower Development Plan (HMDP))
Working experience	Relevant working experience in molecular genetics, biochemical genetics or cytogenetics in a clinical laboratory a) Experience in performing or supervising the molecular testing services provided, reporting results, quality management, inspection, accreditation and licensing procedures.
Supporting documents	Appropriate documents to show working experience in molecular genetics, biochemical genetics or cytogenetics in a clinical laboratory (any of the following) a) Records e.g., results review, reports signed off, External Quality Assessment (EQA) review, approval of new tests/methods, evidence of consultation with regard to testing/results interpretation b) Letter[1] signed by work organisation to document work experience within a clinical laboratory.

[1] Minimum components required in the letter include: (i) name of individual; (ii) number of years of working experience (for cumulative working experience, also include the duration which spans the cumulative working experience); (iii) summary of individual's scope of work; (iv) location/address of the organisation which the individual had acquired working experience; (v) name and qualifications of individual's supervisor (for individuals who do not meet the specific qualification requirements and are under direct supervision of an individual who has met the requirements); and (vi) certification of true copy by supervisor/organisation.

Annex C-IV: Examples of Relevant Qualifications, Training and Working Experience for Personnel Providing LGT services (cont'd)

Requirement	**(2) Staff – Trained Personnel**
Qualifications or training	a) <u>Diploma in medical laboratory technology or an equivalent qualification</u> Example of equivalent qualification(s): i. Any scientific diploma involving scientific coursework b) <u>Degree in a relevant science subject</u> Examples of relevant science subjects: i. Biomedical Science ii. Biochemistry iii. Genetics iv. Microbiology v. Molecular Cell Biology vi. Engineering vii. Chemistry viii. Nutrition
Working experience	<u>Relevant working experience in molecular genetics, biochemical genetics, or cytogenetics in a clinical laboratory</u> a) For molecular genetics: Able to perform molecular tests with standard molecular techniques such as PCR, sequencing, and proficient in results analysis b) Laboratory Officer c) Medical Laboratory Technologist d) Clinical Laboratory Scientist e) Scientific Officer f) Laboratory Quality Officer
Supporting documents	<u>Appropriate documents to show working experience in molecular genetics, biochemical genetics, or cytogenetics in a clinical laboratory (any of the following)</u> a) Letter[1] from work organisation explaining work experience b) Records of training, competency assessment and continuing education

Annex C-V: List of Approved Laboratory Accreditation Bodies

A CLS Licensee intending to outsource tests to a foreign clinical laboratory must ensure that the foreign clinical laboratory providing the tests has been accredited by an accreditation body approved by DGH (see Regulation 41 of the CLSRS Regulations). The list of approved laboratory accreditation bodies is as follows:

1. Accreditation Canada (Canada)
2. American Society for Histocompatibility and Immunogenetics (USA)
3. ANSI National Accreditation Board (ANAB) (USA)
4. Association for the Advancement of Blood & Biotherapies (AABB) (USA)
5. College of American Pathologists (USA)
6. Danish Accreditation [DANAK] (Denmark)
7. Deutsche Akkreditierungsstelle (DAkkS) (Germany)
8. Dutch Accreditation Council [Raad voor Accreditatie] (The Netherlands)
9. Foundation for the Accreditation of Cellular Therapy (USA)
10. International Accreditation New Zealand (New Zealand)
11. National Association of Medical Examiners (USA)
12. National Association of Testing Authorities (Australia)
13. National Pathology Accreditation Advisory Council (Australia)
14. Singapore Accreditation Council-Singapore Laboratory Accreditation Scheme (Singapore)
15. Swiss Accreditation Services (Switzerland)
16. Taiwan Accreditation Foundation (Taiwan)
17. The Joint Commission (USA) (formally Joint Commission on Accreditation of Healthcare Organizations)
18. United Kingdom Accreditation Service (formally known as Clinical Pathology Accreditation) (UK)

Annex C-VI: List of Approved Laboratory Accreditation Bodies for Level 3 Clinical Laboratory Genetic/Genomic Testing

- Accreditation Canada (Canada)
- College of American Pathologists (USA)
- Deutsche Akkreditierungsstelle (DAkks) (Germany)
- Singapore Accreditation Council-Singapore Laboratory Accreditation Scheme (Singapore)
- United Kingdom Accreditation Service (formally known as Clinical Pathology Accreditation) (UK)

* Licensees shall engage the respective accreditation bodies directly on the scope of the accreditation.